



5-1-2018

The Return of the Plague: Inequitable Conduct After *Regeneron V. Merus*

Avery, Matthew

Kempf, Matthew

Liang, Amy

Follow this and additional works at: <https://digitalcommons.law.scu.edu/chtlj>



Part of the [Intellectual Property Law Commons](#), and the [Science and Technology Law Commons](#)

Recommended Citation

Avery, Matthew; Kempf, Matthew; and Liang, Amy, *The Return of the Plague: Inequitable Conduct After Regeneron V. Merus*, 34 SANTA CLARA HIGH TECH. L.J. 328 (2018).

Available at: <https://digitalcommons.law.scu.edu/chtlj/vol34/iss4/1>

This Article is brought to you for free and open access by the Journals at Santa Clara Law Digital Commons. It has been accepted for inclusion in Santa Clara High Technology Law Journal by an authorized editor of Santa Clara Law Digital Commons. For more information, please contact sculawlibrarian@gmail.com, pamjadi@scu.edu.

THE RETURN OF THE PLAGUE: INEQUITABLE CONDUCT AFTER *REGENERON V. MERUS*

Matthew Avery,[†] Matthew Kempf,[‡] & Amy Liang[§]

In July 2017, the Federal Circuit decided Regeneron Pharmaceuticals Inc. v. Merus, where a split panel upheld the district court’s decision to infer prosecution misconduct by Regeneron based on its subsequent litigation misconduct during the patent case, thus holding its patent unenforceable based on the doctrine of inequitable conduct. The decision raises new questions regarding the relevance of litigation misconduct to the unenforceability of a patent, which has traditionally been determined based upon evidence of misconduct before the U.S. Patent and Trademark Office (i.e., pre-litigation misconduct). The Regeneron decision also raises new questions regarding the standard of proof needed to establish inequitable conduct as a defense to patent infringement. In 2011, the Federal Circuit raised the bar for proving inequitable conduct in Therasense, Inc. v. Becton, Dickinson & Co., where an en banc panel held that clear and convincing evidence was needed to prove intent to deceive the USPTO, and that intent to deceive cannot be inferred by proving other elements of the defense. Prior to Therasense, claims of inequitable conduct were once so prevalent that the court wrote that the defense had “become an absolute plague” on patent litigation. By indicating that it is willing to consider litigation misconduct to infer a finding of inequitable conduct, the Federal Circuit appears to have expanded the scope of the doctrine, which may encourage defendants to raise inequitable conduct as a defense. If subsequent cases follow this expanded theory, the consequences could be far-reaching, exposing patent holders to a new wave of inequitable conduct charges. This Article examines the effect of Regeneron on the inequitable conduct defense and further discusses considerations for practitioners in light of the Federal Circuit’s opinion in Regeneron.

[†] Mr. Avery is a Senior Associate at Baker Botts LLP in San Francisco, California, and an Adjunct Professor at U.C. Hastings College of Law.

[‡] Mr. Kempf is an Associate at Baker Botts LLP in Palo Alto, California.

[§] Ms. Liang is an Associate at Baker Botts LLP in Palo Alto, California.

TABLE OF CONTENTS

INTRODUCTION	330
I. INEQUITABLE CONDUCT UNDER <i>THERASENSE</i>	332
II. THE EVOLUTION OF INEQUITABLE CONDUCT AFTER <i>THERASENSE</i>	335
A. <i>But-For Materiality After Therasense</i>	336
B. <i>Specific Intent to Deceive After Therasense</i>	340
C. <i>State of the Law Just Before Regeneron</i>	343
III. <i>REGENERON</i> AND THE POTENTIAL RETREAT FROM <i>THERASENSE</i>	344
A. <i>The Regeneron District Court Decision</i>	344
B. <i>The Regeneron Federal Circuit Opinion</i>	346
1. Materiality	347
2. Intent to Deceive	348
3. Judge Newman’s Dissent	349
4. <i>The Regeneron Majority Versus Dissent on Aptix Decision</i>	350
IV. THE IMMEDIATE IMPACT OF <i>REGENERON</i> AT DISTRICT COURT	352
V. THE PRACTICAL IMPACT OF <i>REGENERON</i> : TIPS FOR PRACTITIONERS	353
A. <i>Disclosures During Prosecution</i>	354
B. <i>Post-Allowance Disclosures</i>	356
C. <i>Pre-Litigation Diligence</i>	359
D. <i>Strategic Assertion</i>	360
CONCLUSION	361

INTRODUCTION

Under the patent law doctrine of inequitable conduct, a patent can be held unenforceable if a court finds that the patentee obtained the patent by engaging in improper conduct before the U.S. Patent and Trademark Office (USPTO).¹ Once referred to as an “absolute plague” on the patent system by the Court of Appeals for the Federal Circuit, inequitable conduct was routinely asserted by defendants in patent cases.² Common examples of such conduct include making false statements to the patent office or intentionally withholding material information during prosecution.³ In 2011, the Federal Circuit issued an en banc decision in *Therasense, Inc. v. Becton, Dickinson & Company*, setting forth a heightened standard for proving inequitable conduct.⁴ To prove inequitable conduct under *Therasense*, a patent defendant must show that the patent applicant (1) withheld or misrepresented “but-for” material information, and (2) acted with specific intent to deceive the USPTO. A critical aspect of the *Therasense* holding is that specific intent must be shown by clear and convincing evidence, and that such intent cannot be inferred merely because material information was withheld or misrepresented.⁵ Since this decision was handed down, use of the inequitable conduct defense in patent litigation has sharply dropped.⁶

However, just six years later, the Federal Circuit issued an opinion that appears to have weakened the foundations of the *Therasense* standard. In July 2017, Chief Judge Prost issued a precedential opinion in *Regeneron Pharmaceuticals v. Merus N.V.*,

1. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011).

2. *Id.* at 1289 (where the court cited to a study that estimated eighty percent of patent infringement cases included allegations of inequitable conduct, and agreed that the defense “has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system.”); see also *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”); *Therasense*, 649 F.3d at 1289 (“Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system.”). Note, however, that the en banc court in *Therasense* heightened the standard for finding inequitable conduct, as discussed in more detail in Part II, *infra*.

3. See, e.g., *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (“To prove inequitable conduct in the prosecution of a patent, [the defendant] must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.”).

4. 649 F.3d 1276 (Fed. Cir. 2011).

5. *Id.* at 1276.

6. Ryan Davis, *Inequitable Conduct a Dying Defense 2 Years Post-Therasense*, LAW360 (May 23, 2013, 9:13 PM), http://bit.do/law360_inequitableconduct.

which affirmed a finding of inequitable conduct *without* a finding of specific intent as was required by *Therasense*.⁷ In *Regeneron*, the patentee failed to disclose several prior art references to the USPTO during prosecution of the patent at issue, and the district court found these withheld references to be “but-for” material information.⁸ However, the district court did not specifically determine whether the patentee acted with a specific intent to deceive the USPTO, but rather inferred intent to deceive primarily based on misconduct during discovery in the patent litigation proceedings.⁹ Based on this inference, the district court held the patent unenforceable.¹⁰ Notwithstanding its prior holding in *Therasense*, that specific intent must be shown by clear and convincing evidence, the Federal Circuit affirmed the *Regeneron* district court decision on appeal.¹¹

This Article explores the effects of *Regeneron* on inequitable conduct challenges, and whether it heralds a return of the “plague” to the patent system. Part I provides an overview of the doctrine of inequitable conduct under the *Therasense* standard, which requires a showing that the patent holder’s conduct was both material to patentability and done with the specific intent to deceive the patent office. Part II discusses several post-*Therasense* cases that illustrate how district courts and the Federal Circuit have applied the *Therasense* standard. Part III discusses how *Regeneron* appears to retreat from the heightened standard previously set by the Federal Circuit in *Therasense*. Part IV discusses several post-*Regeneron* cases that illustrate its impact on patent litigation. Finally, Part V provides strategic considerations for prosecution and litigation counsel for avoiding charges of inequitable conduct.

7. *Regeneron Pharm., Inc. v. Merus N.V.*, 864 F.3d 1343 (Fed. Cir. 2017) [hereinafter *Regeneron II*].

8. *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 571 (S.D.N.Y. 2015) [hereinafter *Regeneron I*], *aff’d sub nom. Regeneron II*.

9. *Regeneron I*, 144 F. Supp. 3d at 561, 595-96 (“An inference of intent to deceive is appropriate where the applicant engages in ‘a pattern of lack of candor’ including where the applicant repeatedly makes factual representations ‘contrary to the true information he had in his possession.’” *Regeneron* had shown “a long pattern of litigation choices that [had] caused delay, inefficient use of resources, and diversion from the merits.” “The Court therefore infers that Drs. Smeland and Murphy together knew of each of the Withheld References, knew they were material, and made a deliberate decision to withhold them. In short, they acted with the specific intent to deceive the patent office. The Court finds that this is ‘the single most reasonable inference able to be drawn from the evidence.’”).

10. *Id.* at 596.

