DRAFT: WORK IN PROGRESS

THERASENSE V. BECTON DICKINSON: A FIRST IMPRESSION

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INTRODUCTION

This purpose of this essay is to provide an early analysis of some of the most substantial law and policy concerns raised by the very recent *en banc* decision of the United States Court of Appeals for the Federal Circuit in the now famous *Therasense v. Becton Dickinson* case. The doctrinal issue central to the case is inequitable conduct, a judicially created doctrine developed to punish patent applicants who behave inappropriately during patent prosecution, the *ex parte* process of patent creation.

The core thesis of this essay is that *Therasense* could have a much more significant, complex, and nuanced impact on the legal infrastructure of American innovation than the opinion for the court appears to appreciate. In view of these complexities, the court may be too sanguine in its expectations for the instrumental effect of its decision, a decision that holds the potential to erode some of the core pillars upon which the legal infrastructure of American innovation is built.

To enhance understanding of the concerns developed in the analysis, the first Part of the essay provides a background that explains the innovation context and history of the case and describes the relevant legal dispute. The second Part of the essay is devoted to an early analysis of substantial innovation law and policy concerns raised by the decision of the court.

I. BACKGROUND

United States Patent No. 5,820,511, the patent at the heart of *Therasense v. Becton Dickinson*, had its origins in a United Kingdom laboratory in the early 1980's. There, a team of pioneering scientists came together to develop a groundbreaking way for diabetes patients to monitor their blood glucose levels – a crucial advance in the treatment of diabetes, a disease

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whose growth rate over the past few decades has reached epidemic proportions. To give a sense of the magnitude of the epidemic, government statistics show that in 1980 5.6 million Americans were diagnosed with the difficult to manage and potentially debilitating disease.[1] By 2010 that number climbed to a startling 18.8 million Americans (with another 7.0 million believed to be undiagnosed).[2]

The device developed by these scientists was simple and elegant. It began with the creation of an improved sensor coated with biochemical compounds that produced a tiny flow of electricity in the presence of glucose, an invention that led to patent number 4,545,382 in the United States and patent number 0078,636 in Europe.[3] The scientists next placed the new sensor on a test strip that could be inserted into a meter to produce a digital readout of the blood glucose level, and then thrown out. This innovation made it possible for anyone to test their blood glucose at any time, leading to a revolution in diabetes patient care.

As with the sensor invention, the scientists sought a patent for the disposable test strip. However, unlike the patent application directed to the glucose sensor – the one that gave rise to the '382 patent – the patent application directed to the disposable test strip was repeatedly rejected by the patent office. The rejection of the scientists' claims was based, perhaps ironically, on the earlier invention of the '382 patent. Medisense, the assignee of the patent application and the company commercializing the test strips, repeatedly sought to overcome the rejections, amending the proposed claims and submitting declarations to distinguish the prior art or tout the commercial success of its disposable test strips. For fourteen years, these attempts failed to sway the examiner.

All these failures turned into apparent success, however, when in 1996 Abbott Laboratories acquired Medisense and assigned one of its in-house patent attorneys, Lawrence Pope, to take over the prosecution of the disposable test strip patent application. Mr. Pope was a highly experienced

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[1] Data sourced from U.S. Department of Health and Human Services, Center for Disease Control and Prevention (available online at http://www.cdc.gov/diabetes/statistics/prev/national/figpersons.htm).

[2] Department of Health and Human Services, Center for Disease Control and Prevention, 2011 National Diabetes Fact Sheet (available at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf). The CDC estimates that 35% of U.S. adults aged 20 years or older have prediabetes, a condition associated with a high risk of developing diabetes.

[3] Background information comes from Therasense v. Becton Dickinson and Co., No. 2008-1511, -1512, -1513, -1514, -1595, Slip Op. (May 25, 2011) (en banc) (hereafter "Slip Op."); Therasense, Inc. v. Becton, Dickinson and Company, 593 F.3d 1289 (Fed. Cir. 2010) (rehearing en banc granted, opinion vacated); Therasense, Inc. v. Becton, Dickinson and Company, 565 F.Supp.2d 1088 (N.D. Cal. 2008).

patent attorney with years of experience representing patent applicants before the patent office. He and a Medisense scientist, Dr. Gordon Sanghera, brainstormed various patentabilty arguments, striking upon a potential point of novelty in the disposable test strip application that had been previously overlooked: the application described a disposable test strip with a glucose sensor for use *without any membrane protecting the sensor from the many constituents of whole blood*, while the older technology had required the use of a protective membrane to separate the blood from the sensor. Emphasizing the fact that the disposable test strip invention did not require a protective membrane might be sufficient to overcome the patent office's rejections and render the claims patentable.

The difficulty Mr. Pope and Dr. Sanghera faced, however, was that a portion of the '382 patent discussed membraneless sensors. It read:

> 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.

Because this passage had the potential to defeat the patentability of the disposable test strip application, Pope argued that skilled artisans in 1983 would have believed that a membrane was essential even in the face of the '382 disclosure – in other words, that skilled artisans would not have taken the quoted sentence literally.

The problematic passage was discussed at a meeting between Pope and the patent examiner during which the examiner agreed that rejections based on the '382 could be overcome if an affidavit or other evidentiary showing was made that at the time of the invention a membrane was considered essential. This evidence was provided in the form of a declaration by Dr. Sanghera, in which he explained that:

> [B]ased on his historical knowledge he is confident that on the filing date of the earliest application leading to the present application on June 6, 1983 and for a considerable time thereafter one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. Therefore he is sure that one skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally [sic] or merely preferred.

Along with the declaration, Pope submitted remarks based on Sanghera's representation that argued that a person of ordinary skill in the

art would have understood the passage in the '382 patent to be mere "patentese," as opposed to a technical teaching. Shortly thereafter, the '511 patent was allowed, and Abbott subsequently asserted it against several manufacturers and distributors of electrochemical diabetes test strips including Becton Dickinson ("BD") and Bayer.

