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The Federal Circuit Seeks to Rein in Inequitable Conduct in *Therasense*



BY JAMES STRONSKI AND CHIEMI SUZUKI

In the much-anticipated *Therasense, Inc. v. Becton, Dickinson and Co.* decision, a divided U.S. Court of Appeals for the Federal Circuit, sitting en banc, made fundamental changes to the law of inequitable conduct. Chief Judge Rader, writing for the majority in the 6-1-4 decision, explained: “This court now tightens the standards for finding both intent and materiality in

James Stronski (jstronski@crowell.com) is a partner with Crowell & Moring LLP in New York. Chiemi Suzuki (csuzuki@crowell.com) is counsel with the firm in New York. The views, opinions, and statements expressed in this article are those of the authors and do not represent the views of Crowell & Moring LLP or its clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

order to redirect a doctrine that has been overused to the detriment of the public.”¹

Many patent holders and patent prosecutors will cheer this opinion because it raises and clarifies the standards for proving both the materiality and intent-to-deceive elements, and it also eliminates the balancing step in which those elements were balanced such that a strong showing on one could compensate for a weaker showing on the other. When considered in light of the Federal Circuit’s 2009 *Exergen Corp. v. Wal-Mart Stores, Inc.* decision—requiring that inequitable conduct be pled with particularity²—these heightened substantive standards are expected to significantly curtail the assertion of inequitable conduct in litigation. By setting a new single standard for materiality and by clarifying what is needed to prove intent to deceive, *Thera-*

¹ Slip op., *Therasense, Inc. v. Becton, Dickinson and Co.* (Fed. Cir. May 25, 2011) (en banc) (Nos. 2008-1511, -1512, -1513, -1514, -1596) (9 PLIR 661, 6/3/11).

² 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

sense may foster a more consistent, albeit limited, application of the doctrine by district courts. In so doing, *Therasense* may limit, as designed, an overuse of the inequitable conduct doctrine, which had been considered a “plague” by some. But it may deprive defendants of an important defense to patents obtained improperly.

The split decision in which six judges joined the majority opinion, four joined the dissenting opinion, and one a concurring opinion, underscores the importance of this decision and the strong—yet divergent—views held within the Federal Circuit on the proper scope of the inequitable conduct doctrine. This article reviews each of these opinions, suggests some practical considerations for litigants faced with these new standards, and with reference to the U.S. Supreme Court’s patent jurisprudence of the recent past, this article questions whether *Therasense* may be the kind of decision that the Supreme Court would review.

I. Background

Abbott (formerly *Therasense, Inc.*) owns U.S. Patent No. 5,820,551 (“the ’551 patent”) directed to disposable glucose test strips for diabetes management.³ Abbott filed the original application leading to the ’551 patent in 1984 and after thirteen years of protracted prosecution, the patent issued on October 13, 1998.⁴ During prosecution, the original application was repeatedly rejected over Abbott’s own U.S. Patent No. 4,545,382 (“the ’382 patent”).⁵ In 1997, Abbott’s patent attorney and Abbott’s Director of Research and Development presented a new reason for patentability to overcome the rejection over the ’382 patent.⁶ Submitting an affidavit and attorney argument to the U.S. Patent and Trademark Office (“PTO”), applicants stated that “[o]ne skilled in the art would not have read the disclosure of the [’382 patent] as teaching that the use of a protective membrane with whole blood samples was optional.”⁷ But several years prior to making this argument, while prosecuting the European counterpart to the ’382 patent, Abbott made contrary representations to the European Patent Office (“EPO”) regarding that same language, and these contrary representations were not disclosed to the PTO.⁸

