

REPORT

THE FEDERAL CIRCUIT ANNOUNCES A MORE STRINGENT STANDARD FOR PROVING INEQUITABLE CONDUCT

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On May 25, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued its *en banc* decision in *Therasense, Inc. v. Becton, Dickinson and Company*, raising the standard to prove that a patent is unenforceable for inequitable conduct. We previously reported on the *Therasense* case in our February 2, 2010 Special Report, entitled "U.S. Duty of Disclosure Is Clarified Regarding Materiality of Patent Prosecution Statements."

Therasense increases the burden of proof for an accused infringer to establish that a patent is unenforceable due to inequitable conduct. According to *Therasense*, in a case involving nondisclosure of information, an accused infringer must prove (1) that the patentee acted with specific intent to deceive the USPTO by making a deliberate decision to withhold known material information, and (2) that the patent would not have issued "but for" the nondisclosure. With respect to the "but for" materiality standard, an exception can exist in cases involving affirmative egregious misconduct. *Therasense* neither limits the types of information that are subject to disclosure nor the USPTO's standard for determining materiality of information.¹ The decision may be subject to further review by the U.S. Supreme Court.

As discussed further below, we do not recommend significant changes in our clients' U.S. information disclosure policies at this time. However, the decision could reduce both the number of patents held unenforceable due to inequitable conduct and the litigation costs in cases where inequitable conduct allegations could previously have been raised.

¹ On May 26, the USPTO issued a press release indicating that it expects to issue guidance soon regarding its disclosure requirements in light of the *Therasense* decision.

I. Background**A. The Facts of the Case**

Abbott Diabetes Care, Inc. (formerly Therasense, Inc.) and Abbott Laboratories (collectively "Abbott") own the patent-at-issue, which involves disposable blood glucose test strips for diabetes management. The patent claims a test strip with an electrochemical sensor for testing whole blood without a membrane over the electrode.

Over thirteen years after the original application was filed and rejected on multiple occasions for anticipation and obviousness, Abbott's U.S. patent attorney and its Director of Research and Development ("R&D Director") decided to present claims directed to a sensor that did not require a protective membrane when used with whole blood. In presenting such claims, Abbott sought to distinguish the claimed sensor from a prior art sensor described in a U.S. patent also owned by Abbott that Abbott argued required a protective membrane when used with whole blood.

The prior art patent stated: "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules." The USPTO Examiner requested an affidavit to show that one of skill in the art would have understood the prior art sensor to have unconditionally required a protective membrane when used with whole blood. Abbott responded by submitting an affidavit from Abbott's R&D Director. According to the affidavit, the "optionally, but preferably" language would not have been understood as a technical teaching. Instead, one of skill in the art would have read the passage as being "mere patent phraseology." The attorney made similar arguments when submitting the affidavit. The Examiner accepted Abbott's position and the USPTO issued the patent.

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Several years earlier, while prosecuting the counterpart European patent application for the same prior art sensor, Abbott made representations to the European Patent Office ("EPO") regarding the "optionally, but preferably" language. There, Abbott sought to distinguish the claimed sensor having a protective membrane from a prior art sensor having a diffusion-limiting membrane semipermeable to glucose. Abbott's European counsel explained that the purpose of the claimed protective membrane was to serve as a safety measure, but the membrane did not control permeability, and was not required. Abbott's European counsel stated that this interpretation of the "optionally, but preferably" teaching is "unequivocally clear." Abbott's U.S. attorney and its R&D director were aware of the statements made to the EPO, but did not disclose them to the USPTO.

B. The District Court Action

Abbott sued Becton, Dickinson and Co. ("Becton") for infringement of three U.S. patents, including the patent-at-issue.

Among other things, the District Court held the patent-at-issue unenforceable for inequitable conduct because Abbott did not disclose to the USPTO the positions taken during prosecution of the European counterpart to the prior art patent. The District Court found that the statements made in the EPO briefs were material under the USPTO's materiality standard embodied in 37 C.F.R. §1.56 ("Rule 56"), and further found intent to deceive based in part on the absence of a good faith explanation for the attorney's and the R&D Director's failure to disclose the EPO briefs.²

The District Court made five underlying factual findings to support its inequitable conduct determination: (1) the affidavit representations made to the USPTO were