During the infringement litigation, BD and Bayer discovered that before Abbott acquired Medisense, the '636 patent (the European counterpart to the '382 patent, with an essentially identical written body) was the subject of an *inter partes* proceeding at the European Patent Office that challenged the patent's validity. Important to the opposition to the '636 patent in Europe was a document known as the "D1" reference. In the opposition proceeding, Medisense argued that D1 could be distinguished on two grounds: first, that the '636 invention used a certain type of chemical (a ferrocene mediator), and second that D1 required a semi-permeable membrane to control the flow of glucose while the '636 invention did not. In arguing the latter ground, Medisense specifically referenced the "Optionally, but preferably" passage shared by the '382 and '636 patents that would later become central to Pope and Sanghera's strategy to secure the '511 patent. Specifically, Medisense's European appeal brief argued that:

> 10. The above object is solved by a glucose sensor as defined in claim 1 of the patent in suit [′382/′636]. Apart from the important feature of utilizing a ferrocene or ferrocene derivative as mediator, another important difference over D1 resides in that the claimed glucose sensor-contrary to that of D1 which requires a membrane-does not have and **must not** have a semipermeable membrane within the meaning of D1. Contrary to the semipermeable membrane of D1, the **protective** membrane **optionally** utilized with the glucose sensor of the patent [in] suit is **not** controlling the permeability of the substrate (as set forth above under IV.2), in the membrane of D1 the permeability for the substrate **must** be kept on a low value to achieve a linear relationship between the measures [sic] currency and the substrate concentration in the test solution. Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:
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> > 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 bolded words and indentation are original to Medisense's brief. A

similar passage in a subsequent brief added that:

> It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules. This teaches the skilled artisan that, whereas the semipermeable membrane of D1 must be constructed, for example by crosslinking, in such a way that the membrane will in fact control the permeability of the glucose at the required low value, the purpose of the protective membrane in the patent in suit is not to control the permeation of the glucose molecules. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1.

A. The Case

The three passages quoted above formed the centerpiece of the *Therasense* bench trial on the issue of inequitable conduct. As noted in the Introduction, inequitable conduct is a judicially created doctrine designed to punish patent applicants who behave inappropriately during patent prosecution, which is the *ex parte* process of obtaining a patent. There are three aspects to an inequitable conduct assertion: first, an act or omission on the part of the patent applicant that is *material* to the decision to allow a patent to issue; second, the material act or omission must have been done with the *intent to deceive* the patent office; and third, assuming materiality and intent to deceive have been found, a court must weigh the equities to determine whether the patent applicant's conduct warrants the harsh sanction of inequitable conduct: patent unenforceability.

At the heart of the trial lay the issue of whether Medisense's argument to the European patent office that the "Optionally, but preferably" sentence in the '636 meant that using any membrane at all was unnecessary or whether the argument instead related only to the *type* of membrane in the D1 reference. The accused infringers asserted the former: that the passages were inconsistent with Pope and Sanghera's assertions to the U.S. patent office and thus, because there was no dispute that Pope and Sanghera were aware of the '636 proceedings, the failure to disclose the fact that Medisense, in defending the '636 patent in Europe, had taken a position directly contradictory to the argument it made to secure the allowance of the '511 patent in the U.S. amounted to intent to deceive. On the other side,

Abbott argued that the passages were not inconsistent or contradictory, and provided lengthy testimony from Pope and Sanghera explaining what they understood the relevant statements to mean and explaining why they did not disclose the European proceedings to the U.S. patent office.

The outcome of the trial did not favor Abbott. The district court agreed with the defense, holding that the statements should have been disclosed under 37 C.F.R 1.56, arguably the broadest of several Federal Circuit-sanctioned frameworks for analyzing materiality.[4] Rule 1.56(b) states that information is material to patentability when:

> (1) It establishes, either by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

After deciding that the statements were material because they were "flatly inconsistent with the main point being made by Attorney Pope and Abbott to [the patent office]," the judge found that both Pope and Sanghera intended to deceive the patent office by failing to disclose the '636 proceedings. The trial court based its decision on the reasoning that both "knew or should have known that the withheld information would have been highly material to the examiner," and "had no plausible reason for consciously withholding the EPO submissions."[5] The court further found that Pope and Sanghera lacked credibility at trial. Given the court's finding of both high materiality and intent to deceive, it entered a judgment of inequitable conduct, subsequently awarding the accused infringers millions in attorneys' fees.[6]

Abbott appealed to the Federal Circuit, challenging the judgment of inequitable conduct (and a related finding of obviousness based on the '382

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[4] Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984) (commenting that the Rule 1.56 standard "appears to be the broadest, thus encompassing the others.").

[5] 565 F.Supp.2d at 1113.

[6] The district court awarded BD/Nova approximately $6 million in attorneys' fees, and while Bayer and Abbott settled the fee award for an undisclosed amount, Bayer's initial fee petition sought approximately $12 million. *See* Therasense, Inc. v. Becton, Dickinson and Company, Case No. C04-2123 WHA, Order re Award of Attorney's Fees (N.D. Cal. March 19, 2009); Abbott Diabetes Care Inc. v. Roche Diagnostics Corp., Case No. C05-3117 WHA, Declaration of Jason Bartlett in Support of Bayer's Petition for Attorneys' Fees and Costs (N.D. Cal. September 25, 2008); Abbott Diabetes Care Inc. v. Roche Diagnostics Corp., Case No. C05-3117 WHA, Stipulation Regarding Fees Claimed by Bayer (N.D. Cal. December 4, 2008).

patent). The appeal received a forceful rejection from two of the three judges assigned to the case. Judge Dyk, writing for himself and Judge Friedman, rejected each of Abbott's arguments in turn. Applying, as the district court did, Rule 1.56, Judges Dyk and Friedman found the district court's conclusion about the inconsistency not only "not clearly erroneous," but "manifestly correct."[7] According to the court, "To deprive an examiner of the EPO statements - statements directly contrary to Abbott's representations to the patent office - on the grounds that they were not material would be to eviscerate the duty of disclosure."[8]

On the subject of intent, the majority likewise affirmed the district court, concluding that, given the high materiality of the EPO statements coupled with Pope and Sanghera's knowledge of them, the lack of a credible explanation for their withholding was a sufficient basis to infer intent to deceive. Moreover, the trial court's credibility determination, the majority held, was "virtually unreviewable." The court, accordingly, affirmed the district court's judgment of inequitable conduct.

The panel's decision was not unanimous, however. Judge Linn issued a strong dissent in which he rejected both the trial judge's finding of materiality and the trial judge's findings concerning intent to deceive. Three months later, the Federal Circuit granted Abbott's petition for rehearing *en banc*. The scope of the order was unprecedented in the history of the doctrine, and suggested that the court was willing to reconsider almost anything and everything about the doctrine.[9] An overwhelming number of amici responded, submitting at least 39 briefs advocating a range of options, including the elimination of the doctrine altogether. Most suggested some form of modification to, or clarification, of the materiality or intent elements of the existing analysis.