In March 2004, Becton, Dickinson and Co. (“BD”) sued Abbott in the U.S. District Court for the District of Massachusetts seeking a declaratory judgment of non-infringement of U.S. Patent Nos. 6,143,164 (“the ’164 patent”) and 6,592,745 (“the ’745 patent”).⁹ Abbott countersued BD in the U.S. District Court for the Northern District of California, alleging infringement of the same patents, and additionally the ’551 patent.¹⁰ The District of Massachusetts transferred this case to the Northern District of California, and the Northern District of California consolidated the cases.¹¹ The Northern District of California also consolidated an action Abbott brought against BD’s supplier, Nova Biomedical Corp. (“Nova”) on the ’164, ’745, and ’551 patents, and

an action Abbott brought against Bayer Healthcare LLC (“Bayer”) on the ’745 and ’551 patents.¹² Of relevance here, the Northern District of California held the ’551 patent unenforceable for inequitable conduct for Abbott’s failure to disclose to the PTO its briefs and contrary representations to the EPO during prosecution.¹³

Abbott appealed to the Federal Circuit and on the issue of unenforceability, the panel affirmed, with a dissent.¹⁴ Subsequently, the Federal Circuit granted Abbott’s petition for a rehearing en banc and vacated the judgment of the panel.¹⁵ Taking this case as an opportunity to re-examine the inequitable conduct doctrine, the Federal Circuit, in its en banc order, specifically requested briefing on the following six issues:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office’s rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality? See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.¹⁶

In response, Abbott advanced a standard requiring a showing that the patentee acted with specific intent to deceive the PTO into granting the patent, and that the patent would not have issued but for the misconduct.¹⁷ Bayer and BD also each argued for a specific intent standard, but they each separately advanced a materiality standard based on the PTO’s own Rule 56, 37 C.F.R. 1.56, and not a “but for” standard.¹⁸ Thirty-four parties

¹² *Id.*

¹³ *Id.* at 14 (citation omitted).

¹⁴ *Id.* at 15 (citation omitted).

¹⁵ Order, *Therasense, Inc. v. Becton, Dickinson and Co.*, 374 Fed. Appx. 35 (Fed. Cir. April 26, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1595).

¹⁶ *Id.*

¹⁷ Abbott Diabetes Care, Inc. and Abbott Labs’ Br. on Reh’g En Banc (Corrected Copy), *passim*, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 3390233 (Fed. Cir. July 26, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1595).

¹⁸ Def.-Appellee Bayer Healthcare LLC’s Br. on Reh’g En Banc, *passim*, *Therasense, Inc. v. Becton, Dickinson and Co.*,

³ Slip op. at 1-2.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* at 10-11.

⁷ *Id.* at 11 (citing prosecution history).

⁸ *Id.* at 11-12 (citing prosecution history).

⁹ *Id.* at 13.

¹⁰ *Id.* at 13-14.

¹¹ *Id.* at 14.

filed amicus briefs, including the U.S. Solicitor General on behalf of the PTO. Most amici argued in favor of specific intent. Regarding the materiality standard, however, the amici advocated for a variety of different tests, including the aforementioned but-for standard and Rule 56 standards, and also the “reasonable examiner standard,”¹⁹ and common law fraud.²⁰

II. The Decision

The 6-1-4 decision illuminates the divergent standards for materiality that cluttered Federal Circuit and district court opinions and ultimately resulted in the Court’s taking this case en banc.²¹ While the three opinions all require proof of specific intent and agree on the elimination of the balancing step or “sliding scale” where a strong showing of intent could compensate for a weaker showing as to materiality (and vice versa), the opinions articulate very different standards for, among other things, materiality.

A. The Majority

The Court held that the accused infringer must prove by clear and convincing evidence that the patentee acted with specific intent to deceive the PTO.²² Reaffirming *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008), the majority explained that “to meet the clear and convincing evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’”²³ “[T]he evidence ‘must be sufficient to require a finding of deceitful intent in the light of all the circumstances.’”²⁴ This clarifies that negligence, or even gross negligence, is not the standard,

2010 WL 4310671 (Fed. Cir. Oct. 8, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1595); En Banc Br. of Defs.-Appellees Becton, Dickinson and Co. and Nova Biomed. Corp., *passim*, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 4310685 (Fed. Cir. Oct. 8, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1595).