² Rule 56(b) indicates that information is material to patentability when it is not cumulative and (1) establishes, by itself, or in combination with other information, a *prima facie* case of unpatentability of a claim, or (2) refutes, or is inconsistent with, a position the applicant takes in opposing an argument of unpatentability or asserting an argument of patentability. Material information may include (1) arguments and factual assertions made during foreign prosecution and (2) U.S. and foreign Office Actions and responses in related applications. See our February 2, 2010 Special Report, discussed above, and our October 9, 2009 Special Report, entitled "The U.S. Duty of Disclosure as Applied to U.S. and Foreign Office Actions."

critical in overcoming the Examiner's rejection; (2) the statements in the EPO briefs contradicted representations made to the USPTO; (3) Abbott's U.S. patent attorney and its R&D Director both knew of the EPO statements and consciously withheld them from the USPTO; (4) neither Abbott's U.S. patent attorney nor its R&D Director provided a credible explanation for failing to disclose the statements in the EPO briefs; and (5) Abbott's U.S. patent attorney's and its R&D Director's explanations for withholding the EPO briefs were so incredible that they supported a finding of deceptive intent. Abbott appealed to the Federal Circuit.

C. The Federal Circuit Panel Decision

The majority of the three-judge Federal Circuit panel (Judges Dyk and Friedman) affirmed the District Court's judgment of unenforceability due to inequitable conduct, but Judge Linn dissented as to this issue. Regarding the District Court's underlying factual findings (1)-(5) discussed above, the panel majority held that findings (1) and (3) were undisputed on appeal and finding (2) was not clearly erroneous. The panel majority upheld findings (4) and (5) regarding deceptive intent, as being amply supported taking into account the District Court's assessment of witness credibility. In dissent, Judge Linn disagreed with the majority that Abbott had failed to provide a good faith explanation for believing that the EPO briefs were immaterial.

Abbott requested and was granted *en banc* review of the panel's decision regarding unenforceability due to inequitable conduct, and the panel decision was vacated.

II. The *En Banc* Federal Circuit Decision

The eleven members of the *en banc* court delivered a "6-1-4" decision on unenforceability. Chief Judge Rader wrote the majority opinion, in which Circuit Judges Newman, Lourie, Linn, Moore and Reyna joined. Circuit Judge O'Malley wrote a concurring-in-part and dissenting-in-part opinion. Circuit Judge Bryson wrote a dissenting opinion, in which Circuit Judges Gajarsa, Dyk and Prost joined.

As discussed below, the majority raised the burden of proving both deceptive intent and materiality in order to support an inequitable conduct defense, and vacated and remanded the case to the District Court to determine whether inequitable conduct should be found under the higher burdens. The other opinions, also discussed below, primarily disagreed with the majority's newly articulated

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standard for determining materiality and, thus, the judges authoring or joining in those opinions would have ruled differently.

A. The Majority's More Stringent Legal Standard

The majority opinion recognized that, to prevail on the defense of inequitable conduct, the accused infringer must prove, by clear and convincing evidence, that the patent applicant misrepresented or omitted material information with the specific intent to deceive the USPTO. Establishing inequitable conduct requires that an accused infringer prove both (1) materiality, and (2) intent to deceive, which are separate requirements. The majority acknowledged precedent requiring that, if the accused infringer meets its burden of proving deceptive intent and materiality, then the court must balance the equities to determine whether the patent applicant's conduct before the USPTO warrants rendering the entire patent unenforceable.³

The majority pointed out that inequitable conduct is a judge-made doctrine having its roots in a trio of U.S. Supreme Court cases (*Keystone*, *Hazel-Atlas* and *Precision*), in which the U.S. Supreme Court applied the unclean hands doctrine to dismiss patent cases involving egregious misconduct.⁴ From those roots, the majority traced how the inequitable conduct doctrine has come to embrace a wider scope of misconduct, including the mere nondisclosure of information to the USPTO, and has come to require findings of both intent to deceive and materiality.

³ The majority also acknowledged that, as a general rule, proof of inequitable conduct renders an entire patent unenforceable and, in one instance, flatly stated that inequitable conduct, "if proved, bars enforcement of a patent."

⁴ *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) (involving the manufacture of a false affidavit stating that a prior use was instead an abandoned experiment); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds* (involving the patentee's attorneys writing an article describing the invention as a remarkable advance in the art and having a well-known expert pass it off as his own work); *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945) (involving the suppression of perjured statements asserting false dates of conception and reduction to practice of the invention in an interference proceeding before the USPTO).

The majority acknowledged that the standards for proving intent to deceive and materiality have fluctuated and been weakened over time.