B. *The* En Banc *Opinion*

On May 25, 2011, the court issued an opinion that sought to radically reshape the landscape of inequitable conduct. The result was as close as any opinion the court had previously issued. On materiality, six judges – including Judge Jimmie V. Reyna, who had joined the court just a month and a half earlier – voted to require "but for" materiality, a standard that the court intends to be much stricter than the patent regulation-driven standard that had traditionally governed.

Under a "but for" standard, materiality is only established if the patent would not have issued but for the alleged material act. For example, if an

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[7] 593 F.3d 1289, 1303.

[8] 593 F.3d at 1304-5.

[9] Therasense, Inc. v. Becton, Dickinson and Co., 374 Fed. Appx. 35 (Fed. Cir. April 26, 2010) (nonprecedential).

applicant fails to disclose prior art during the prosecution, "that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art."[10] Of course, the majority commented, "but for" materiality implicates the relevant legal rules for the patent application process, not those of an infringement action. Thus, when making the assessment, courts must apply a preponderance of the evidence standard (as opposed to a clear and convincing standard) and give claims their broadest possible construction (as opposed to applying the Federal Circuit law that governs the determination of patent claim scope).

The court's new materiality standard is subject to a crucial exception, however: "When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material."[11] The court's rationale hinges the patentee's belief that the misconduct will result in obtaining a patent. "After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent."[12] Adding another layer, the exception is subject to its own exception: "neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct."[13]

Just as the court specified a stricter standard for materiality, so too did it raise the bar for establishing intent. Before *Therasense* there was some uncertainty about the level of intent needed to establish culpability for violations of the duty of candor. In the opinion, the court specified that going forward inequitable conduct will require the "specific intent"[14] to deceive the patent office: "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."[15] As before, intent must be established separate from materiality, viz. a district court may not infer intent solely from materiality.

II. LAW AND POLICY ISSUES RAISED BY *THERASENSE*

The Federal Circuit's opinion in *Therasense v. Becton Dickinson* raises serious concerns about innovation law and policy. This Part of the essay

[10] Slip Op. at 27.
[11] Slip Op. at 29.
[12] *Id*.
[13] *Id*. at 29-30.
[14] *Id*. at 24. ("To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.")
[15] *Id*. at 24.

identifies some of the concerns raised by the opinion and provides an early analysis of their significance. A suitable place to begin is with the majority's *ipse dixit* that the holding of *Therasense* will favorably address "adjudication cost and complexity . . . likelihood of settlement . . . burdened courts . . . strained PTO resources . . . increased PTO backlog . . . and impaired patent quality"[16] – a veritable slam-dunk in terms of public benefit. As we demonstrate below, there are reasons to be concerned that Chief Judge Rader might be too sanguine in his predictions.

A. A Patent Handout

From nearly any perspective the Federal Circuit's holding in *Therasense* represents a naked attempt to shift economic rents from the public and the patent office to the patent bar and those who seek patents. Prior to *Therasense*, patent applicants were required to take due care when prosecuting patent applications. This in part meant that an applicant was required to disclose to the patent office information that the applicant knew about and which the applicant knew a reasonable examiner would have considered important in deciding whether to allow a patent application to issue as a patent. After *Therasense*, patent applicants no longer have this duty, at least to the extent it will be enforced by courts, unless the information at issue falls into a very narrow category. Specifically, information known to the patent applicant and unknown to the patent office that the applicant knows if he discloses to the patent office will cause the patent office to not allow the claims in his application (or at least those that are litigated in the future) to issue as a patent.[17] In addition, after *Therasense* a patent applicant must by his actions or omissions specifically intend to mislead the patent office into issuing claims it would not have otherwise issued, whereas before a patent applicant could have had sufficient mental culpability if he knew or objectively should have known that its actions were misleading.

Because the court's holding pushes in the direction of reducing the care and patent quality responsibilities that applicants have in their dealings with the patent office, it is logical to predict that the court has made patent examination marginally less expensive for patent applicants. But making patenting cheaper by requiring less of patent applicants in the course of patent creation presents concerns because it occurs in a context in which it

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[16] Id. at 24.

[17] The court recognized an exception "in cases of affirmative egregious misconduct." This exception, according to the majority, is required by a set of Supreme Court cases dealing with fraud and unclean hands in the context of patent acquisition and seems targeted generally at planned "'scheme[s]' to defraud the PTO and the Courts." (Slip Op. at 29).

is commonly accepted (1) that the patent office already does not have the resources to ensure that only deserving inventions receive patents, and (2) that some of the costs of patent creation – in particular costs of information about what the invention is, how it relates to prior innovations, and often whether it actually meets the statutory requirements for patentability – are more efficiently borne by patent applicants. Thus, while the *Therasense*-encouraged shift in rents may be a good outcome for patent lawyers and for those who seek cheap patents, it may be less of a good outcome for the patent office, competitors, and the public.

Our reasoning is based on the stated purpose of the majority opinion. On its own terms, the holding of *Therasense* seeks to reduce the private resources devoted to patent examination. But unless one adopts the position that those private resources were in the past mostly wasted (in which case spending less on patent creation might be fine), *someone* must pay the cost if the same level of investment in patent creation is to be maintained. With patent applicants no longer paying as much of the cost of the patent creation process as they were before, the institution most likely called upon to compensate will be the patent office. Unfortunately, it is already conventional wisdom that the patent office cannot meet the investment that the pre-*Therasense* law required of it. It therefore should come as no surprise that the patent office argued directly *against* the new rules for inequitable conduct that the Federal Circuit imposed in *Therasense*.[18] Thus, it is difficult to reasonably expect the patent office to increase its investment in the patent creation process.

In its quest to make patenting cheaper for patent applicants, the *Therasense* majority also ignores almost entirely the concern that patent applicants are often the most efficient (i.e., lowest cost) providers of certain information important to the patent creation process. For example, some information will be readily available to the patent applicant due simply to the fact that the applicant may be a regular patenter in a particular industry. Other information may be at the applicant's fingertips because it is information the applicant discovered and utilized in determining how to address the innovation problem it confronted – and which led to the patent application at issue. Still other information may be literally sitting on the applicant's desk because the applicant discovered it when preparing the patent application. In many instances it will be cheaper for the applicant to provide this sort of information to the patent creation process than it will be for the patent office to discover the information on its own and appreciate

[18] *See* Therasense v. Becton Dickinson and Co., No. 2008-1511, -1512, -1513, -1514, -1595, Slip Op. Dissent at 8-9 (May 25, 2011) (en banc) (Bryson dissenting) (hereafter "Dissent").

its significance. And in some circumstances, this information may be uniquely (or nearly so) within the knowledge and control of the applicant.