¹⁹ See, e.g., Br. of Amicus Curiae of the Assoc. of Citizens for Patent Protection in the Public Interest in Supp. of Defs.-Appellees and Affirmance at 8-12, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 4622533 (Fed. Cir. Oct. 15, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598); Br. of Amicus Curiae Intel Corp. in Supp. of the Appellees at 8-12, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 4622534 (Fed. Cir. Oct. 15, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598); Br. of Amicus Curiae Apotex, Inc. Not Supp. Any Party at 14-15, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 3390240 (Fed. Cir. July 30, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598) (recommending in addition that Rule 56 be retained).

²⁰ See, e.g., Amicus Br. and Appx. of the Amer. Bar Assoc. as Amicus Curiae at 15-19, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 2751537 (Fed. Cir. June 17, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598).

²¹ See generally Br. of the Fed. Cir. Bar. Assoc. as Amicus Curiae in Supp. of No Party at 9-13, *Therasense, Inc. v. Becton, Dickinson and Co.*, No. 2008-1511, -1512, -1513, -1514, -1598 (Fed. Cir. Aug. 2, 2010) (discussing five different materiality standards that had been recognized by the Federal Circuit); Br. of the U.S. as Amicus Curiae on Reh’g En Banc in Supp. of Neither Party at 8, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 3390234 (Fed. Cir. Aug. 2, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598).

²² Slip op. at 24.

²³ *Id.* at 25 (citing *Star Scientific*, 537 F.3d at 1366).

²⁴ *Id.* at 25-26 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867,873 (Fed. Cir. 1988) (en banc)).

and that a core “single most reasonable inference” inquiry for inferring specific intent will govern.

The majority declined to adopt the PTO’s Rule 56 for its materiality standard, instead holding that inequitable conduct requires “but-for materiality”—in other words, where “the PTO would not have allowed a claim had it been aware of the undisclosed prior art.”²⁵ The majority singled out as an exception, cases of affirmative egregious misconduct.²⁶ “This exception to the general rule requiring but-for proof incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with ‘deliberately planned and carefully executed scheme[s]’ to defraud the PTO and the courts.”²⁷

The majority also eliminated the “‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”²⁸ As the Court makes clear: “a court must weigh the evidence of intent to deceive independent of its analysis of materiality.”²⁹

B. The Dissent

The dissent describes the majority opinion’s adoption of a but-for standard for materiality as a “significant and . . . unwise departure from this court’s precedents.”³⁰ Looking to precedent, the dissent cites the PTO’s own disclosure rule, Rule 56, as the materiality standard it would apply.³¹ Judge Bryson, writing for the dissent and joined by Judges Gajarsa, Dyk, and Prost, reasons:

First, the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher standard of materiality adopted by the majority will not provide appropriate incentives for patent applicants to comply with the disclosure obligations the PTO places upon them.³²

Additionally, the dissent takes on the majority for its “radical approach,” stating that “the majority has adopted a test that has no support in this court’s cases and is inconsistent with a long line of precedents dating back to the early years of this court.”³³ Continuing, the dissent warns that the majority’s but-for test “comes close to abolishing it [the doctrine of inequitable conduct] altogether.”³⁴ The dissent continues: “This court has repeatedly rejected the ‘but-for’ test as too restrictive in light of the policies served by the inequitable conduct doctrine.”³⁵

One rationale for raising the inequitable conduct standards is to address overdisclosure before the PTO, purportedly caused by concern over later inequitable conduct allegations. Addressing this, the dissent relies

²⁵ *Id.* at 27.

²⁶ *Id.* at 29.

²⁷ *Id.* (citing *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944)).

²⁸ *Id.* at 25.

²⁹ *Id.*

³⁰ Slip op. at 3 (Bryson, C.J., dissenting) (hereinafter “Dissent”).

³¹ *Id.*

³² *Id.*

³³ *Id.* at 5.