11. *Regeneron II*, 864 F.3d at 1364 (“[T]he district court did not abuse its discretion by drawing an adverse inference of *Regeneron*’s specific intent to deceive the PTO. Thus, the district court did not abuse its discretion in holding the ‘018 patent unenforceable due to *Regeneron*’s inequitable conduct.”).

I. INEQUITABLE CONDUCT UNDER *THERASENSE*

Inequitable conduct is an affirmative defense in patent litigation, in which the defendant asserts that the patentee obtained its patent through improper conduct before the USPTO.¹² This judicially-created doctrine originated from a trio of Supreme Court cases dealing with the equitable doctrine of unclean hands.¹³ Prior to the development of the inequitable conduct doctrine, a patentee who had engaged in egregious misconduct, and thus came to the court with “unclean hands,” would often be denied an injunction against the alleged infringer.¹⁴ The modern inequitable conduct defense is tantamount to an accusation of fraud on the USPTO, and the consequences are much more severe. If the defense is proven, the entire patent (and possibly all related patents in the same family) can be held unenforceable, even if the claims of the patent are otherwise valid.¹⁵ In fact, a finding of inequitable conduct may jeopardize a company’s entire patent portfolio, and may even give rise to additional antitrust and unfair competition claims.¹⁶ The effects of such a finding are so severe that the Federal Circuit, in *Therasense*, referred to the doctrine as an “atomic bomb,” and elevated the standard of what must be shown to prove the defense.¹⁷

As obtaining a patent is an *ex parte* procedure, all persons substantively involved in the prosecution of the patent application owe a duty of candor to the USPTO to disclose *all* known information

12. *Therasense*, 649 F.3d at 1285.

13. *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1993); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945).

14. *Therasense*, 649 F.3d at 1287.

15. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988); *J.P. Stevens & Co. v. Lex Tex. Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984); *see, e.g., Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990). Inequitable conduct committed in prosecution of one patent may render related patents unenforceable as well. Generally, an “intimate relation” between the patents or an “immediate and necessary relation” between the inequitable conduct and the second patent is required to render the second patent unenforceable. *See Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc.*, 53 U.S.P.Q.2d 1302, 1321, 1328, 1999 WL 1077882 (N.D. Ill. 1999), judgment aff’d in part, rev’d in part on other grounds, 15 Fed. Appx. 836 (Fed. Cir. 2001) (reversed on factual grounds).

16. *See Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1471 (Fed. Cir. 1998) (where inequitable conduct gave rise to an unfair competition claim); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965) (where inequitable conduct gave rise to antitrust action); *see also* Gregory Michael et al., *The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution*, 25 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 747 (2015).

17. *Therasense*, 649 F.3d at 1288 (citations omitted).

material to patentability.¹⁸ Acts typically constituting inequitable conduct include failing to submit material prior art known by the applicant, failing to explain references written in a foreign language, misstatements of facts concerning patentability, and misstatements of inventorship.¹⁹ To prove inequitable conduct post-*Therasense*, an accused infringer must show by clear and convincing evidence that the patentee either failed to disclose, misrepresented, or submitted false information to the patent office (1) that was material to patentability *and* (2) with the specific intent to deceive the patent office.²⁰ Materiality and intent are separate elements that the defendant must prove, and the *Therasense* court made clear that the existence of one cannot provide the basis for inferring the other.²¹ Proving that a reference was material and not submitted to the USPTO, for example, does not by itself prove specific intent to deceive the USPTO.²²

Under *Therasense*, the defendant must show but-for materiality with respect to the patentee's omission or misrepresentation to the patent office.²³ Therefore, even when a patentee withholds information, it only warrants a finding of inequitable conduct if, "but-for" the withholding, the patentee would not have been successful in

18. 37 C.F.R. § 1.56(a) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office ... [All persons involved in the patent application owe] a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

19. See *McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 913-26 (Fed. Cir. 2007) (finding inequitable conduct where attorney failed to disclose material information from related patent application); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256-57 (Fed. Cir. 1997) (inferring intent where applicant "knew or should have known" that information was relevant to the prosecution); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1350-54 (Fed. Cir. 2005) (finding inequitable conduct for failure to cite an FDA proceeding); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007) (finding inequitable conduct for failing to disclose test data inconsistent with data disclosed in the specification); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1194-95 (Fed. Cir. 2006) (finding inequitable conduct where applicant failed to disclose that declarations from outside experts had been previously employed by the applicant); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1229-30 (Fed. Cir. 2007) (inequitable conduct found where applicant improperly claimed small entity status).

20. *Regeneron II*, 864 F.3d at 1350-51.

21. *Therasense*, 649 F.3d at 1290 (rejecting the "sliding scale" approach where a court requires less evidence of intent where a reference is highly material).

22. See *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (where the court emphasized that clear and convincing evidence of deceptive intent must be shown as a threshold matter, even if by circumstantial evidence, otherwise a court "cannot hold the patent unenforceable regardless of the relative equities or how it might balance them.").

23. *Therasense*, 649 F.3d at 1291.

prosecuting the claim.²⁴ However, in heightening the standard to but-for materiality, the *Therasense* court carved out an exception in cases of affirmative egregious misconduct.²⁵ Where a patent applicant has engaged in egregious misconduct during prosecution, the materiality prong is met regardless of whether the claim would have issued.²⁶ Examples of affirmative acts of egregious misconduct include intentionally filing false affidavits, failing to cure a false affidavit, and making false representations to the USPTO's patent appeals board.²⁷ In heightening the standard for what constitutes "egregious" conduct, the *Therasense* court made it clear that merely failing to disclose prior art references, even those that are "but-for" material, does not necessarily constitute such misconduct.²⁸

The second element of the inequitable conduct analysis requires proving that the patentee acted with specific intent to deceive the USPTO, in that the "evidence must show that the applicant made a deliberate decision to withhold a known material reference."²⁹ Specifically, "the defendant must prove that the patentee deliberately decided to withhold, misrepresent, or falsify information to the USPTO."³⁰ This element, which must be proven with clear and convincing evidence, poses a significant hurdle for defendants, with courts describing this high burden as an "insurmountable standard" that "severely limit[s] the ability of district court judges to make inferences based on the evidence."³¹ However, the *Therasense* court

24. *Id.* (a prior art reference is "but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.").

25. *Id.* at 1292 (carving out an exception for cases where a patentee "deliberately planned and carefully executed scheme[s]" to defraud the USPTO).

26. *See Regeneron I*, 144 F. Supp. 3d at 582, 585 (where the District Court found that, even though each of the four withheld references met the rigorous "but for" materiality standard, Regeneron's conduct during prosecution also amounted to "egregious misconduct," even "without need for application of an adverse inference").

27. *Therasense*, 649 F.3d at 1292 ("When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.").

28. *Id.* at 1287, 1290-91 ("As the inequitable conduct doctrine evolved ... it came to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct ... but also the mere nondisclosure of information to the PTO." "This court now tightens the standards for finding both intent and materiality ... [t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.").

29. *Therasense*, 649 F.3d at 1290 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

30. *Therasense*, 649 F.3d at 1290.

31. *General Elec. Co. v. Mitsubishi Heavy Industries Ltd.*, 946 F. Supp. 2d 582, 590-91 (N.D. Tex. 2013) (stating that it was reluctantly ruling there was no inequitable conduct for not disclosing prior art that the court considered to be material because of insufficient evidence of intent to deceive).

stated that such intent can be inferred from indirect and circumstantial evidence, provided that such an inference is “the single most reasonable inference able to be drawn from the evidence.”³² The evidence presented must, therefore, be “sufficient to require a finding of deceitful intent in the light of *all* the circumstances.”³³ A patentee’s deceptive intent, therefore, cannot be inferred where multiple reasonable inferences may be drawn from the same evidence.³⁴

By heightening the standards for both materiality and specific intent, the *Therasense* court hoped to “redirect a doctrine that has been overused to the detriment of the public.”³⁵ However, others maintain that it has become too difficult to successfully raise an inequitable conduct defense, and that *Therasense* improperly restricts the discretion of district courts.³⁶

II. THE EVOLUTION OF INEQUITABLE CONDUCT AFTER *THERASENSE*

Prior to *Therasense*, inequitable conduct was raised as a defense in nearly every patent litigation.³⁷ But the new standard made is so difficult to prove inequitable conduct that it is now rarely raised as a defense, and even more rarely successful.³⁸ Proving that a plaintiff had *intentionally* withheld prior art from the USPTO has been an exceedingly burdensome challenge that few defendants have been able to meet.³⁹ Additionally, under the new heightened standard for materiality, it has been difficult to show that the patent would not have issued “but for” the undisclosed reference. Practitioners described the inequitable conduct defense before *Therasense* as a “way to punish patent holders any time they made a mistake during prosecution, regardless of its significance,” but after *Therasense*, it has evolved into a “way to punish people who knowingly deceived the patent office in a way that affects the outcome of the patent . . . a much smaller category of conduct.”⁴⁰

32. *Therasense*, 649 F.3d at 1290 (“Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.”) (citing *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009)).

33. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988) (emphasis added).

34. *Therasense*, 649 F.3d at 1290-91.

35. *Id.* at 1290.