When information pertaining to patentability is uniquely within the control of the patent applicant, the comparative efficiency gains in having the applicant provide the information can skyrocket. The information described above mostly concerns the innovation context of the invention. But there is other information, information outside the innovation context of the invention that is nonetheless crucial to the issue of patentability. Much of this other type of information, such as the timing of the invention, public uses and sales, abandonments and the like, may be uniquely (or nearly so) within the control of the patent applicant. In many instances it may be fairly inexpensive for the applicant to make the disclosure (although it may adversely affect the patentability of the claims the applicant seeks and thus increase the costs and fees that will be paid to a patent agent or attorney to negotiate the issuance of a patent). By contrast, it is much more expensive – in practical terms approaching infinity – for the patent office to bring information uniquely within the control of the applicant to bear on the patent creation process.

The majority's purpose in *Therasense* is to make patent creation cheaper for the patent bar and for those who seek patents. The savings comes in the form of requiring less care from patent applicants in the patent creation process and of requiring a lower contribution to patent quality on the part of patent applicants. *Therasense* is, therefore, *A Patent Handout*. Reflected back against Chief Judge Rader's claims for the *Therasense* holding, the above discussion raises concerns about whether *Therasense* really will favorably address "strained PTO resources." Indeed, if the patent office attempts to add resources to the patent creation process to compensate for those that private parties are now able to retain, it is possible that exactly the opposite will happen: patent office resources may become more strained than they were before.[19] And if the patent office does not find some way to

[19] Although it may be somewhat politically helpless, the patent office is not legally helpless in the face of the *Therasense* opinion. Presumably it might still enforce Rule 56 on its own. It might raise patent application fees and maintenance fees; the net affect of such a strategy could be to take back some of the profits that the Federal Circuit handed to patent applicants in *Therasense*, although such a strategy should be expected to be less efficient for reasons discussed above as well as for the reason that the costs will not be nearly as specifically targeted to the parties that impose the costs. Another alternative still is for the patent office to demand, through Rule 105 requests, the same kind of information rule 56(b) requires of applicants. Failure to respond truthfully to such requests can result in abandonment. Another possibility is the increased use by the government of 18 U.S.C. 1001 (2006), which makes it a crime to "knowingly and willfully" make a "materially false . . . statement" or "conceal . . . a material fact" "in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States."; *cf.* United States v. Markham, 537 F.2d 187 (5th Cir. 1976) (affirming a conviction under 18

pick up the tab for the private savings, then it is likely the public will, in the form of inefficiently higher prices for goods and services. The reason for this is that more low quality patents might be expected as a consequence of the *Therasense* decision. It is to that issue that we turn next.

B. Implications for Patent Quality

There has been much hue and cry in the last decade about the quality of patents, viz. a conventional wisdom has developed that many patents issue from the patent office that should not have issued because the inventions disclosed and claimed in the patents do not satisfy the statutory requirements for patentability. Chief Judge Rader boldly asserts that *Therasense* will favorably address "impaired patent quality." While the future is not yet written, we develop an analysis below that suggests Judge Rader might be incorrect. We suggest instead that after *Therasense*, for those not cynical enough to believe that patent quality is already hopelessly low, it is reasonable to expect the quality of patents to suffer even more than it already does. The main reason is that the patent office, which is already thought to be fairly poorly informed when it determines patentability, will be even less well informed about the invention, the relevant art, and other facts that relate to the technicalities of applying the statutory standards for patentability. In other words, the patent office will be even more in the dark when conducting patent examination after *Therasense* than it was before. In the words of the patent office (referring to earlier efforts on the part of the patent bar to impose a standard like the one the Federal Circuit imposed in *Therasense*):

> The suggested "but for" standard would not cause the Office to obtain the information it needs to evaluate patentability so that its decisions may be presumed correct by the courts. If the Office does not have needed information, meaningful examination of patent applications will take place for the first time in an infringement case before a district court. Courts will become increasingly less confident of the Office's product if they get the impression that practitioners and inventors can routinely withhold information from the Office, or that practitioners and inventors can make up their own minds about what is patentable.[20]

It is common ground to most who study the patent system that when

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U.S.C. 1001 based on the act of attempting to conceal from the patent office the true inventor of the process for which a patent was sought).

[20] 57 Fed. Reg. at 2024.

patents are issued for inventions that do not satisfy the requirements of patentability there are competitive costs to be paid. The reason is that the patent system is itself not costless. By creating private property for limited times in inventions, the patent system both confers benefits *and* imposes costs. The benefits are often touted. The main one being the optimization of the production of new and useful information, a generally nonrivalrous and nonexcludable good that theory suggests will be underproduced without some kind of positive interference in the market. The costs of a patent system, on the other hand, include the supramarginal cost pricing that may be imposed when patents are used – as they were intended – to reduce competition in a market.

Because of the competitive impact of patents, patent policy has long been chary of patents that do not meet the requirements of patentability. Stated generally, the reasons are straightforward. Low quality patents – those that should not have issued because they do not meet the statutory requirements for patentability – may give patentees some pricing power in instances where the patentee has not given the public sufficiently valuable new and useful information. It is, in a sense, money for nothing (or at least money for not good enough). The result is that competitors and the consuming public pay more for goods and services than they need to, patentees profit more from the patent system than policy requires, and the efficiency benefits of competition are not optimized. Indeed, the *Therasense* case arguably embodies this very concern: the Federal Circuit concluded that the '511 patent apparently should not have issued in view of the '382 patent (according to the court, it was not an invention over existing information – in patent parlance, it was obvious when the application was filed). Assuming the court's analysis is correct, diabetics using products that were embodiments of the invention claimed in the '511 patent might have been paying too much for their treatment, not to mention the fact that research into new innovations for diabetics might also have been marginally suppressed.[21]

As discussed at length in the previous part, the direction of the *Therasense* holding is to require from patent applicants less care in and less contribution of information to the patent creation process. Given the sort of information that may go missing, again discussed *ante*, it is reasonable to suspect that the marginal quality of information brought to bear on the patentability determination by the patent office will be poorer. However, little else about the patent granting process has changed. When an applicant files an application and pays a fee, it is presumably entitled to a patent unless the patent office can successfully demonstrate why it is not. This

[21] We use this merely as a hypothetical example of patent theory, and do not mean to suggest that this is what actually occurred for this specific patent.

suggests the interpretation that patent quality may be discouraged, rather than encouraged, by the Federal Circuit's decision in *Therasense* because the patent office will not have the information it needs to lawfully reject patent claims.