The majority commented that "inequitable conduct [in its weakened form] has become a significant legal strategy" that "cast[s] a dark cloud over the patent's validity and paint[s] the patentee as a bad actor." The majority further noted that charges of inequitable conduct "increas[e] the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." The majority went on to comment that "[l]eft unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system," and that "[w]ith inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury the PTO examiners with a deluge of prior art references, most of which have marginal value." The majority clearly intended to reign in this "plague" by establishing a new, stricter standard for evaluating allegations of inequitable conduct and, thus, raised the burden of proving both deceptive intent and materiality.

1. Intent

The majority held that, in a case involving the nondisclosure of information, a showing of intent to deceive requires the accused infringer to prove that the patent applicant made a deliberate decision to withhold known material information from the USPTO. This requires a showing that the patent applicant (1) knew of the information, (2) knew that the information was material, and (3) made a deliberate decision to withhold the information in order to deceive the USPTO. The majority confirmed that the fact that the patent applicant "should have known" that the information was material does not satisfy the intent to deceive standard.

The majority recognized that direct evidence of deceptive intent is rare, and thus a court may infer deceptive intent from indirect and circumstantial evidence. However, deceptive intent must be the single most reasonable inference that can be drawn from the evidence. When multiple reasonable inferences may be drawn, some of which do not involve deceptive intent, deceptive intent cannot be found. Moreover, the majority held that a court may not infer deceptive intent solely from materiality and a patentee need not offer any good faith explanation unless the accused infringer first proves a threshold level of intent to deceive by clear and convincing evidence.

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2. Materiality

The majority concluded that "but for" materiality is the standard for determining materiality, i.e., there must be a showing that the patent would not have issued but for the omission or misrepresentation.⁵ Determinations of patentability before the USPTO are governed by a "preponderance of the evidence" standard, requiring that it be more likely than not that a claim is allowable given its broadest reasonable interpretation in light of the specification.⁶ The policy behind the "but for" materiality standard recognized by the majority in the litigation context is that an entire patent should only be rendered unenforceable where the misconduct resulted in the patentee receiving an unwarranted claim.

Although "but-for" materiality generally must be separately established to prove inequitable conduct, an exception can exist for cases of affirmative egregious misconduct. The majority noted that affirmative egregious misconduct includes instances of, e.g., perjury, the manufacture of false evidence, or the suppression of evidence in schemes to defraud the USPTO or the courts. The majority reasoned that a patentee is unlikely to have undertaken such misconduct unless the patentee subjectively believed that the misconduct was necessary to obtain issuance of the patent. The "affirmative egregious misconduct" exception was recognized by the majority to provide enough flexibility to the inequitable conduct analysis to capture varying manifestations of egregious and abusive conduct.

⁵ The majority expressly rejected the USPTO's Rule 56 standard as governing materiality with respect to inequitable conduct determinations in the courts. However, pending any changes by the USPTO, Rule 56 still governs the duty of disclosure before the USPTO during prosecution of patent applications. As noted above, the USPTO has announced that it is reviewing its disclosure requirements in view of *Therasense*.

⁶ In contrast, a patent in litigation can only be rendered invalid by clear and convincing evidence, which generally requires a court to interpret the meaning of the claims. In interpreting claim meaning, a court is not bound to give the claims their broadest reasonable interpretation in light of the specification.

3. Balancing of Intent and Materiality to Determine Unenforceability

The majority left unanswered the question of whether clear-and-convincing showings of both deceptive intent and materiality necessarily render the entire patent unenforceable due to inequitable conduct, or whether a court may balance the showings and potentially arrive at another equitable remedy short of complete unenforceability. It may be inferred that the majority did not squarely address the balancing element of the inequitable conduct analysis because it was not necessary to reach its decision.

However, the majority made clear that, because deceptive intent and materiality are separate requirements for establishing inequitable conduct, a court may not use a "sliding scale" to allow an accused infringer to cure a weak showing of deceptive intent, i.e., a deceptive intent showing not proved by clear and convincing evidence, with a strong showing of materiality. Thus, the majority rejected this "sliding scale" approach, which had been followed in some prior decisions.

B. Holding

Because the District Court found intent to deceive based on the absence of a good faith explanation by Abbott, and relied upon the "should have known" negligence standard, the majority vacated the finding of inequitable conduct and remanded for further proceedings. On remand, the District Court is to analyze intent to deceive under the "knowing and deliberate" standard enunciated by the majority. In particular, the District Court must determine whether the evidence demonstrates that Abbott's U.S. attorney and its R&D Director knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the USPTO.