36. Ryan Davis, *Inequitable Conduct a Dying Defense 2 Years Post-Therasense*, LAW360 (May 23, 2013, 9:13 PM), http://bit.do/law360_inequitableconduct.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

A. *But-For Materiality After Therasense*

In *Therasense*, the Federal Circuit explained that a defendant must prove “but-for” materiality to support an inequitable conduct defense because “this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”⁴¹ Courts have hewed closely to this standard and considered not only the technical disclosures that were withheld or misrepresented, but also the patent examination standards of the USPTO.⁴²

The most common “but-for” material action is failing to disclose printed references to the USPTO. For instance, in *American Calcar v. American Honda*, the patentee described a prior art reference in the background section of its patent application, but this background description failed to discuss critical features disclosed in the prior art that were similar to features claimed in the patent.⁴³ While the patentee presented strong evidence against but-for materiality—the validity of one of the patents-at-issue over the information at issue had been upheld during an *ex parte* reexamination at the USPTO—the district court nonetheless found inequitable conduct.⁴⁴ The district court opined that the inventor failed to disclose critical aspects of the prior art that were relied on to distinguish over the cited prior art, and also that the “only reasonable inference from the evidence” was that the patentee had withheld the information with “specific intent to deceive the PTO.”⁴⁵ The Federal Circuit affirmed on this same basis.⁴⁶ Judge Newman dissented, reasoning that the withheld prior art could not be but-for material because the USPTO considered the very same art during reexamination and still allowed the claims.⁴⁷ The majority did not address this point, presumably finding that since the reexamination did not address the two patents for which the finding of inequitable conduct was made, the reexamination was not relevant. The appellate court held that the withheld prior art could still be considered a but-for cause of the patent issuing in the first place

41. *Therasense*, 649 F.3d at 1292.

42. *See, e.g.*, *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1192 (Fed. Cir. 2014).

43. *Id.*

44. *Id.*

45. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, No. 06CV2433 DMS KSC, 2012 WL 1328640, at *9 (S.D. Cal. Apr. 17, 2012), *aff’d*, 768 F.3d 1185 (Fed. Cir. 2014).

46. *Am. Calcar*, 768 F.3d at 1185.

47. *Id.* at 1192 (Newman, J., dissenting) (asserting that the majority had distorted the *Therasense* standards, and had “ignored the PTO reexamination, cast[ed] the jury aside, and generally disregard[ed] the safeguards that this court adopted *en banc*.”).

because the USPTO only requires rejections to be supported by a preponderance of evidence, a much lower standard than the clear and convincing evidence required to invalidate an issued patent in court.⁴⁸ Though not directly addressing Judge Newman's concerns, the majority's ruling seems to imply that the USPTO would have found at least one of the claims obvious under the lower preponderance-of-evidence standard if it had seen the withheld prior art during its initial examination.⁴⁹

Failure to submit physical samples of a prior art product to the USPTO can also be but-for material. For example, in *Worldwide Home Products, Inc. v. Bed, Bath and Beyond, Inc.* the district court granted summary judgment in favor of the defendant, dismissing the case and finding that the patent at issue was unenforceable due to inequitable conduct because the patentee misrepresented a prior art product and withheld physical samples of the product from the patent office.⁵⁰ The omission of the product sample was found to be but-for material in view of the examiner's statements in the prosecution history of the patent.⁵¹ During prosecution, Worldwide's patent attorney had submitted low-resolution photographs of the prior art product, which were not clear enough show the claimed features.⁵² After considering the photographs, the examiner allowed Worldwide's patent application, mistakenly stating that the photos did not show the claimed features.⁵³ The court found the withheld samples to be but-for material because they embodied the exact features that the patentee had claimed and the examiner had agreed were patentable.⁵⁴

A number of scenarios may be relevant to and raise questions of fact regarding but-for materiality of a withheld reference or misleading act. For instance, in *Masimo Corp. v. Philips Electric North America Corp.*, the patentee failed to disclose a district court's claim interpretation that contradicted the patentee's position in a reexamination proceeding.⁵⁵ Specifically, the district court had

48. *Id.*

49. *Am. Calcar*, 768 F.3d at 1188-89.

50. *Worldwide Home Prod., Inc. v. Bed, Bath & Beyond, Inc.*, 74 F. Supp. 3d 626, 638 (S.D.N.Y. 2015), *aff'd*, *Worldwide Home Prod., Inc. v. Time, Inc.*, 626 F. App'x 1009 (Fed. Cir. 2015).

51. *Id.* at 630-31.

52. *Id.* at 629.

53. *Id.*

54. *Id.* at 638.

55. *Masimo Corp. v. Philips Elec. North Am. Corp.*, No. cv 09-80-LPS-MPT, 2014 WL 4365191, *4 (D. Del. Sept. 2, 2014).

construed the claims to require that the claimed calculators actually determined a particular ratio, but during prosecution the patentee argued the opposite—that the claimed calculators do not require calculating the particular ratio.⁵⁶ While the “broadest reasonable construction” standard used during reexamination was broader than the claim construction standard applied during litigation, the court found the patentee’s failure to disclose the prior claim construction was sufficient to support a finding of inequitable conduct.⁵⁷

Lastly, not all omissions or misrepresentations are “but-for” material, even if they are directly relevant to the claimed inventive limitation that was in dispute during prosecution. In *Novo Nordisk A/S v. Caraco Pharmaceutical Labs., Ltd.*, the patentee submitted a misleading declaration that omitted relevant facts, and the prosecuting attorney made misleading statements about the declaration.⁵⁸ The examiner stated that “[b]ased solely on the [d]eclaration,” the rejection of certain claims was withdrawn.⁵⁹ Specifically, the patent claimed a method of treatment that utilized the synergistic effect of a combination of two drugs.⁶⁰ To overcome the examiner’s rejection that the synergies and combination therapies were well-known in the art, the applicant submitted an expert declaration regarding results of the expert’s study of the efficacy of the claimed drug combination in obese rats.⁶¹ The prosecuting attorney asserted that the declaration showed clear evidence of synergy as well as surprising results of the two drug combination for treatment of Type II diabetes.⁶² However, the patentee and attorney had omitted other remarks by the expert regarding the fact that the expert’s test results did not necessarily translate to treatment of Type II diabetes in humans.⁶³ Nonetheless, the Federal Circuit found that while the omissions and misleading statements were “troubling,” they were not “but-for” material because the expert’s test protocols were disclosed to the examiner and the attorney “employed carefully-chosen language which tracked the qualified nature” of the expert’s opinion.⁶⁴

56. *Id.* at *3-*4.

57. *Id.* at *2.

58. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 775 F. Supp. 2d 985, 1022 (E.D. Mich. 2011).

59. *Id.* at 1001.

60. *Id.* at 989.

61. *Id.* at 1013.

62. *Id.* at 1006-07.

63. *Id.* at 1020.

64. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1359 (Fed. Cir. 2013).

The *Therasense* court recognized that the doctrine of inequitable conduct originated from the doctrine of unclean hands. To continue to deter patentees and applicants from committing bad acts, the Court created an “egregious misconduct” exception to the requirement of “but-for” materiality. That is, if the patent defendant shows that the patent holder committed egregious misconduct during prosecution, then the defendant need not prove “but-for” materiality because materiality would be presumed based on the conduct.⁶⁵

The Federal Circuit applied this exception in *Intellect Wireless, Inc. v. HTC Corp.*, where an inventor submitted “unmistakably false” declarations to the USPTO during the prosecution of the patent-at-issue and other patents in the same family.⁶⁶ The applicant submitted declarations to the USPTO falsely swearing that it had actually reduced its invention to practice on a specific date when, in fact, it had not.⁶⁷ The prosecution attorney “quickly” submitted a revised declaration in which it purportedly cured the misrepresentation, but which the court found only “obfuscated the truth” because it never expressly negated the misrepresentation.⁶⁸ Consequently, even though the false declarations were not technically but-for material because of the revised declarations, the Federal Circuit still affirmed a finding of inequitable conduct.⁶⁹ The Court found that the patentee engaged in “affirmative egregious misconduct,” which rendered the false declarations material.⁷⁰

The Court rebuked the patentee for failing to “expressly advise the PTO of [the misrepresentation’s] existence, stating specifically wherein it resides.”⁷¹ Further, “if the misrepresentation is of one or more facts, the PTO [must] be advised what the actual facts are.”⁷² Finally, the applicant must

take the necessary action . . . openly. It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate

65. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292-93 (Fed. Cir. 2011).

66. *Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339, 1342-43 (Fed. Cir. 2013).

67. *Id.*

68. *Id.* at 1343.

69. *Id.* at 1346.

70. *Id.* at 1344.

71. *Id.* at 1343 (quoting *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983)).

72. *Intellect Wireless*, 732 F.3d.

his own conclusions.⁷³

The Court concluded that the applicant had not met these requirements, and “rather than expressly admitting the earlier falsity, dance[d] around the truth.”⁷⁴ *Intellect Wireless* demonstrates that deceitful misconduct can result in unenforceability of the patent-in-question, even when but-for materiality is not directly proven.