Not only might patent quality be discouraged by *Therasense*, but an even more unhappy result might be promoted. Less able to distinguish deserving applications from undeserving ones, examiners may more often reject claims that should be allowed. The effect of this eventuality, should it come to pass, would be to reduce the public's access to new innovations. Spurious rejections of claims to meritorious inventions also damages the incentive structure of the patent system by discouraging some set of potential innovators from innovating or disclosing their innovations.

Obviously, whether *Therasense* will have a positive impact on patent quality, as Judge Rader suggests, remains to be seen. Above we provide an analysis that suggests there may be some reasons why his prediction might turn out to be incorrect. Indeed, *Therasense* could encourage exactly the opposite outcome: low quality patents might be even more prevalent than they we before, and inventors of genuine innovations – the sort policy desires to encourage with the patent system – might even be marginally discouraged.

If more low quality patents issue because of *Therasense*, then one might anticipate – as the patent office did years ago[22] – that there will consequences to patent litigation. In the next Part, we consider the majority's claim about the salutary benefits of *Therasense* on patent litigation.

C. Implications for Patent Litigation

In the opinion for the court, Chief Judge Rader makes a number of claims about the salutary impact of the *Therasense* holding on patent litigation. In particular, that the holding will favorably address the "increased adjudication cost and complexity, reduced likelihood of settlement, [and] burdened courts"[23] that arose from the pre-*Therasense* inequitable conduct doctrine. In this Part we use theoretical logic and common sense to develop an analysis that challenges the claim that *Therasense* will have an efficiency enhancing impact on patent litigation. We emphasize four specific points. First, if *Therasense* encourages more low quality patents, that fact may adversely impact the amount and intensity of patent litigation. Second, *Therasense* did not get rid of patent acquisition

[22] *See supra* note 20.
[23] Slip Op. at 24.

misconduct doctrine – it might even have made it more complex and dangerous to patent practitioners and the patent system's reputation. Third, *Therasense* adjusted the risk incentives of the patent bar, and the expectations for agent risk-taking of those who seek patents. Fourth, building on the third point, we explain that if the majority's holding ends up permitting conduct that competitors find inappropriate, something akin to moral outrage at patent applicant behavior may encourage competitors to more intensely pursue litigation than they might otherwise.

The previous Part discusses many of the concerns raised by the prospect that *Therasense* may encourage low quality patents. So here we will be brief. We postulate two things: (1) more low quality patents issued by the patent office means that more patent enforcement actions will involve low quality patents, and (2) competitors will resist the enforcement of patents that they feel are illegitimate. Since low quality patents are illegitimate by definition, our point here resolves to a simple syllogism: If *Therasense* increases the amount of low quality patents, then competitors will (at least on the margins)[24] spend more to resist the enforcement of patents. If that turns out to be the case, and if patent enforcers are unwilling to back down, then *Therasense* may well increase adjudication cost instead of reducing it as the court's opinion predicts.

Another reason that *Therasense* may not favorably address "increased adjudication cost and complexity, . . . likelihood of settlement, [and] burdened courts" is that *Therasense* did not get rid of patent acquisition misconduct doctrine. Although it appears entirely unappreciated by the initial response to the case by the patent bar, *Therasense* arguably made patent acquisition more complex and dangerous to patent practitioners. Before *Therasense* only one patent acquisition misconduct doctrine was substantially used in patent litigation. After *Therasense* there are now three separate legal theories that must be analyzed when a claim based on misconduct during patent prosecution is made. The first is unclean hands, a defense that was probably so unused that the Federal Circuit's reawakening of the defense is likely the equivalent of raising it from the dead. Perhaps it was unavoidable, but as the court sought to place limits on the doctrine of inequitable conduct, it discussed and then set aside this old Supreme Court doctrine as untouchable. In so doing the majority may have inadvertently

[24] Note that we accept that patent litigation is mostly an economic exercise, viz. that when it makes sense to spend money defending the suit, defendants will do so; when it does not make sense, they probably will not. On this point, we offer two thoughts: First, we speculate that because of *Therasense* there will develop marginally more cases where it makes sense for defendants to spend more resources resisting the enforcement of a patent; Second, because of *Therasense* defendants will face enforcement actions involving patents that would not have been available for enforcement in a pre-*Therasense* legal context.

reinvigorated it by the explicit recognition of its viability. Thus, even before getting to the question of inequitable conduct, expect accused infringers to assert unclean hands, which as the majority noted, "remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases."[25]

In addition to reviving an unclean hands defense, the majority's framework for inequitable conduct itself necessitates two distinct assessments of materiality: the "but for" invalidity analysis and the "affirmative egregious misconduct" analysis. And peeling back another layer, the "but for" determination requires the court to assess validity against the patent office's standards for allowing patents – standards the district courts are unfamiliar with applying in patent cases – rather than the standards that typically apply when conducting infringement proceedings in the district court. Thus, for example, claim scope in patent litigation has for decades been determined according to rules laid down by the Federal Circuit. A district court, when determining patent infringement, patent invalidity, and a host of patent-related questions, must still apply those rules. Moreover, when district courts apply the substantive law of infringement and invalidity, they will be applying it to facts developed in anticipation of that law in the context of the clear and convincing evidence standard.

However, when a district court turns its attention to inequitable conduct, it must now change gears and apply different legal rules in the context of a different standard of proof. Rather than apply, for example, the familiar law of patent claim construction, district courts will be asked to determine patent claim scope for inequitable conduct purposes by applying the standard that the patent office uses, viz. courts should give patent claims their "broadest reasonable construction" (instead of the construction they have received for the rest of the litigation). Next courts will need to determine not whether the patent claims properly construed are invalid, but instead whether the patent office would have allowed the claims to issue as a patent. Moreover, courts will be applying that novel standard in the context of a burden of proof different from that with which they and patent litigants are ordinarily familiar, namely, courts and litigants must operate in the context of a preponderance of the evidence standard (as opposed to the traditional clear and convincing evidence standard).[26] This framework raises obvious issues about the complexity and substantive accuracy of patent acquisition misconduct litigation going forward.