The majority also vacated the District Court's findings of materiality because materiality was evaluated using the USPTO's materiality standard and not "but-for" materiality. It thus remanded to have the District Court determine whether the USPTO would not have granted the patent but for Abbott's failure to disclose the statements in the EPO briefs, consistent with the majority's test for materiality.

The majority did not make any specific holding as to whether the content of the EPO briefs was material. Employing the majority's test, the briefs would be material

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if the District Court determines that they meet the "but for" standard.

C. The Concurring and Dissenting Opinions

The non-majority expressed broad consensus with the majority regarding the deceptive intent standard. However, as discussed below, the non-majority sharply disagreed with the adoption of "but for" materiality.

1. The Concurring-in-Part and Dissenting-in-Part Opinion

Judge O'Malley concurred that the case should be remanded to have the District Court assess deceptive intent, in the first instance, under the "knowing and deliberate" standard. However, Judge O'Malley argued that the majority and dissent were both straining too hard to impose "hard and fast" rules regarding materiality. Instead, Judge O'Malley would seek to provide general guidance, and commented that conduct should be deemed material where (1) the patent would not have issued but for the affirmative act or intentional nondisclosure (as discussed by the majority), (2) the conduct constitutes a false or misleading representation of fact, or (3) a court finds the behavior so offensive that the court is left with a firm conviction that the integrity of the USPTO application process was wholly undermined. Judge O'Malley would also allow courts, upon finding inequitable conduct, to decide to render fewer than all claims unenforceable, to dismiss the action before it, or to fashion some other reasonable remedy.

Applying that guidance to the facts, Judge O'Malley would have affirmed the District Court's finding that the nondisclosure was material even if governed by the majority's "but-for" standard. Judge O'Malley accepted that the EPO briefs contained representations critical to understanding the prior art patent. Judge O'Malley also agreed with the District Court that Abbott's U.S. attorney was duty-bound to submit the inconsistent extrinsic evidence with the affidavit to the USPTO because the Examiner was completely dependent on Abbott to act impartially.

2. The Dissenting Opinion

The dissent would have adopted the USPTO's Rule 56 materiality standard. Under that standard, inequitable conduct requires proof that the information at issue either (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability, or (2) is inconsistent with a position taken by the applicant before the USPTO with respect to patentability. The dissent

maintained that (1) the USPTO is in the best position to know what information Examiners need to conduct effective examination, and (2) "but for" materiality will not provide appropriate incentives for applicants to comply with the duty of disclosure. The dissent expressed its concern that "an open door may tempt a saint."

The dissent would have affirmed the District Court's findings regarding deceptive intent because it found that the District Court adequately determined that (1) Becton offered evidence sufficient to prove that Abbott intentionally did not disclose the inconsistent statements in the EPO briefs with the specific purpose of deceiving the USPTO, and (2) Abbott failed to establish a plausible good faith reason sufficient to refute Becton's evidence of deceptive intent. Regarding materiality, the dissent would have affirmed the District Court's findings because it found that Abbott's representations to the EPO contradicted its representations to the USPTO and were highly material.

III. Possible U.S. Supreme Court Review

On June 1, Becton indicated that it would petition the U.S. Supreme Court for review of the *en banc* decision. It is uncertain whether the U.S. Supreme Court will exercise its discretion to review the decision upon petition. If reviewed, it is possible that the U.S. Supreme Court may reject the bright-line "but for" materiality standard as lacking sufficient flexibility. The U.S. Supreme Court has, on other occasions, rejected bright-line tests announced by the Federal Circuit in the area of patent law.⁷

IV. Analysis

The *en banc Therasense* decision left intact the framework for proving inequitable conduct, which requires that the accused infringer prove both specific intent to deceive and materiality by clear and convincing evidence. However, the decision raises the burden of proof for an accused infringer to prove inequitable conduct by more

⁷ See, e.g., *Bilski v. Kappos*, 561 U.S. ____ (2010) (rejecting the machine-or-transformation test as the sole test to determine patentable-subject-matter eligibility); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (rejecting the teaching-suggestion-motivation test as the sole test for combining or modifying prior art to determine obviousness); *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002) (rejecting the automatic and absolute bar of the application of the doctrine of equivalents to a patent claim that was narrowed during prosecution).

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stringently defining what constitutes each of the deceptive intent and materiality requirements and by strictly limiting the extent to which proof of materiality may be used to infer deceptive intent.