B. *Specific Intent to Deceive After Therasense*

The Federal Circuit made clear that *Therasense* heightened the standard for proving intent. For example, in *Ist Media, LLC v. Electronic Arts, Inc.*,⁷⁵ the court reiterated that it was not enough to show “carelessness, lack of attention, poor docketing or cross-referencing or anything else that might be considered negligent or even grossly negligent.”⁷⁶ Rather, to sustain a charge of inequitable conduct, “clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”⁷⁷

In *Ist Media*, the named inventor and his attorney withheld from the USPTO three material references and information about rejections in two related applications.⁷⁸ The prosecuting attorney testified that his usual practice was to provide the USPTO with all relevant prior art references, and also testified that he did not remember why he did not disclose one of the prior art references and that his failure to do so must have been an oversight.⁷⁹ The district court found the testimony not to be credible, and thereby inferred the requisite intent to deceive.⁸⁰ However, the Federal Circuit reversed, concluding that the evidence was inadequate to sustain the burden because there was no evidence of a *deliberate decision* to withhold those references from the patent office, as required under *Therasense*.⁸¹ In essence, *Ist Media* held that even if a withheld reference is material, a court cannot simply infer intent to deceive, but instead must have actual evidence of such intent.

73. *Id.*

74. *Id.* at 1345.

75. 694 F.3d 1367 (Fed. Cir. 2012).

76. *Ist Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1375 (Fed. Cir. 2012).

77. *Id.* at 1372.

78. *Id.* at 1369. The original action was filed in the District of Nevada, *Ist Media LLC v. doPi Karaoke, Inc. et al.*, No. 2:07-cv-01589-JCM-NJK, 2013 WL 1250834 (D. Nev. Mar. 27, 2013).

79. *Ist Media*, 694 F.3d at 1371.

80. *Id.* at 1371.

81. *Id.* at 1376-77.

Likewise, the lack of evidence of specific intent to deceive in *Hospira, Inc. v. Sandoz, Inc.* compromised the defendant's ability to establish inequitable conduct.⁸² In *Hospira*, a table in the patent specification contained erroneous data.⁸³ The prosecution history indicated that the examiner relied on the data and the patentee's argument based on that data to find the claims allowable, thus making the error but-for material.⁸⁴ However, because the inventor could not recall whether the corrected data had been submitted to his patent department, the court was unable to find that the applicant had a specific intent to deceive the USPTO.⁸⁵ Accordingly, the court refused to find that patentee committed inequitable conduct.⁸⁶

Despite the high bar for proving intent, the Federal Circuit has affirmed several findings of inequitable conduct after *Therasense*. For example, in *Apotex Inc. v. UCB, Inc.*, the Federal Circuit affirmed a finding of clear and convincing evidence of specific intent to deceive where the inventor misrepresented the nature of an existing drug already on the market to the USPTO, withheld relevant prior art, and misrepresented that he had conducted experiments relevant to the invention.⁸⁷ The lower court held that the patent was unenforceable, opining that the case involved "an orchestrated scheme to deceptively obtain a patent" and was "illustrative of inventive litigation as opposed to the scientific discovery that the patent laws were designed to promote."⁸⁸ On appeal, the Federal Circuit agreed that there was clear and convincing evidence that the inventor knowingly omitted important details regarding the prior art and made knowing misrepresentations of material facts in order to overcome rejections from the USPTO, and based on that evidence, affirmed that the single most reasonable inference was that the inventor had specific intent to deceive the PTO.⁸⁹ The inventor's specific intent to deceive the USPTO regarding but-for material facts rendered the patent unenforceable due to inequitable conduct.⁹⁰

82. *Hospira, Inc. v. Sandoz, Inc.*, No. 09-4591 (MCL), 2012 WL 1587688 (D.N.J. May 4, 2012).

83. *Id.* at *31.

84. *Id.* at *31.

85. *Id.* at *32.

86. *Id.*

87. 763 F.3d 1354, 1362 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 2868 (2015).

88. *Apotex Inc. v. UCB, Inc.*, 970 F. Supp. 2d 1297, 1301 (S.D. Fla. 2013), *aff'd*, 763 F.3d 1354 (Fed. Cir. 2014).

89. *Apotex, Inc.*, 763 F.3d at 1362 (Fed. Cir. 2014).

90. *Id.* at 1363.

In *TransWeb, LLC v. 3M Innovative Properties Co.* (Fed. Cir. 2016), the Federal Circuit upheld the lower court finding of inequitable conduct where the patentee and its in-house counsel knowingly misrepresented the nature of the prior art.⁹¹ During 3M's prosecution of the patent-at-issue, the examiner initially allowed all claims.⁹² 3M then submitted a sample of defendant TransWeb's prior art product, which it had received at an expo more than one year before 3M's priority filing date.⁹³ In response, the examiner reversed his position and rejected the claims as obvious in view of TransWeb's product.⁹⁴ 3M traversed this rejection by arguing that TransWeb's prior art was only available under a confidentiality agreement, and thus was not prior art, which caused the examiner to withdraw the rejection.⁹⁵ However, numerous emails and other evidence showed that 3M was actually "very much aware" that TransWeb's product had been publicly displayed, and that it intentionally chose to withhold this fact from the examiner in order to overcome rejection.⁹⁶ Additionally, 3M's in-house counsel "undertook an intentional scheme to paper over the potentially prior art nature" of its TransWeb samples that a 3M collaborator (and later subsidiary) had received from TransWeb one month after the expo.⁹⁷ This evidence supported both the materiality and specific intent prongs of the inequitable conduct standard under *Therasense*.⁹⁸ These cases show that, although *Therasense* raised the bar for proving inequitable conduct, patentees that make clear lies or misrepresentations to the USPTO can still be punished by the court.

91. *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016) [hereinafter *Transweb II*]

92. *Transweb II*, 812 F.3d at 1304.

93. *Id.* at 1304-05.

94. *Id.* at 1304.

95. *Transweb, LLC v. 3M Innovative Properties Co.*, 16 F. Supp. 3d 385, 397 (D.N.J. 2014), *aff'd*, 812 F.3d 1295 (Fed. Cir. 2016) [hereinafter *Transweb I*].

96. *TransWeb II*, 812 F.3d at 1304-06.

97. *TransWeb I*, 16 F. Supp. 3d at 401-03.

98. *TransWeb I*, 16 F. Supp. 3d at 397-98.

C. *State of the Law Just Before Regeneron*

In the months leading up to *Regeneron*, courts continued to apply the heightened *Therasense* standard and continued to look for evidence of specific intent to deceive the USPTO during the prosecution of disputed patents.

For example, in *Asghari-Kamrani v. United Services Automobile Association*, the district court refused to find specific intent to deceive when there were plausible alternative explanations for the alleged misconduct.⁹⁹ The patent owner in *Asghari-Kamrani* claimed continuation priority within a patent family, thereby avoiding rejections based on disclosures in its earlier-filed patent applications.¹⁰⁰ During litigation, evidence showed that the patents were continuations-in-part rather than continuations as claimed on the applications and the face of the issued patents.¹⁰¹ However, multiple witnesses testified that the patent owner had hired a series of different patent counsel to draft and file the applications of the patent family due to cost concerns, and that the misstatement of priority may have been inadvertent.¹⁰² The district court refused to find inequitable conduct because, “where a plausible alternative explanation that does not go to inequitable conduct also exists, a court cannot find a specific intent to deceive.”¹⁰³

Similarly, in *Barry v. Medtronic, Inc.*, the district court did not find a specific intent to deceive where there were multiple reasonable explanations for why the patentee failed to correct a mistake during prosecution.¹⁰⁴ The defendant in *Barry* alleged inequitable conduct in part based on the fact that the patent holder submitted an inaccurate figure and withheld more accurate figures of the invention.¹⁰⁵ The court found no specific intent to deceive and, as a result, no inequitable conduct.¹⁰⁶ Specifically, the evidence showed that the patent applicants had images that supported the invention and that they could have submitted at the time of prosecution and did submit those corrected images when they discovered the error.¹⁰⁷ Of a number of reasonable inferences that could be drawn to explain the

99. 252 F. Supp. 3d 562, 586 (E.D. Va. 2017).

100. *Id.* at 575.

101. *Id.* at 576.

102. *Id.* at 581.

103. *Id.*

104. 245 F. Supp. 3d 793, 806 (E.D. Tex. 2017).

105. *Id.* at 804-05.

106. *Id.* at 805.