³⁴ *Id.*

³⁵ *Id.* at 8 (citations omitted).

on the PTO's amicus brief, which argued that this concern is best addressed by tightening the intent-to-deceive element, not by but-for materiality. The dissent argues that "[s]ince the problem of overdisclosure directly affects the PTO, there is no reason not to credit the PTO's asserting that a tightening of the intent element of the inequitable conduct doctrine should be sufficient to address the problem and that a drastic modification of the materiality element not only is not required, but would be contrary to the PTO's interest in efficient examinations."³⁶ The dissent also observes that the PTO, in its amicus brief, argued that the but-for standard is too restrictive and is not an "effective deterrent to ensure that material information will not be withheld during prosecutions."³⁷

C. The Concurrence

Judge O'Malley's concurrence is a direct challenge to the bright line rules of the majority and dissent, calling instead for a more flexible lens through which to assess materiality. The concurrence chides rigid rules, as they "fail to provide district courts with flexibility to find inequitable conduct in an extraordinary case where the conduct in question would not be defined as such under either test. This result is contrary to the very nature of equity and centuries of Supreme Court precedent."³⁸ Rather, "[w]e should adopt a test that provides as much guidance to district courts and patent applicants as possible, but, in doing so, we may not disregard the equitable nature of the inquiry at hand. Thus, we must make clear that, while we believe that the test we offer encompasses all forms of conduct sufficient to warrant a finding of inequitable conduct, we leave open the possibility that some form of intentional misconduct which we do not currently envision could warrant equitable relief."³⁹

In keeping with the call for flexibility in the application of this equitable doctrine, the concurrence also comments that the remedy—rendering unenforceable all claims—is overly harsh, as some commentators and amici have argued.⁴⁰ Judge O'Malley points out that

³⁶ *Id.* at 7-8.

³⁷ *Id.* at 9-10.

³⁸ Slip op. at 5 (O'Malley, J. concurring) (hereinafter "Concurrence"); see *id.* at 6 ("We should adopt a test that provides as much guidance to district courts and patent applicants as possible, but in doing so, we may not disregard the equitable nature of the inquiry at hand. Thus, we must make clear that, while we believe that the test we offer encompasses virtually all forms of conduct sufficient to warrant a finding of inequitable conduct . . .").

³⁹ *Id.* at 6.

⁴⁰ See, e.g., Br. of Amicus Curiae Intel Corp. in Supp. of Appellees at 16-18, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 4622535 (Fed. Cir. Oct. 15, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598); Br. of Eisai Co., Ltd. and Eisai Inc. as Amici Curiae on Reh'g En Banc in Supp. of Neither Party at 21-22, 2010 WL 3390220 (Fed. Cir. Aug. 2, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598); at Br. of Amicus Curiae of the Intellectual Prop. Law Assoc. of Chicago Supp. Neither Affirmance Nor Reversal at 20-28, 2010 WL 3390227 (Fed. Cir. Aug. 2, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598); Br. of Wash. Legal Found. as Amicus Curiae in Supp. of Pls.-Appellants, Urging Reversal at 17-21, *Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 3390237 (Fed. Cir. Aug. 2, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598) (citing, *inter alia*, Nicole M. Murphy, *Inequitable-Conduct Reform: Is the Death Penalty for Patents Still Appropriate?* 93 Minn. L. Rev.

such remedy "is neither compelled by statute, nor consistent with the equitable nature of the doctrine."⁴¹ Instead, a district should have the flexibility in fashioning an appropriate remedy that is "commensurate with the violation."⁴²

III. Inequitable Conduct in the Post-*Therasense* World

The majority opinion in *Therasense* clarifies the requirements for proving inequitable conduct and directs litigants as to the proper standards for inequitable conduct claims. Practically speaking, this standard increases the hurdles for claiming and proving inequitable conduct. Considered in concert with *Exergen*, which requires accusers to plead inequitable conduct with particularity,⁴³ *Therasense* may sound the death knell for some inequitable conduct claims and should reduce the number of cases in which it is proven.