Because the majority remanded the case to have the District Court determine whether the statements in the EPO briefs were material under the "but for" standard, it confirms that statements made in related foreign applications are the type of information that may be material and, if material, subject to the U.S. duty of disclosure. Indeed, Judge O'Malley, in concurrence with the majority, stated that she would have found that the statements in the EPO briefs were material under the majority's "but for" standard.

Regarding deceptive intent, in cases involving nondisclosure of material information, the *Therasense* decision requires the accused infringer to prove that the patent applicant deliberately withheld known material information for the purpose of deceiving the USPTO. This is a significant departure from some prior decisions in that, even if a patent applicant acted with negligence in failing to ascertain or appreciate that the information was material, when the applicant should have known that the information was material, deceptive intent cannot be found on that basis alone.⁸ Thus, while a patent applicant cannot deliberately turn a blind eye to material information, one should be able to defend against later inequitable conduct allegations in litigation based on failures of the applicant to discover material information or understand the materiality of information known to the applicant if the applicant acted without bad faith.

Regarding materiality in nondisclosure cases, the *Therasense* decision requires that the accused infringer prove that the patent would not have issued but for the nondisclosure of the information in dispute. USPTO Rule 56 differentiates between different forms of material information on the basis of information that establishes

prima facie unpatentability and information that is inconsistent with positions taken by applicant or the USPTO regarding patentability. Unlike Rule 56 materiality, "but for" materiality does not allow an accused infringer to merely prove that the information could be used to establish *prima facie* unpatentability.⁹ Moreover, the fact that the information is inconsistent with positions taken by the applicant or the USPTO regarding patentability is insufficient, without more, to establish "but for" materiality. Further, the decision provides that materiality determinations cannot merely be based on what a reasonable examiner would have considered important, which has been analyzed in prior decisions based on materiality under a prior version of Rule 56.

"But for" materiality requires the accused infringer to prove by clear and convincing evidence that the USPTO would not have issued the patent but for the nondisclosure of the information. However, patentability determinations before the USPTO are governed by the "preponderance of the evidence" standard. The "preponderance of the evidence" standard allows the USPTO to find that an invention is not patentable if the evidence establishes that it is more likely than not that the claimed invention is, e.g., anticipated or obvious. Additionally, during patentability determinations before the USPTO, the claims are given their broadest reasonable interpretation in light of the specification. In comparison, an invalidity determination in litigation requires clear and convincing evidence of a claim's invalidity. Additionally, a court is not required to interpret claims consistent with their broadest reasonable interpretation in light of the specification, but can more narrowly construe the claims. Accordingly, an accused infringer could fail to prove invalidity of a claim on the basis of undisclosed prior art, since invalidity in litigation must be proved by clear and convincing evidence and the claims may be construed narrowly. At the same time, inequitable conduct could be found based on clear and convincing evidence that the examiner would not have allowed the claim under the preponderance standard and/or a broader construction. However, such situations as a practical matter are likely to be rare.

As discussed above, the *Therasense* decision may be subject to further review by the U.S. Supreme Court and

⁸ Over twenty years ago, the *en banc Kingsdown* decision held that even a showing of gross negligence was insufficient to establish deceptive intent. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.* 863 F.2d 867 (Fed. Cir. 1988). However, some Federal Circuit panel decisions issued since *Kingsdown* have ignored this holding by suggesting that a showing that the patent applicant "knew or should have known" that the information was material is sufficient to establish deceptive intent.

⁹ *Prima facie* unpatentability is present when the USPTO could have rightly rejected patent claims if it was aware of the information without considering arguments or evidence to the contrary.

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could be overturned or significantly modified if reviewed. If not reviewed, the case will be remanded to the District Court for further findings on inequitable conduct in view of the Federal Circuit's decision. Thus, the final judgment regarding inequitable conduct in the case is yet to be entered and further developments in the case are likely to offer some clarification regarding inequitable conduct determinations applying the more stringent standard adopted by the majority. In any event, further clarification from courts, especially from the Federal Circuit, in deciding other cases involving inequitable conduct allegations is needed to determine the extent to which the decision affects inequitable conduct jurisprudence. Accordingly, while the *Therasense* decision provides clarification and guidance on how an assertion of inequitable conduct should be evaluated in litigation, inequitable conduct remains a developing area of patent law.