107. *Id.*

patentee's submission of the wrong figure, the court found intent to deceive the USPTO less plausible than other explanations.¹⁰⁸

Courts have also required clear and convincing evidence of specific intent to deceive the USPTO when the charge of inequitable conduct is based on actions by the patentee during *inter partes* review proceedings. For example, in *UUSI, LLC v. United States*, the defendant argued that the patent owner had committed egregious misconduct during the prosecution of the patent by misrepresenting the expiration date of two patent claims during the institution stage of an *inter partes* review of the patent.¹⁰⁹ In the *inter partes* review, the difference in expiration dates may have impacted whether the claims were construed more narrowly under *Phillips* standard if the claims were expired or under the broadest reasonable interpretation standard if the claims had not expired.¹¹⁰ However, the patent owner's actions "lacked the requisite indicia of fraud or unmistakable falsehood" required to show affirmative egregious misconduct.¹¹¹ The court concluded that

[a]n erroneous and ill-conceived argument about the expiration date of two patent claims, fully aired before the PTAB and rejected by that tribunal, is a far cry from the type of misconduct courts have found to be inherently egregious such as perjury, bribery or manufacturing evidence.¹¹²

Because the defendant did not otherwise show "but-for" materiality, the court dismissed the defendant's inequitable conduct claims.¹¹³ *UUSI* shows that even misconduct during the litigation-like *inter partes* review is judged under the same standards as in *Therasense*. Critically, the misconduct in *UUSI* was not used to infer specific intent to deceive the USPTO for purposes of showing inequitable conduct.

III. *REGENERON AND THE POTENTIAL RETREAT FROM THERASENSE*

A. *The Regeneron District Court Decision*

In March 2014, Regeneron sued Merus for infringing U.S. Patent Number 8,502,018 (the '018 patent), which relates to targeting and

108. *Id.* at 805-06.

109. *UUSI, LLC v. United States*, 133 Fed. Cl. 263 (2017).

110. *Id.* at 271-72.

111. *Id.* at 270-71.

112. *Id.*

113. *Id.* at 273.

modifying endogenous genes and chromosomal loci in eukaryotic cells.¹¹⁴ Only claim 1 of the patent was at issue, which recited “[a] genetically modified mouse, comprising in its germline human rearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus.”¹¹⁵ In essence, the patent claims a particular kind of genetically modified mouse used for scientific research, which allows users to “target and modify specific genes in mice so that the mice develop antibodies that can be used by humans.”¹¹⁶

Merus asserted that the patent was unenforceable due to inequitable conduct, in that Regeneron’s patent attorneys intentionally withheld four references (Brüggemann, Wood, Taki, and Zou) from the PTO during prosecution of the ’018 patent that were material to patentability.¹¹⁷ Regeneron did not dispute that it knew of the references, or that it failed to disclose them, but rather argued that the references “were not but-for material, that they were cumulative of references the PTO actually relied on during prosecution, and that [it] did not have any specific intent to deceive the PTO.”¹¹⁸ A third-party cited these references during prosecution of a related application after Regeneron received a Notice of Allowance for the ’018 patent.¹¹⁹ Regeneron did not submit these references in the application that became the ’018 patent, but did in all other related applications that were pending.¹²⁰ The district court also noted a purported irregularity in prosecution of the ’018 patent, where Regeneron’s counsel made representations that a transgenic mouse had been produced in accordance with the claims, and yielded surprising results.¹²¹ In fact, the evidence was “overwhelming” that no such mouse existed at the time the application was filed.¹²² Before even addressing application of an adverse inference, the court found “by clear and convincing evidence, and without need for application of an adverse inference, that Regeneron made false and misleading statements” and found “by

114. *Regeneron I*, 144 F. Supp. 3d at 530; *see also* U.S. Patent No. 8,502,018, at col.1 ll.17-33 (filed Jun. 20, 2011).

115. *Id.* at col. 29 ll. 24-26.

116. *Regeneron II*, 864 F.3d at 1347.

117. *Regeneron I*, 144 F. Supp. 3d at 571.

118. *Regeneron II*, 864 F.3d at 1346.

119. *Id.* at 1349.

120. *Id.* at 1350.

121. *Id.* at 1349.

122. *Regeneron I*, 144 F. Supp. 3d at 584.

clear and convincing evidence that this constitutes egregious affirmative misconduct.”¹²³

However, the court decided to address Regeneron’s “questionable conduct” and numerous “shenanigans” in light of Regeneron’s pattern of, among other things, choosing “tactics over substance.”¹²⁴ It was Regeneron’s sword and shield use of attorney-client privilege, asserting and waiving the privilege when most beneficial, that inspired the court to issue sanctions.¹²⁵ Regeneron asserted the privilege during discovery to shield documents relating to the patent’s prosecution, making it more difficult for Merus to prove its inequitable conduct defense, and then tried to “have it both ways at trial” by submitting the same info contained in those documents in the form of witness affidavits when it strongly supported their position at trial.¹²⁶ In fact, the court’s *in camera* review of Regeneron’s privileged log revealed a “Pandora’s Box” of serious discovery issues, including numerous non-privileged documents related to topics at issue throughout the litigation withheld on the basis of privilege, and other documents that should have been produced pursuant to an earlier order from the court.¹²⁷ Due to the extent and depth of Regeneron’s pattern of misconduct, the court felt that ordinary sanctions (such as striking the affidavits and precluding the witness testimony) would not suffice to remedy the many broad issues that had spread throughout the case.¹²⁸ Instead, after carefully considering the issue, the court determined that the appropriate remedy for the litigation conduct was to draw an adverse inference of a specific intent to deceive the USPTO, and thereby found that Regeneron had engaged in inequitable conduct in connection with prosecution of the ’018 Patent.¹²⁹

B. *The Regeneron Federal Circuit Opinion*

On appeal, the Federal Circuit affirmed the district court’s decision, and held that it had not abused its discretion under regional circuit law by imposing an adverse inference of specific intent to deceive because of, among other things, litigation misconduct during efforts to enforce the ’018 patent.¹³⁰ The court addressed both

123. *Id.* at 585.

124. *Id.* at 585-86.

125. *Id.* at 586.

126. *Id.* at 589-93.

127. *Id.* at 530, 594.

128. *Regeneron I*, 144 F. Supp. 3d at 595.

129. *Id.* at 595-96.

130. *Regeneron II*, 864 F.3d at 1364.

materiality and intent, finding that Regeneron's litigation misconduct was properly used to infer inequitable conduct, rendering the '018 patent unenforceable.¹³¹

1. Materiality

On appeal, Regeneron argued that none of the withheld references were but-for material to the prosecution of the '018 patent, and that the District Court had therefore erred in finding otherwise.¹³² The Federal Circuit, however, disagreed. Following *Therasense*, it defined the materiality required to establish inequitable conduct as "but-for materiality," and emphasized that an alleged infringer can show but-for materiality "if the PTO would not have allowed a claim had it been aware of the undisclosed prior art."¹³³ To determine materiality, the Court reiterated, a court "place[s] itself in the shoes of a patent examiner" and therefore "applies the preponderance of the evidence standard and gives the claims their broadest reasonable construction."¹³⁴ After addressing each of the four withheld references, the Circuit agreed with the District Court and found that it did not clearly err in finding the references but-for material and not cumulative, and that "had the reference(s) been before the examiner at the time," the claims of the '018 patent would not have been allowed to issue.¹³⁵

Recall that the four withheld references were Brüggemann, Wood, Taki, and Zou.¹³⁶ Regeneron argued that the Brüggemann reference was not but-for material because, according to its narrow construction, it did "not disclose a reverse-chimeric mouse."¹³⁷ However, since the Circuit did not adopt Regeneron's narrow construction, and instead did not limit the construction of Claim 1 to only reverse-chimeric mice, it found that the District Court did not clearly err in finding the reference but-for material.¹³⁸ As to the other three withheld references, the Court reviewed the references themselves, the testimony of Merus' expert witnesses, and the finding of the lower court before ultimately concluding that "the references both individually and in combination teach one of skill in the art to

131. *Id.* at 1364.

132. *Id.* at 1352.

133. *Id.* at 1350 (quoting *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011)).

134. *Id.*

135. *Id.* at 1353-56.

136. *Regeneron II*, 864 F.3d at 1353.

137. *Id.*

138. *Id.*

genetically modify mice by inserting exogenous, including human, variable region gene segments endogenously into a mouse immunoglobulin locus.”¹³⁹ The Circuit also found two of the withheld references (Taki and Zou) but-for material at least partially because they provided “the motivation to combine these references to develop the genetically modified mouse.”¹⁴⁰

Regeneron also argued that even if the withheld references were but-for material, at least three of those references (Brüggemann, Taki, and Zou) were cumulative of others considered by the Examiner during the ’018 patent’s prosecution.¹⁴¹ Importantly, if a reference is merely cumulative, the reference cannot be but-for material.¹⁴² A patent owner can show that a reference is cumulative if the reference “teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO.”¹⁴³ After considering each of the three potentially cumulative References, the Court found that they were in fact not cumulative, and therefore did not preclude the District Court’s finding of materiality.¹⁴⁴

2. Intent to Deceive

In response to Merus’ counterclaim of unenforceability due to inequitable conduct against Regeneron, the District Court indicated it would bifurcate the trial based on the two elements of the claim, conducting one bench trial focused on the element of materiality, and another focused on intent.¹⁴⁵ However, the court only finished the first bench trial regarding materiality—it never held the second bench trial to address the Regeneron’s specific intent.¹⁴⁶ Instead, after the first bench trial, the District Court extensively discussed Regeneron’s discovery misconduct occurring throughout litigation, and as a sanction for this misconduct, drew an adverse inference of specific intent to deceive the USPTO.¹⁴⁷ The Federal Circuit agreed that the District Court was within its broad discretion to “fashion[] an appropriate sanction, including the discretion to . . . proceed with a

139. *Id.* at 1354-55.