A. Practical Considerations for Alleged Infringers

Exergen requires inequitable conduct to be pled with particularity, and *Therasense* now lays out the requirements for specific intent and but-for materiality that a litigant must show. For a defendant who believes a patent was obtained through inequitable conduct, these heightened standards dictate that discovery be taken as soon as feasible concerning at least the "specific intent." This means discovery of individuals who may have been involved in the alleged inequitable conduct and developing the record on which a court may apply the "single most reasonable inference" analysis. Additionally, these new standards may raise the importance of patent law and PTO experts, whose testimony will be sought on whether the new but-for standard has been met, and whether the new egregious misconduct exception applies.

In some cases, the presence of witnesses domiciled abroad may make it difficult to develop the "specific intent" narrative. In other cases, scheduling orders or local rules on when pleadings may be amended also may make it practically difficult to take the needed discovery before a deadline for the amendment of pleadings. Each party will want to negotiate a date for amendment of the pleadings that benefits their respective positions in view of these new standards.

These new standards may raise the importance of patent law and office practice experts at trial, who will provide testimony on the new but-for materiality element and the egregious misconduct exception. Accordingly, it may be wise to engage patent law experts, in addition to technical experts, earlier on in a case whenever there is a possibility that inequitable conduct may become an issue. These experts may play an important role to testify on standards that would have governed the consideration of the misrepresentation or omission before the PTO in the context of determining whether such conduct satisfies the materiality standard. Illus-

2274, 2298 (2009)); Br. of Verizon Commc'ns Inc. as Amicus Curiae in Support of Neither Party on Reh'g En Banc at 12-20, 2010 WL 2861897 (Fed. Cir. June 30, 2010) (Nos. 2008-1511, -1512, -1513, -1514, -1598).

⁴¹ Concurrence at 7.

⁴² *Id.* at 7-8 (citing *Columbus Bd. of Educ. v. Pennick*, 443 U.S. 449, 465 (1979); *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944); *Miller v. French*, 530 U.S. 327, 360 (2000)).

⁴³ 575 F.3d at 1328-29.

trating the importance of this inquiry, the majority explained the differing standards that apply to patentability (i.e., but-for causation) and invalidity, stating:

Often the patentability of a claim will be congruent with the validity determination—if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO. However, even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO’s different evidentiary standards. See MPEP §§ 706 (preponderance of the evidence), 2111 (broadest reasonable construction).⁴⁴

Accordingly, expert testimony on what would or would not have blocked patent issuance under the PTO’s different evidentiary standards and practices, among other things, may now become critical evidence at trial.

B. Practical Considerations for Patentees

One would expect that *Therasense* may lead to a notable decline in the number of defendants raising inequitable conduct. But it also stands to reason that the quality of these claims after *Therasense* may be better (i.e., more likely to be meritorious) than those in the preceding years.

Patentees should conduct a thorough pre-suit investigation into the prosecution of the patents that may be asserted. This includes analysis of the patent family, as well as foreign counterparts, with a special focus on discrepancies between disclosures and arguments. Depending on the technologies at issue, it may make sense to engage technical experts early on, as well as to seek the consultation of a patent law expert, to assist in this pre-suit analysis. In most cases, this should give patentees a significant advantage and head start in developing a strong narrative on the specific intent and but-for materiality elements. And it may lead to decisions on which patents to assert.

Once a case has begun, the specific intent narrative will depend largely on documents produced by the patentee and the inventors and the depositions of the inventors and patent prosecutors. If the patentee has done a good pre-suit investigation, not only will it have had the opportunity to exclude from suit patents potentially at risk of an inequitable conduct finding, but also to best manage discovery and the schedule based on the strengths and weaknesses of that specific intent narrative for the patents in suit.

Because few, if any cases, have a true “smoking gun” evidentiary admission of specific intent, that element will now be determined based on the “single most reasonable inference” inquiry. Accordingly, defendants in most cases will need to develop circumstantial evidence to support the conclusion, by clear and convincing evidence, that the single most reasonable inference is to find specific intent to deceive, and not mere mistake, negligence or even gross negligence.⁴⁵ Where the

⁴⁴ Slip op. at 28.