This new multi-layered inequitable conduct framework may also add to

[25] Slip Op. at 20.
[26] Slip Op. at 28.

litigation costs and burdens in other ways. For example, the new structure might strongly encourage additional trials on inequitable conduct. Prior to *Therasense*, separate trials on inequitable conduct (as opposed to questions of validity and infringement) were sometimes held due to the concern that inequitable conduct claims could poison juries addressing the broader issues involved in the infringement proceeding. Under the *Therasense* framework, however, the analysis courts must undertake to determine inequitable conduct seems to have become more, rather than less, complex and involved so that not only do the traditional issues of prejudice still exist, but there will be additional issues about which prejudice will be a concern and about which jurors and jurists can get confused. Thus, the need to analyze inequitable conduct claims under a wholly separate set of legal standards than apply to the rest of patent litigation raises the specter of an increase, rather than decrease in the requirement of double trials.

Another unintended consequence of the need to apply two different patent scopes in a single patent litigation may be that doing so will give the accused infringer a second bite at the apple. Accused infringers will first be able to advocate a claim construction that favors their invalidity positions and then, if the court rules against them, will be able to assert inequitable conduct claims based on their broad, putatively "reasonable" construction.

Given these concerns, it is at least possible that the new framework articulated by the majority will not reduce the cost or complexity of individual determinations of inequitable conduct allegations.[27]

A third concern presented by *Therasense* that impacts patent litigation is the concern that the opinion adjusts the risk incentives of the patent bar, and the expectations for agent risk-taking of those who seek patents. Attorneys

[27] We also question the impact that inequitable conduct really has on discovery costs, an assertion for which there is at present a lack of empirical evidence. Nor do we see much of a change in this area as a result of *Therasense*, in part, we speculate, because limits on the scope of discovery are often a function of the tolerances of the parties and the relevant judge as opposed to the specific legal theories advanced. Moreover, even without the doctrine of inequitable conduct, many other patent law doctrines permit and invite an inquiry into the patent holder's documents that goes well beyond the documentation necessary to support conception and reduction to practice. To take just the example given by the majority, that "[a] charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing," that discovery can be justified under a number of doctrines, from challenging best mode to exploring patent ownership issues to contesting objective evidence of nonobviousness. Indeed, a more important tool for limiting the discovery costs of inequitable conduct probably existed before *Therasense*. Inequitable conduct is required to be pled with particularity. Until it is a patent holder's counsel may be able to successfully oppose some inequitable conduct-related discovery on the ground that it is irrelevant. In short, while inequitable conduct may be an arrow in litigation discovery counsel's quiver, it is by no means the only one, or even the most potent in most cases.

naturally push the boundaries of the law – it is their job, after all. Even patent attorneys, who long have cultivated the image of neutral participants in the patent application process, are nevertheless *ethically obligated* to advocate on behalf of their clients. Yet with *Therasense*, the veneer of being a neutral participant in an *ex parte* proceeding has largely been stripped away, and it is reasonable to expect that no matter how noble the person, attorneys involve in patent acquisition will act more like their counterparts in other fields, aggressively jockeying for the most advantageous outcome for their clients.[28]

It is therefore reasonable to suspect that *Therasense* may encourage patent applicants and attorneys to engage in riskier behavior – to move closer to the new line that the court has drawn as the boundary of acceptable behavior. Today's egregious conduct may become tomorrow's run-of-the-mill inequitable conduct allegation, while yesterday's inequitable conduct will become tomorrow's mandatory practice. For reasons already discussed, and for some that follow, there is little reason to think that this shift in risk incentives will result in fewer charges of inequitable conduct. Instead, a more likely consequence might be that future charges will reflect claims of much uglier and serious misconduct than courts regularly see today.

A final point to raise also involves adjusted risk incentives. Inequitable conduct (or patent misconduct litigation) may, over time, be stimulated by *Therasense* because the conduct *Therasense* might protect as "acceptable" might normatively be seen as unacceptable by some patent lawyers and by defendants in patent litigation suits. If so, defendants might vigorously pursue inequitable conduct claims even in the face of unfavorable rules.

At bottom, this point is about rules not aligning well with norms. It is quite conceivable that some inequitable conduct charges are not really about technical violations of rules laid down by the Federal Circuit. Rather, they may be driven by a litigant's or a judge's moral view of right and wrong – a moral compass, if you will. Unlike the rules of inequitable conduct, this normative standard may be harder to move with a Federal Circuit opinion, especially among district court judges, whose moral compasses may have a fixed bearing as a result of their exposure to a range of misconduct charges outside the boundaries of patent law.

So while patent attorneys, and perhaps even the Federal Circuit, may see that the rules of *Therasense* permit certain forms of conduct that previously

[28] We do not mean to suggest that all patent attorneys and agents engage in risky behavior. But when one looks at the incentives that *Therasense* creates, they unquestionably lean in favor of permitting riskier behavior when it comes to obtaining a patent.

were prohibited, that conduct may still be perceived as "wrongful" by district court judges and other front line decisionmakers. And if, as we speculate above, future inequitable conduct claims involve behavior that is more readily perceived as morally wrongful, front line decisionmakers may be inclined to let those claims proceed all the way through to trial, rather than summarily dismissing them. The end result might be greater costs and greater complexities in patent litigation.

D. A Glimpse of the New Federal Circuit

The Federal Circuit has recently seen many judges of long tenure move to senior status or leave the court entirely, and the last few years have seen the appointment of several new circuit judges.[29] There is a general expectation that with such substantial change in active membership, the complexion of the court is likely to change. *Therasense* provides, perhaps, our first glimpse at the new Federal Circuit. In particular, we note the important role that the three newest appointees to the court played in the outcome: both Judges Moore and Reyna joined with the majority opinion, and Judge O'Malley concurred with its result. With the court so closely divided on the issue of inequitable conduct, the addition of these judges to the mix may have produced a completely different result than would have been the case even a year ago.

As we have throughout this essay, we raise issues specifically implicated by the majority's opinion in the *Therasense* case. It is especially important to keep this limitation in mind in this Part as we base our analysis on the anecdote of a single opinion, and, at that, not even one signed by all of the judges[30] to make some observations about what the new generation of the Federal Circuit might look like.

1. An Ex Post, not an Ex Ante Patent System

For years, Congress, the Supreme Court, and the Federal Circuit have developed patent jurisprudence based on the conception that the patent system is a property rights-based system. The policies implicated by the concept include an emphasis on voluntary transactions around patent rights, with litigation being the exception. In short, the patent system is supposed to promote the allocation of resources through markets, not through federal

[29] In the last four years, four judges (Judges Mayer, Clevenger, Schall and Michel) (roughly a third of the court) have taken senior status or left the court entirely, while three new judges (Judges Moore, O'Malley, and Reyna) have been appointed.