140. *Id.* at 1355.

141. *Id.* (arguing that Brüggemann was cumulative of U.S. Patent No. 6,114,598 to Raju Kucherlapati [“Kucherlapati”], Wood was cumulative of U.S. Application No. 11/009,873 to Nils Lonberg et al. [“Lonberg”] and Taki was cumulative of both Kucherlapati and Lonberg).

142. *Dig. Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006).

143. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575 (Fed. Cir. 1997).

144. *Regeneron II*, 864 F.3d at 1355-56.

145. *Regeneron I*, 144 F. Supp. 3d 530, 537 (S.D.N.Y. 2015).

146. *See id.*

147. *Regeneron I*, 144 F. Supp. 3d at 595.

trial and give an adverse inference instruction . . . [when] sanctioning parties for violating discovery obligations.”¹⁴⁸ Therefore, it found that the lower court’s decision to forego the second part of the bifurcated trial on inequitable conduct, and to draw an adverse inference of intent to deceive, was not an abuse of discretion.¹⁴⁹

On appeal, *Regeneron* did not “meaningfully dispute any of the factual findings underlying the district court’s decision.”¹⁵⁰ As previously discussed, those findings included improperly withholding and citing on privilege logs documents clearly not privileged (such as experimental data), withholding as privileged information where the privilege had been waived, and withholding evidence of patent prosecution counsels’ reasoning and state of mind relevant to whether counsel had an intent to deceive.¹⁵¹ *Regeneron* did not dispute that it had engaged in this litigation misconduct, but rather asserted that the court’s imposed sanction was an abuse of discretion, amounting to not merely a sanction but rather to a finding of unenforceability, or even a dismissal.¹⁵² The Federal Circuit disagreed, and emphasized that the “widespread litigation misconduct” was tied directly to evidence relevant to the intent inquiry.¹⁵³ It noted that the litigation misconduct directly affected the ability of both Merus and the court to determine *Regeneron*’s intent with respect to the withheld references, and also clarified that the sanction imposed only established the element of intent, and “[o]nly after Merus proved the remaining elements of inequitable conduct did the district court hold the patent unenforceable.”¹⁵⁴

Ultimately, *Regeneron* should likely be read to demonstrate that district courts have broad discretion in awarding adverse inferences based on litigation misconduct, so long as the litigation misconduct relates to the underlying inequitable conduct inquiry. However, such a reading is also clearly in tension with *Therasense*.

3. Judge Newman’s Dissent

Judge Newman penned a strong dissent, based on her belief that her “colleagues appl[ied] incorrect law and add[ed] confusion to

148. *Regeneron II*, 864 F.3d at 1363.

149. *Id.*

150. *Id.* at 1356.

151. *Id.* at 1356-63.

152. *Id.* at 1363.

153. *Id.* at 1364 (In addition to the “widespread litigation misconduct,” “*Regeneron* is accused not only of post-prosecution misconduct but also of engaging in inequitable conduct during prosecution.”).

154. *Id.*

precedent.”¹⁵⁵ Newman interpreted *Therasense* to teach that intent to deceive cannot be inferred, but must be proven by clear and convincing evidence.¹⁵⁶ She pointed out that there was “no evidentiary record developed on intent to deceive, with no testimony and no opportunity for examination and cross-examination of witnesses.”¹⁵⁷ In her view, the majority merely “engage[d] in innuendo based on its careful selections from documents not admitted into evidence . . . thus convict[ing] Regeneron, its counsel, and its scientists, with no trial, no evidence, and no opportunity to respond in their defense.”¹⁵⁸ However, the majority emphasized that direct evidence of intent was not required, and that intent may be inferred “where the applicant engages in a ‘a pattern of lack of candor,’ including where the applicant repeatedly makes factual representations ‘contrary to the true information he had in his possession.’”¹⁵⁹

Judge Newman also disagreed with the majority on the materiality of the references, believing that neither the district court nor the majority had established that the references led to unpatentability. Instead, the district court stated, and she agreed, that the references disclosed only “motivations, benefits, and cumulative teachings.”¹⁶⁰ However, in Judge Newman’s view, this still did not amount to but-for materiality, “whether taken alone, or with the cited references.”¹⁶¹

4. The *Regeneron* Majority Versus Dissent on *Aptix* Decision

Judge Newman based her dissent largely on the Court’s prior decision in *Aptix Corp. v. Quickturn Design Systems, Inc.*¹⁶² In her view, *Aptix* instructed that “litigation misconduct in the infringement suit ‘does not infect, or even affect’ the patent right” and that the majority erred in “‘infecting’ its analysis of inequitable conduct with counsel’s purported litigation misconduct years later in the infringement trial.”¹⁶³ However, the majority found that in the case at

155. *Regeneron II*, 864 F.3d at 1365 (Newman, J., dissenting).

156. *Id.* at 1365.

157. *Id.*

158. *Id.*

159. *Id.* at 1351 (citing *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014)).

160. *Id.* At 1396.

161. *Regeneron II*, 864 F.3d at 1369 (Newman, J., dissenting).

162. *See Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001).

163. *Regeneron II*, 864 F.3d at 1367 (Newman, J., dissenting) (quoting *Aptix*, 269 F.3d at 1375).

hand, *Aptix* was inapposite.¹⁶⁴ In that case, *Aptix* submitted falsified engineering notebooks to the court during litigation, and there was absolutely no evidence of misconduct in the patent's prosecution, or that the company participated in any wrongful conduct *during litigation or before the PTO*.¹⁶⁵ Where the district court erred was in declaring the patent unenforceable as a form of relief solely for the litigation misconduct, which it felt "necessary for deterring *Aptix* and other parties from engaging in future misconduct."¹⁶⁶ The Circuit Court emphasized the flexibility of the unclean hands doctrine, upon which the inequitable conduct defense is based, declaring that "[t]here is no limit inherent in the doctrine of unclean hands that prevents declaring a patent unenforceable based on the post-issuance conduct of the party seeking relief."¹⁶⁷ However, despite the doctrine's flexibility, the Court found that it "does not reach out to extinguish a property right based on misconduct during litigation to enforce the right."¹⁶⁸

The *Aptix* court skipped past an inequitable conduct analysis, moving straight to a declaration of unenforceability as a sanction for the solely post-prosecution litigation misconduct.¹⁶⁹ Unlike *Aptix*, there was evidence that Regeneron had engaged in *both* pre-and-post-prosecution misconduct, which led the district court to draw its adverse inference based on *both* types of misconduct.¹⁷⁰ In the majority's view, the district court's sanction was not, as in *Aptix*, punishing Regeneron by holding the patent unenforceable, but instead only that an element of the inequitable conduct defense was established. The unenforceability of the '018 patent was not found until after Merus proved the remaining elements of inequitable conduct.¹⁷¹

The dissent appears to have equated the ultimate holding in the case with the sanction imposed for Regeneron's litigation misconduct. While the adverse inference sanction did ultimately affect the final decision of the court on the issue of enforceability, allowing Merus to meet its burden to prove inequitable conduct, the sanction itself was

164. *Regeneron II*, 864 F.3d at 1364.

165. *Aptix*, 269 F.3d at 1371, 1377.

166. *Id.* at 1377-78.

167. *Id.* at 1379-80.

168. *Aptix*, 269 F.3d at 1375.

169. *See Aptix Corp. v. Quickturn Design Sys., Inc.*, No. 98-00762, 2000 WL 852813, at *32 (N.D. Cal. June 14, 2000), *aff'd in part, vacated in part*, 269 F.3d 1369 (Fed. Cir. 2001).

170. *Regeneron II*, 864 F.3d at 1364 ("Regeneron is accused not only of post-prosecution misconduct but also of engaging in inequitable conduct *during* prosecution.").

171. *Id.*

not non-enforceability. Therefore, it seems that the majority properly distinguished *Aptix* since the actions of the parties and the remedy declared by the court was different than that of the case at hand.

IV. THE IMMEDIATE IMPACT OF *REGENERON* AT DISTRICT COURT

As of February 2018, only two district court cases have cited to the *Regeneron* decision for the proposition that courts may draw an adverse inference regarding the prosecution and scope of a patent based on misconduct during litigation. Because neither case reached a conclusion regarding whether the patents at issue were unenforceable for inequitable conduct, neither case demonstrates a significant departure from the law prior to *Regeneron*. Although there are a limited number of cases that have come out in this area since *Regeneron*, it appears that the Federal Circuit's decision in *Regeneron* has emboldened more courts to consider a wider range of misconduct to draw adverse inferences regarding inequitable conduct to limit or terminate patent rights.