⁴⁵ See generally *id.* at 26 (“Because the party alleging inequitable conduct bears the burden of proof, the ‘patentee need

record may just as reasonably be explained by a inference of mistake, negligence or gross negligence, this new standard may lead to the greater use of motions for summary judgment to dispose of these claims. Similarly, the heightened but-for standard of materiality may lead to an increase in dispositive motion practice by patentees.

C. Practical Considerations for Patent Prosecutors

The majority opinion rejected PTO Rule 56 as the materiality standard, adopting instead the heightened but-for standard. By raising the materiality standard, the majority opinion seeks to reduce the practice of providing extraneous art to the PTO. The majority explains: “Because PTO Rule 56 sets such a low bar for materiality, adopting this standard would inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy.”⁴⁶ As before, a patent prosecutor must comply with the requirements of Rule 56, but the but-for causation standard of *Therasense* can be expected to lessen the practice of submitting cumulative or other references simply out of concern that an omitted reference will be the basis for an inequitable conduct defense.

D. Practical Considerations in Hatch-Waxman Litigation

The practical considerations for litigants discussed above apply equally to patent litigations brought under the Hatch-Waxman Act against filers of an Abbreviated New Drug Application (“ANDA”). New practical considerations for both the patentee and the alleged infringer arise in the context of discovery (i.e., determining whether a claim of inequitable conduct can be brought), pre-trial dispositive motions, and trial.

Because an ANDA filer will have at least prepared a notice letter, including the factual and legal bases of the applicant’s opinion that the patent is invalid, unenforceable, or will not be infringed, the ANDA filer will have an early opportunity to focus on the viability of an inequitable conduct claim.⁴⁷ Many inequitable conduct claims are related to invalidity defenses in that they concern arguments and statements made, or art withheld, that concern patentability. In analyzing the Orange Book-listed patents for purposes of the notice letter, the ANDA filer will be in a position to focus on potential inequitable conduct theories and evaluate whether the present case is one in which an inequitable conduct claim may be viable. This analysis should be done at the earliest time.

Given the specificity required to plead inequitable conduct with particularity, in many cases at the time of the Answer, an ANDA filer will not have sufficient information to “identify the specific who, what, when, were, and how, of the material misrepresentation or omissions committed before the PTO” and to sufficiently allege the underlying facts regarding intent and

not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence’ . . . The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.” (citation omitted).

⁴⁶ *Id.* at 34.

⁴⁷ See 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

materiality.⁴⁸ But a well conceived discovery plan may allow an ANDA filer to uncover the particular facts related to this potential claim, including obtaining the relevant New Drug Application (“NDA”) and Investigational New Drug Application (“IND”), the prosecution of related patents in the PTO and in other jurisdictions, and depositions of patent prosecutors and other individuals involved in the suspected inequitable conduct.

But in some cases, timing and getting to trial without delay is critical to commercial success. The zealous pursuit of inequitable conduct discovery must be balanced against the particular strategic considerations inherent in many Hatch-Waxman cases where the ANDA filer seeks to expedite the case and limit issues that may delay trial. Pursuing a possible claim of inequitable conduct will not only increase the cost of litigation, but also potentially extend the discovery schedule and delay trial. Additionally, *Therasense* may result in an increased likelihood of dispositive motion practice on the part of the plaintiff.

In sum, the practical considerations for litigants in Hatch-Waxman cases largely parallel those for litigants in traditional patent cases. The practical effect of *Therasense* may be that fewer claims of inequitable conduct make it to trial, but those that do may be more likely to be successful. A defendant now faces a new, heightened barrier to successfully pleading inequitable conduct to meet the substantive standards of *Therasense*. That and the additional cost and delay potentially involved in developing the evidence to support an inference of specific intent may deter some from bringing viable inequitable conduct claims. And where inequitable conduct has been pled successfully, some district court may allow greater dispositive motion practice by plaintiffs seeking dismissal of these claims before trial. While this may reduce the number of inequitable conduct claims that are litigated and tried, it also may lead to a greater success rate among those that are tried, as we can expect there to be a greater culling process in which the claims that are tried are more likely to have the evidence to support an inference of specific intent.