[30] To this point, it should be clear that while we paint with a broad brush – as is appropriate in talking about an opinion for the court – it must be acknowledged that at least four of the court's judges specifically rejected the majority's decision, and even if that were not true our observations cannot be applied to any of the court's judges individually.

district court judges. Crucial to this concept is the ability of market participants to transact *ex ante* – before litigation. As the Supreme Court bluntly put it almost fifty years ago, "[t]o await litigation – is for all practical purposes – to debilitate the patent system."[31]

The *Therasense* decision suggests the possibility that the new Federal Circuit might be willing to abandon these core principles in favor of a system that is, at least marginally, more of an *ex post* system – one where more transactions happen after (or through) litigation. In other words, *Therasense* may foreshadow a patent system in which litigation will become more important and *ex ante* negotiation, licensing and contracting less so. This is possible because, as we have speculated in the previous Parts, the direction of the change in the law produced by *Therasense* is to make patents cheaper and easier to get. Moreover, it is probable that the patent office will be forced to determine patentability in view of even less information about whether the invention should be patented than the patent office utilized before *Therasense*. If this eventuality is realized, it suggests that patentees will own more patents that could be found invalid by a district court judge. In other words, the first *real* patent examination would occur at the patent infringement stage, not at the patent application stage. Logically, this could lead to greater ex ante uncertainty around patent rights and raise the cost of negotiation to the point that it is cheaper to negotiate using litigation. If so, the result may be more patent allocation decisions being made by federal district court judges rather than by private parties transacting in the marketplace.[32]

2. A Highly Political Federal Circuit?

The opinion for the majority in *Therasense* has the flavor of an announcement as opposed to a detailed analysis of the relevant public policy. And since it is an announcement that at least facially favors perhaps the court's most influential constituencies – the patent bar and those who seek patents – it raises the specter that the new Federal Circuit might be substantially more political than the old one.

From the majority's opinion it seems evident that the patent bar and those who seek patents strongly desired the holding; the opinion contains several pages of citations to the concerns of the patent bar, which it clearly finds relevant – if not determinative – to its decision to raise the standard

[31] Graham v. John Deere of Kansas City, 383 U.S. 1 (1966).

[32] This analysis leaves aside the concern that *Therasense* might in time spawn a cottage industry of patent acquisition misconduct litigation. If that also happens, it should be expected to push even further in the direction of an ex post system.

for establishing inequitable conduct.[33] The bar's actual concerns were, however, rather vague, essentially amounting to unsubstantiated empirical claims about the patent acquisition and patent litigation burdens of inequitable conduct. The litigation burden claim has become even more questionable since the Federal Circuit heard the case, and the patent office, the institution the bar claimed needed to be protected from the overdisclosure of information relating to the patentability of inventions, downplayed the concern in its own brief.[34] In fact, the patent office asked *not* to be relieved of the information patent applicants were required to submit. It expressed the concern that it would be unable to perform quality patent examination unless it could get information from applicants beyond that which would be just "but for" patent defeating.

Thus, it is somewhat discouraging that, other than some conclusory statements to the effect that the public will benefit from its decision (mostly, it appears, on the predictions that (1) less will be spent litigating inequitable conduct, and (2) patents will cost less to obtain), the majority opinion in *Therasense* offers almost no analysis of the issues involved from the perspective of the public. This stands in sharp contrast to the dissent, which provides a much deeper analysis of the policy issues implicated by the law of inequitable conduct and analyzes the issues with a focus on the public consequences of the decision.[35]

So perhaps, just perhaps, we are seeing a more political Federal Circuit emerging. Perhaps the days of Federal Circuit judges staying largely in the background and "deciding cases" are giving way to a period in which the Federal Circuit will be a court that seeks to be more "in tune" with the constituencies affected by its decisions. In administrative law lingo, perhaps we are seeing the receding of a public interest Federal Circuit and the emergence of a public choice Federal Circuit.

3. A Pro-Patentee Federal Circuit?

Therasense seems to be a remarkably pro-patentee opinion. The rationale for this interpretation has already been discussed in the earlier Parts of this essay. The direction – indeed the stated purpose – of the opinion is to protect patent lawyers and those who seek patents from claims and defenses that dealings with the patent office were not prosecuted with complete candor. Unfortunately, because the issue is one about which the patent bar seemed to have such intense feeling, it is difficult to speculate about how generalizable this observation might be. Perversely, however, if

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[33] *See* Slip Op. at 21-24.

[34] *See* Dissent at 8-9.

[35] We are not suggesting that the dissent is necessarily correct; only that its opinion contains substantially more rigorous analysis than the majority opinion.

our predictions in the preceding Parts turn out to be correct, the eventual result of *Therasense* may actually be that future patentees are worse off than they are presently due to increased uncertainty about whether their patent rights are enforceable, and, potentially a diminished public opinion about the patent system.

E. Will Therasense *Really Change Case Outcomes?*

We think its clear that the Federal Circuit thought it was making a sea change with its decision in *Therasense*. The early reaction from the bar and some commentators has been jubilation,[36] which suggests that patent lawyers and those who seek patents also believe they got something in the decision. To this point in the essay, we have analyzed the opinion as if it did mean something, as if a change had really been effected. But we would be remiss to not at least consider the possibility that less has happened than everyone seems to think. In this Part, we consider that possibility, concluding that there is a case to be made that at the end of the day, *Therasense* might turn out to be much ado about nothing.[37]

The ultimate question for courts and lawyers is whether the Federal Circuit's opinion will affect outcomes in particular cases. Certainly there is good reason for the patent bar's jubilant belief that it will: the majority opinion clearly indicates an intent to make it more difficult to establish inequitable conduct and this alone may be sufficient to cause trial judges to find inequitable conduct less often.