The first district court decision that cited *Regeneron* relied on its precedent to support an inference of specific intent for failing to disclose relevant prior art during prosecution. In *Shuffle Tech International LLC v. Sci. Games Corp.*, the patent owner Scientific Games moved for summary judgment contending, among other things, that no reasonable juror could infer that the original patentee had specific intent to defraud the PTO during the prosecution of the disputed patent.¹⁷² Shuffle Tech alleged that the original patent owner had committed inequitable conduct by failing to disclose relevant pieces of prior art during the prosecutions and reexaminations of two of its patents.¹⁷³ Shuffle Tech further alleged that Scientific Games violated antitrust laws under *Walker Process*, by utilizing a patent obtained through intentional fraud on the USPTO to create or preserve a monopoly.¹⁷⁴ To establish of the original patent owner's intent to defraud the USPTO, Shuffle Tech presented evidence that the patent owner had made contradictory statements during prosecution of the patent. The court found this evidenced that the patent owner had a "lack of candor" and knowingly misrepresented the state of the prior art to the PTO. Citing *Regeneron* for authority,

172. *Shuffle Tech Int'l LLC v. Sci. Games Corp.*, No. 1:15-cv-3702, 2017 WL 3838096, at *1-*2 (N.D. Ill. Sept. 1, 2017).

173. *Id.* at *2.

174. *Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80 (1965).

the court then drew an adverse inference of fraudulent intent.¹⁷⁵ The court found that Shuffle Tech had provided sufficient evidence to support a finding that SHFL acted with fraudulent intent in omitting the withheld references at issue, and that a reasonable jury could infer from that “lack of candor” that the omission was for the purpose of defrauding the PTO.¹⁷⁶ While *Shuffle Tech* is unlike *Regeneron* in that the patent owner’s misconduct was before the USPTO and there was no evidence of litigation misconduct, it is notable that the court cited *Regeneron* to support drawing an adverse inference, which appears to be directly contrary to the primary holding of the Federal Circuit in *Therasense*.

The second district court decision case that cited *Regeneron* did so to support the proposition that mere discovery disputes during litigation could be used to infer specific intent. In *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc.*, the plaintiff alleged that TWi’s generic drug product would infringe Supernus’ patents.¹⁷⁷ Supernus sought discovery regarding TWi’s selection of a particular drug ingredient. While TWi argued that the ingredient was selected for routine reasons, it also invoked attorney-client privilege to protect information regarding TWi’s selection of the ingredient from discovery. The parties submitted briefing as to whether the Court should draw an adverse inference from TWi’s invocation of the attorney-client privilege. Citing *Regeneron* for support, the court stated that it was “tempted” to draw an adverse inference from “TWi’s caginess on the issue” and TWi’s use of privilege as a sword and shield. However, the court ultimately declined to draw an adverse inference because there was other “ample evidence” establishing why TWi chose to use the ingredient in its generic drug.¹⁷⁸

V. THE PRACTICAL IMPACT OF *REGENERON*: TIPS FOR PRACTITIONERS

While the *Regeneron* decision did not explicitly change the standard for inequitable conduct, it appears to have created a new way for defendants to prove the elements of the affirmative defense. Because the *Regeneron* decision implicated both the patent prosecution counsel and litigation counsel in its finding, prosecutors and litigators should each consider taking precautionary measures to

175. *Shuffle Tech*, 2017 WL 3838096, at *13.

176. *Id.* at *14.

177. *Supernus Pharm., Inc. v. TWi Pharm., Inc.*, 265 F. Supp. 3d 490, 490 (D.N.J. Sept. 21, 2017).

178. *Id.* at *20 (quoting *Regeneron II*, 864 F.3d at 1364-65).

avoid future claims of inequitable conduct. The following tips and considerations can help attorneys guard against new claims of inequitable conduct spurred by *Regeneron*.

A. Disclosures During Prosecution

Having open and honest communications with the USPTO during prosecution is fundamental to avoiding a finding of inequitable conduct. As discussed in greater depth above, prosecutors should be careful to avoid understating the relevance or importance of prior art before the USPTO. By broadening the adverse inference analysis, *Regeneron* may encourage some defendants to rely on arguments that the prosecuting attorney mischaracterized prior art during the prosecution of the asserted patent. To avoid these types of assertions, prosecutors may want to adopt an overly candid approach in making assertions and disclosures to the USPTO, erring on the side of over-disclosure and literal accuracy when characterizing prior art. Creating a clear record of good faith efforts to disclose accurate information during the patent prosecution process is also important. As discussed in further detail below, the same guiding principles hold true for litigation counsel.

As discussed previously, all persons substantively involved in the prosecution of a patent application, including both the inventors and their attorneys, owe a duty of candor to the USPTO to disclose “all information known . . . to be material to patentability.”¹⁷⁹ However, as we have seen in the cases discussed above, what defines “known” and “material to patentability” is often subjective and rarely clear. Too often prosecutors fail to submit thorough Information Disclosure Statements (IDSs) during prosecution, which makes the resulting issued patents more vulnerable to inequitable conduct claims and arguments that the patent is unenforceable. When determining which references to submit in an IDS, applicants must balance numerous strategic concerns regarding administrative burdens and internal costs, as well as concerns regarding possible future litigation risks. While failure to disclose material art may lead to claims that the applicant hid important art, disclosing an overly long list including possibly irrelevant references could lead to claims that the applicant intentionally buried important references in a long list.

179. 37 C.F.R. § 1.56(a) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office [All persons involved in the patent application owe] a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”); 37 C.F.R. § 1.97; MPEP § 609.04(a) (9th ed. Rev. 8, Jan. 2018).

Hypothetically, applicants should endeavor to disclose all reasonably relevant references that are not cumulative. However, determining what a patent examiner would consider cumulative is challenging, and failing to disclose a reference that is clearly cumulative is likely to be seized upon by litigation counsel as evidence of inequitable conduct. Because claims of burying are less common and harder to prove than claims of hiding, and additionally because claims are construed to have their broadest reasonable interpretation during prosecution, applicants should err on the side of disclosure if a reference is arguably relevant, even if it appears to be cumulative.¹⁸⁰ Note that intent is critical to the inequitable conduct analysis, and an applicant should not submit irrelevant or cumulative art with the intent to bury relevant references.

Patent applicants should also pay close attention to references cited by foreign patent offices during the prosecution of any related foreign applications.¹⁸¹ Disclosure of these references will support later claims that the applicant made good faith efforts to comply with their duty of candor and therefore did not intend to deceive the USPTO. Additionally, when citing non-English references in IDS, applicants should provide an English translation of at least the most material parts of the foreign reference to aid examiners.¹⁸² Ideally, the best practice would be to provide a translation of the entire reference to avoid charges that the partial translation was an effort to mislead the examiner by pointing them away from relevant untranslated portions. However, due to the high costs associated with the translation of technical documents, a full translation is often not economically feasible.

Complying with the duty of disclosure can be a burdensome task for applicants, particularly where foreign counterparts or pending domestic family members necessitate numerous IDS filings. Nonetheless, thorough and accurate information disclosure aids the

180. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1185 (Fed. Cir. 1995) (“When a reference was before the examiner, whether through the examiner’s search or the applicant’s disclosure, it cannot be deemed to have been withheld from the examiner.”) (citing *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991)); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 547 (D.N.J. 1999) (holding that defendant could not show deceptive intent to support its claim that the patent owner buried material information by not highlighting the most relevant portions in its submission to the USPTO); *Regeneron II*, 864 F.3d at 1350.

181. MPEP § 2001.06(a); 37 C.F.R. § 1.97-1.98.

182. *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1376 (Fed. Cir. 2000), *amended* (Apr. 5, 2000) (affirming that the patent applicant intended to deceive the USPTO by presenting a partial translation of a foreign reference that omitted translations of the most material disclosures of the foreign reference).

USPTO's examination of the application and can ultimately add substantial value to the patent. Patent examiners are allotted very little time for their prior art searches, and thus clear and accurate disclosures by applicants help the examiners analyze the state of the art in a more complete and timely manner. Extensive disclosure benefits the applicant because all references properly cited to the examiner are listed on the face of the issued patent and are presumed to have been reviewed by the examiner.¹⁸³ If the patent is litigated, courts and juries give considerable deference to the patent office, making it difficult to invalidate the patent over the listed prior art. Consequently, patents with thorough disclosures of prior art are also more valuable for sale and licensing because knowledgeable buyers and licensees recognize that full disclosure during prosecution process tends to support the presumption of validity of the patent.

When preparing Information Disclosure Statements, it is essential that practitioners have systems in place to ensure that all relevant references (prior art or otherwise) are considered for disclosure. To avoid any appearance of impropriety, careful planning prior to submitting the IDS will help to protect the client and practitioner against claims of inequitable conduct. For most clients, time and money are exceedingly important, which may dictate filing strategies that reduce these burdens. For example, when prosecution a group of related patent applications (for example, a group of application claiming priority to a common parent), it may be advisable to file consolidated IDSs at periodic intervals citing art that is relevant to each member of the group. Doing so may allow the applicant to cross-cite all relevant information without spending more than necessary to file IDS forms.

Finally, note that the applicant's disclosure obligations continue throughout the prosecution of the patent application. Thus, applicants should consider continually submitting IDSs to disclose additional relevant and non-cumulative prior art discovered during the prosecution of foreign patent applications, international patent searches, or any other search or analysis conducted during the pendency of a patent application.