IV. The Future of Inequitable Conduct Jurisprudence

The 6-1-4 split leaves the inequitable conduct standard wide open for potential Supreme Court review. Indeed, just one week after the Federal Circuit’s decision, BD and Nova moved the Federal Circuit for a stay of the issuance of mandate for ninety days, pending the filing of a petition for a writ of certiorari to the U.S. Supreme Court.⁴⁹ As support, BD and Nova note the essential disagreement on the materiality requirement, on which the Federal Circuit split 6-5 in favor of the but-for standard.⁵⁰ BD and Nova also argue that “the but-for standard of materiality is inconsistent with the standard ap-

plied by the Supreme Court in several cases out of which the doctrine of inequitable conduct grew.”⁵¹ Further, “the fact that the majority rejects the PTO’s own materiality standard, and thereby reduces considerably a patent applicant’s incentive to comply with the PTO’s Rule 1.56, will give the Supreme Court an additional reason to undertake its own consideration of the appropriate standard for establishing materiality in inequitable conduct cases.”⁵²

Assuming that a petition for a writ of certiorari is filed, whether the Supreme Court takes the case on review is an open question. But considering *Therasense* in the context of the Supreme Court’s review of Federal Circuit decisions generally suggests that there is a reasonable likelihood that the high court would take this case. In the first 10 years after the Federal Circuit was established in 1982, the Supreme Court reviewed only three patent decisions.⁵³ But the Supreme Court’s interest in patent cases has changed since the mid-1990s. In more recent years, it has “increasingly asserted its appellate jurisdiction over the Federal Circuit.”⁵⁴ For the current October 2010 term alone, the Supreme Court granted certiorari in three patent cases—*Global-Tech Appliances, Inc. v. SEB S.A.*, No. 10-6; *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, No. 09-1159; and *Microsoft Corp. v. i4i Limited Partnership*, No. 10-290. This increase in numbers reflects the growing importance of patent cases and the Supreme Court’s interest in them.

The Supreme Court’s growing interest in patent cases, the importance of the inequitable conduct doctrine to patent law, the split within the Federal Circuit on the appropriate standards and the argument that the majority opinion may be inconsistent with Supreme Court precedent, all tend to weigh in favor of the Supreme Court taking this case. But divining whether the Supreme Court would take this case and what it would do with it are largely academic exercises in speculation. That said, we believe that there is at least a reasonable possibility that the Supreme Court will take this case and further revise the standards for proving inequitable conduct. Should the Supreme Court do so, we would expect that it may focus on materiality, and specifically the but-for standard, as well as the potential of introducing greater flexibility in the remedy for inequitable conduct. But for now at least, the *Therasense* majority opinion is the law of the land, and litigants and patent prosecutors need to take into consideration these new heightened standards.

⁵¹ *Id.* at 5; see *id.* at 6 (noting that “Judge Bryson’s dissent reads the same Supreme Court cases as inconsistent with the majority’s new standard”).

⁵² *Id.* at 6.

⁵³ Peter Lee, *Patent Law and the Two Cultures*, 2010 Yale L.J. 2, 42 (2010) (citing John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 Sup. Ct. Rev. 273, 278 (2002)).

⁵⁴ *Id.* at 43 (citing Gregory A. Castanias et al., *Survey of the Federal Circuit’s Patent Law Decisions in 2006: A New Chapter in the Ongoing Dialogue with the Supreme Court*, 56 Am. U. L. Rev. 793, 798-814 (2007)).

⁴⁸ *Exergen*, 575 F.3d at 1328-29.

⁴⁹ Defs.-Appellees Mot. to Stay Mandate at 1, *Therasense v. Becton, Dickinson*, 2008-1511, -1512, -1513, -1514, -1595 (Fed. Cir. June 1, 2011).

⁵⁰ *Id.* at 3-5.