For now, the *Therasense* decision should benefit patent owners seeking to enforce their patent rights against competitors in litigation. In light of *Therasense*, it should be significantly more difficult for a competitor to prove inequitable conduct based on, e.g., alleged failures to properly disclose material information to the USPTO during patent prosecution.¹⁰

The *Therasense* decision should also benefit patent applicants during prosecution because it protects against inadvertent nondisclosure of material information later rendering that patent unenforceable during litigation. In view of such protection, if disclosure is undertaken in good faith, albeit negligently executed, a failure to disclose should not later render a patent unenforceable during litigation.¹¹

¹⁰ This could, for example, reduce litigation costs, since litigation often involves expensive and burdensome discovery aimed at trying to develop or defend against inequitable conduct allegations.

¹¹ In practice, this may allow patent applicants and counsel to dedicate fewer resources to ensuring ideal disclosure, potentially reducing the costs of complying with the U.S. duty of disclosure. Of course, often U.S. disclosure policies are put in place with the aim of obtaining issuance of "strong" patents, i.e., patents less likely to be invalidated post-issuance, because invalidating information was not before the Examiner during prosecution. Thus, any U.S. disclosure policy must take into account the risk of nondisclosure from both unenforceability and invalidity standpoints.

During prosecution of patent applications, the USPTO, and not a court, is responsible for ensuring compliance with the U.S. duty of disclosure by those practicing before it. Consistent with this authority, the USPTO issued a May 26 press release stating that it is studying the *Therasense* decision, and expects soon to issue guidance to assist patent applicants regarding information to be submitted to meet the USPTO's disclosure requirements. Although the decision, on its face, leaves undisturbed the fact that the U.S. duty of disclosure in the USPTO is governed by Rule 56, the USPTO may use the decision as an opportunity to reevaluate its Rule 56 disclosure requirements and better align them with the requirements for establishing inequitable conduct articulated by *Therasense*. In its *amicus* brief, the USPTO indicated that the prospect of it enforcing the Rule 56 duty of disclosure against patent applicants is at least impractical, if not impossible, for multiple reasons.¹² Thus, the USPTO considers the courts to be the best forum in which to consider alleged breaches of the U.S. duty of disclosure in the context of inequitable conduct.

V. Recommendations

We will report on and provide further recommendations once the U.S. Supreme Court decides whether to grant review of the *Therasense* decision and once the USPTO issues guidance on its disclosure requirements. Meanwhile, we provide the following recommendations.

A. Litigation

In the face of developing U.S. law regarding inequitable conduct, we strongly recommend that you immediately consult U.S. attorneys if you foresee potentially facing a charge of inequitable conduct, or are considering raising inequitable conduct in defense of the assertion of a patent.

B. Prosecution

Although we are, as always, sensitive to the high burdens and costs associated with the U.S. duty of

¹² Those reasons include that the threat of disciplinary action is ineffective because the USPTO is statutorily required to bring charges against a practitioner within five years of a violation and the USPTO seldom learns of a violation within that time period. Additionally, the USPTO lacks investigative resources to uncover relevant facts regarding duty of disclosure violations.

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disclosure, especially amidst the backdrop of the current worldwide economy, we do not recommend significant changes in our clients' U.S. information disclosure policies in light of *Therasense*, pending further developments in the areas of U.S. Supreme Court review and the USPTO's issuance of guidance on its disclosure requirements.¹³

Accordingly, the recommendations discussed in our February 2, 2010 Special Report, entitled "U.S. Duty of Disclosure Is Clarified Regarding Materiality of Patent Prosecution Statements," remain relevant. Further, the recommendations discussed in our October 9, 2009 Special Report, entitled "The U.S. Duty of Disclosure as Applied to U.S. and Foreign Office Actions," also remain viable. In particular, we continue to recommend:

- (1) coordinating the handling of related patent applications worldwide to avoid generating inconsistent arguments and factual assertions;
- (2) disclosing inconsistent, or arguably inconsistent, arguments and factual assertions to avoid any appearance of concealment and to resolve them on the record;
- (3) carefully scrutinizing representations made in declarations or affidavits for any potential conflict with arguments and factual assertions made elsewhere;
- (4) tracking related U.S. and foreign applications;
- (5) filing Information Disclosure Statements to cross-disclose U.S. Office Actions between related U.S. applications;

(6) reviewing all foreign Office Actions in related cases to submit translations of the relevant portions or consistently disclosing translations of all substantive foreign Office Actions in related U.S. applications; and

(7) disclosing information in related U.S. applications regarding third party oppositions.

We will keep you informed of significant developments as they occur. Meanwhile, we invite your questions and comments.

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¹³ As with all legal matters, a decision to modify a U.S. disclosure policy should be based on particular circumstances. We would be pleased to counsel any client on its U.S. disclosure policy to tailor it to the client's needs and circumstances in light of the *Therasense* decision.