B. Post-Allowance Disclosures

Upon receipt of a Notice of Allowance, an applicant should review the application and file history to confirm that all potentially relevant documents were disclosed in IDSs, and that the examiner

183. MPEP § 609.06.

considered all cited references in those IDSs. To ensure a clear record that the examiner considered all of the documents disclosed in the IDS, the applicant should verify that the examiner initialed all prior art cited in the IDS filings. If not, it may be appropriate to contact the examiner and request that an initialed IDS be issued and included in the file history. Although an issued patent is presumptively valid, that presumption is strengthened by evidence that the examiner considered all relevant prior art references cited during the prosecution of the patent. Furthermore, should a defendant attempt to assert a cited prior art reference against the patent during litigation, the court and jury will likely give substantial deference to the USPTO's determination that the patent was valid over the cited art.

The applicant's duty to disclose all potentially relevant documents continues until the day the patent issues.¹⁸⁴ Therefore, if an applicant becomes aware of potentially relevant documents at any time prior to the issuance of the patent, the applicant must submit those documents to the PTO in an IDS. This scenario of accidental nondisclosure most often occurs when a patent is examined quickly and the Notice of Allowance arrives before the applicant submitted all of the relevant documents for the IDS to the USPTO. Thus, post-allowance review should include careful consideration of all submitted IDSs and prior art known to the applicant. This cautious review and submission process may prevent the expense of litigation against allegations of inequitable conduct for failing to disclose known material references. Addition of prior art references to the prosecution history also gives applicants the opportunity to record in the prosecution history arguments showing validity of the patent over disclosed references and/or amend claims to ensure validity over the disclosed art.

Note, however, the receipt of a Notice of Allowance officially closes prosecution of the patent application, and IDSs filed after the Notice of Allowance may not be considered by the Examiner. As such, if the applicant realizes that not all potentially relevant documents have been submitted to the PTO, the applicant can file an IDS with a Request for Continued Examination (RCE) to reopen prosecution and have the documents considered. However, if the applicant has already paid the issue fee for the allowed application, then the applicant may need to file a petition to withdraw the application from issuance and then file a supplemental IDS for the examiner's consideration. In both cases, reopening prosecution and submitting the IDS will likely substantially delay the ultimate

184. 37 C.F.R. § 1.97.

issuance of the patent. Thus, patent applicants should weigh the possibility of delay against the relevance and importance of the newly disclosed reference. As another alternative, the USPTO has implemented a Quick Path IDS (QPIDS) pilot program which eliminates the requirement that an applicant file a Request for Continued Examination (RCE) in order to add an information disclosure statement (IDS). Under the QPIDS pilot program, the USPTO will issue a corrected notice of allowability instead of reopening prosecution if the examiner determines that no information in the newly submitted IDS necessitates further prosecution of the patent application.¹⁸⁵

Note that if the patent issues and patentee discovers that a person associated with the prosecution of the patent knew of materially relevant information during the pendency of the application and failed to disclose it to the USPTO, the patentee may want to consider filing a request for supplemental examination, which is referred to as *ex parte* reexamination.¹⁸⁶ In order to ensure a clear record of good faith and compliance, an applicant can request the USPTO to conduct the supplemental examination of the patent to correct, reconsider, or consider information that may be relevant to the patent in question.

During the reexamination process, the USPTO may confirm the validity of patent claims over newly disclosed prior art or the patent holder can amend claims as necessary to overcome the newly disclosed prior art. Because reexamination is often complete within a year, it may even be used to change the scope of claims for a patent that is currently being asserted, resulting in a reissued patent with new claims in the middle of litigation. When reissue of a patent changes the scope of the claims, parties that practiced or prepared to practice the claims prior to reissue may have intervening rights to continue practicing the patent claims. But any information considered during the supplemental examination would be added to the record of information that was submitted and considered during the prosecution of the patent, and the supplemental examination would thus eliminate a defendant's ability to claim in a future infringement litigation that the applicant hid the information from the USPTO. Thus, even if the patentee believes the reference was merely cumulative, reexamination

185. 77 Fed. Reg. 27443 (May 10, 2012). All compliant requests for consideration of an information disclosure statement under the QPIDS pilot program filed on or before September 30, 2018, will be considered.

186. See 35 U.S.C. § 257(a) ("A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish."); see also MPEP § 2802.

proceedings may help avoid inequitable conduct allegations by creating a record clarifying that previously-known art is not material.¹⁸⁷

Finally, if the patent holder becomes aware of a material reference after issuance of the patent, while there is no duty to disclose at this point, the patentee still has the option of submitting a request for supplemental examination in order to create a record that the USPTO considered the prior art and nevertheless still found the claims valid.

C. *Pre-Litigation Diligence*

Although *Regeneron* may change the way courts remedy misconduct after a finding of inequitable conduct, the basic *Therasense* two-prong framework has not changed and the party asserting the defense still must show both materiality and intent.

The “but-for” materiality standard for inequitable conduct asks courts to analyze whether prior art would have prevented the issuance of the patent from the USPTO. Thus, the “broadest reasonable interpretation” claim construction standard used during prosecution at the USPTO is applied for this analysis. As such, a patent holder’s litigation counsel cannot count on a narrow claim construction to rebut but-for materiality of a reference.

While litigation counsel cannot turn back time and change what occurred before the USPTO during prosecution, they can take steps to avoid adverse inferences based on their own conduct during the litigation. Again, honesty with the court as well as opposing counsel in discovery and all other stages of litigation is the best rule of thumb to avoid “intent” accusations. As seen in *Regeneron*, misuse of attorney/client privilege and confidentiality claims can negatively impact the litigation and render the asserted patent completely unenforceable.

Prior to asserting a patent, a patent holder’s litigation counsel should aim to have a clear and complete understanding of all prosecution history for the patent-at-issue. Careful review of communications between the patent holder and its prosecution counsel should be a critical part of the pre-litigation investigation. Litigation counsel should investigate nonprivileged communications and documents that could be interpreted as showing deceptive intent and weigh when and how to disclose these documents to the court and

187. Unless the patent holder intentionally misleads the USPTO during the reexamination process, as the Federal Circuit found in *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1192 (Fed. Cir. 2014).

the opposing party. As *Regeneron* demonstrated, unreasonable attempts to hide these types of documents can be construed as misconduct and result in severe consequences even if the alleged misconduct has little to do with the prosecution process before the USPTO.

D. Strategic Assertion

There are obvious benefits to litigating patent disputes that arise over patents that were prosecuted by the same firm including an expertise in the particular patent and its subject matter, knowledge of the background conception and reduction to practice of the invention, and knowledge and records of the prosecution history of the patent. However, acting as both litigation and prosecution counsel for the same patent holder regarding the same patent may also cause genuine or perceived conflicts of interest issues, complex privilege issues, and/or toll malpractice claims against the patent prosecution counsel.

For instance, to the extent that a defendant's inequitable conduct claims raise issues of misconduct or legal ethics violations by the patent prosecutor, litigation counsel may in certain circumstances be faced with choosing to defend a colleague, the patent prosecutor, or a client, the patent holder. With respect to privilege, it may be difficult to draw the line between litigation privilege and patent prosecution privilege, such that waiver of privilege on one matter may be construed to waive privilege on the other. Additionally, from a practical perspective, it may be difficult to sift through documents to identify which are subject to which privilege. Lastly, if a patent holder believes its patent prosecution counsel committed malpractice, under the "continuous representation doctrine," the statute of limitations on the legal malpractice claim is tolled while the firm continues to represent the patent holder, e.g., during the litigation. If the patent holder wishes to later bring such a malpractice action against the attorney or firm based on the inequitable conduct, depending on the particular state's law, this can mean that even if the limitations period would have run, estopping the client from bringing the claim, the tolling will allow the claim.¹⁸⁸

Litigation counsel should carefully consider these issues before asserting a patent prosecuted by its firm.

188. For a recent case applying this doctrine, resulting in a \$17 million judgment being upheld against a firm (though not in the patent context), see *Red Zone LLC v. Cadwalader, Wickersham & Taft, LLP*, 988 N.Y.S.2d 588, 588 (N.Y. App. Div. June 19, 2014).

CONCLUSION

The Federal Circuit's ruling in *Regeneron* seems to demonstrate that litigation misconduct may be relevant to the intent analysis, at least when the misconduct is closely related to the patent prosecutors' work. In doing so, the decision opens new opportunities for defendants asserting inequitable conduct defenses to challenge the litigation conduct of the patentee or its counsel. While the court considered *Regeneron*'s litigation misconduct egregious, the circumstances that gave rise to it are not uncommon in practice. In fact, disputes over the proper scope or waiver of attorney-client privilege are inherent to inequitable conduct proceedings, which squarely place attorney-client communications and attorney mental impressions 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, *Regeneron* invites defendants to transform disputes over privilege into affirmative arguments in support of an inequitable conduct defense.

While it seems unlikely that the frequency of the inequitable conduct defense will rise to its former plague-like levels, *Regeneron* may still have a significant impact in patent litigation, perhaps providing a new shield for defendants to use against unscrupulous or overly combative plaintiffs.