In addition to the signaling effect the opinion will have for district courts, the formal framework constructed by the majority may also make it easier for patent holders to prevail on claims of inequitable conduct. Even

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[36] *See, e.g.,* Lawrence T. Kass and Nathaniel T. Browand, "'Therasense': Vaccine for a plague," *The National Law Journal*, http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202496036951&Therasense_Vaccine_for_a_plague&slreturn=1&hbxlogin=1 (June 6, 2011) (last visited June 6, 2011); Nate Raymond, "Federal Circuit Guts Inequitable Conduct Defense, Patent Plaintiffs Rejoice," *The American Lawyer*, http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202495333432&Federal_Circuit_Guts_Inequitable_Conduct_Defense_Patent_Plaintiffs_Rejoice (May 25, 2011) (last visited June 6, 2011). Law firms have issued similar commentary. *See, e.g.,* Jeffrey David Mills and Brian Banner, "Federal Circuit makes it more difficult to prove inequitable conduct during patent prosecution," King & Spaulding Client Alert, available at *http://www.kslaw.com/imageserver/KSPublic/library/publication/ca053111.pdf* (May 31, 2011) (last visited June 6, 2011).

[37] In addition to the issues raised in this Part, we also acknowledge the possibility that the Supreme Court may grant certiorari in this appeal. We decline to speculate on this possibility, however, other than to suggest that the likelihood of Supreme Court review of *Therasense* seems somewhat low to us.

leaving aside the arguably pro-patent holder language of the standards, the contraction of the pre-*Therasense* materiality standards to two formal articulations will perhaps force district courts to more clearly articulate their reasoning and will limit their ability to pick the standard that best suits the outcome they would like to arrive at. This is particularly true in *Therasense* itself, where the majority implicitly instructed the district court to reconsider its analysis under a "but for" – as opposed to an "affirmative egregious misconduct" – standard.[38]

But does the analytical framework proscribed by *Therasense* really compel a different result in any specific case? Or is it just as susceptible to being shaped to fit the normative views of judges as the previous incarnation? We suspect that perhaps the latter could be closer to the future reality.

Of the majority's holdings, its materiality framework represents the most dramatic departure from the past, requiring that the relevant conduct pass a "but for" test. Yet that requirement contains an exception: that for "affirmative egregious misconduct." Although its contours have not yet been fully explored, that exception is perhaps so great that it swallows the whole. As the dissent notes, "it is often difficult to draw a line between nondisclosure and affirmative misrepresentation. . . . The distinction between "affirmative acts" and "nondisclosure" is thus apt to become fertile ground for litigation in the future, not to mention the distinction between 'egregious' misconduct and misconduct that is assertedly less than 'egregious.'"[39]

The court's holding on the intent element is even more problematic in terms of mandating specific outcomes. On the relevant standard both the majority and dissent agreed: inequitable conduct requires specific intent to deceive the patent office. Rather than disagreeing about the applicable standard, the disagreement between the majority and dissent turns on a purely factual analysis: whether or not the relevant facts involved in this case, reviewed under a deferential standard of review, satisfy that legal standard. Notably, nowhere in the dissent's opinion does it take issue with the majority's *legal* statements about the applicable standard for intent.

What this dispute suggests to us is that the question of intent will continue to play a key role in the Federal Circuit's review of inequitable conduct determinations, and the court will continue to be sharply divided on this issue. Nothing in the dissent's opinion suggests that it views the legal pronouncements of the majority as limiting its ability to follow its

[38] Although the majority did not explicitly preclude the district court from applying the "egregious misconduct" standard on remand, its remand instruction to analyze "but for" materiality all but forecloses that option.

[39] Dissent at 25-26, fn. 3.

normative views on whether or not particular conduct was intended to deceive the PTO.

We also note that the dissent already has a powerful doctrinal tool should it choose to express its normative views. Within days of the Federal Circuit's opinion in *Therasense*, the Supreme Court issued its opinion in *Global-Tech v. SEB*,[40] a case dealing with the degree of scienter required for inducement of infringement. In *Global-Tech*, the Supreme Court concluded that knowledge for inducement can be established through "willful blindness" – a form of fault that appears to be novel to the patent context. While the doctrine of inducement is distinct from that of inequitable conduct, commentators have already begun to recognize the applicability of willful blindness to inequitable conduct.[41] Specifically, willful blindness allows for a finding of culpable knowledge if the accused party believes that there is a *high probability* that a fact exists and takes deliberate actions to avoid learning of the fact. Applying this mechanism, courts may be able to establish the elements of the *Therasense* "specific intent" test, knowledge of the relevant information and knowledge of its materiality, even in the absence of the high standard *Therasense* seems to require.

What this suggests is that despite the majority's attempt to limit the intent element of inequitable conduct through formal rules, judges will largely be free to apply their own normative perspectives either because they consider any dispute to largely involve factual questions (as the dissent apparently did) or potentially through the invocation of the concept of willful blindness.

CONCLUSION

This purpose of this brief essay has been to provide an early analysis of some of the most substantial law and policy concerns raised by the very recent *en banc* decision of the United States Court of Appeals for the Federal Circuit in the *TheraSense v. Becton Dickinson* case. Using theoretical logic and policy analysis we have identified substantial law and policy concerns that are raised by the court's decision, but that were left largely unaddressed by the court's analysis. Our essay does not show that the "sky will fall" or that the court's opinion in *Therasense* will "destroy the patent system." To the contrary, we think the essay teaches that the impact

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[40] Global-Tech Appliances, Inc. v. SEB S.A., __ U.S. __ (2011).

[41] *See* Kevin E. Noonan, "Global-Tech Appliances, Inc. v. SEB S.A.," *Patent Docs*, http://www.patentdocs.org/2011/06/global-tech-appliances-inc-v-seb-sa-2011.html (May 31, 2011) (last visited June 6, 2011) (noting the potential applicability of the concept of willful blindness to inequitable conduct).

of the *Therasense* decision can only be properly analyzed with an appreciation of the many and complex interactions involved in the patent creation and patent litigation environments.

On the court's side of the ledger can be placed the benefits it predicts for its approach; namely, that it is might be the case that *Therasense* will make patents cheaper to obtain and cheaper to enforce. This essay's contribution is to begin a discussion of what may be counted on the other side of the ledger. We identify a number of possible costs to the court's approach, inter alia, a higher cost in bringing information to bear on the patentability determination, a potential decrease in the quality of information brought to bear on the patentability determination; a potential increase in the number of low quality patents; and the potential reputational and economic costs to the patent system of a misconduct doctrine that might be more complex and dangerous to patent applicants and the patent system than the one it replaced.

From that perspective, our analysis suggests that the opinion for the court may be too optimistic in its expectation that a simple and straight line can be drawn from making patents cheaper to obtain and cheaper to enforce to an increased public, and for that matter, patentee, benefit. That said, it will take time and additional analysis to determine if, at the end of the day, the court's efforts to reduce the risk of inequitable conduct to patent applicants will provide a benefit to the patent system that outweighs the costs.