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## INCONSISTENCY SHOULD NOT BE MATERIALITY: THE FLAWS IN 37 C.F.R. § 1.56(B)(2)

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### ABSTRACT

The doctrine of inequitable conduct is in need of clarification. The Court of Appeals for the Federal Circuit has recently granted en banc review in *Therasense, Inc. v. Becton, Dickinson, & Co.* to determine the appropriate standards for each prong of inequitable conduct doctrine: materiality and intent. While the parties and the amici have almost unanimously proposed that the standard of materiality should be less inclusive than “what a reasonable examiner would want to know in deciding upon patentability,” there is much debate regarding how the standard for materiality should be articulated. One proposal is that the courts should look to 37 C.F.R. § 1.56 (“Rule 56”) in formulating an appropriate standard of materiality. But Rule 56 has two key and distinct subparts, (b)(1) and (b)(2), that provide different definitions of materiality. This paper is an exploration of both the clarity and policy flaws of subpart (b)(2). It is far from clear what “information” is encompassed by subpart (b)(2); how strictly should “inconsistent” be interpreted; and what level of reliability, if any, should be required of “inconsistent” information before it is considered material. This paper suggests that the en banc court in *Therasense* should adopt Rule 56(b)(1) as the sole measure of materiality in judicial inequitable conduct analyses.

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INTRODUCTION

There is wide agreement that the doctrine of inequitable conduct is in serious need of clarification and that the concept of materiality in the case law has become too inclusive. The Court of Appeals for the Federal Circuit has recently granted en banc review in a pure inequitable conduct case, *Therasense, Inc. v. Becton, Dickinson & Co.*<sup>1</sup> to address problems in the concepts of both materiality and intent as they have developed in the case law of inequitable conduct. The parties and the amici have almost unanimously proposed that the standard of materiality should be less inclusive than “what a reasonable examiner would want to know in deciding upon patentability.”<sup>2</sup> One proposal is that the courts should look to 37 C.F.R. § 1.56 (“Rule 56”) in formulating an appropriate standard of materiality.<sup>3</sup> But Rule 56 has two key and distinct subparts, (b)(1) and (b)(2), that provide two quite different definitions of materiality for use in establishing the content of the duty of disclosure required by Rule 56.<sup>4</sup> Subpart (b)(1) provides a definition which, if not completely compatible with most of the positions presented to the Court, comes fairly close. Subpart (b)(2), on the other hand, is seriously flawed from both a clarity and a policy point of view.

This paper is an exploration of both the clarity and policy flaws of subpart (b)(2). It is far from clear what “information” is encompassed by subpart (b)(2); how strictly should “inconsistent” be interpreted and what level of reliability, if any, should be required of “inconsistent” information before it is considered material.<sup>5</sup> Furthermore, it is highly questionable whether an “inconsistency” standard represents a cognizable improvement over a “reasonable examiner” standard in establishing a standard for

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<sup>1</sup> *Therasense, Inc. v. Becton, Dickinson & Co.*, 374 Fed. App'x 35, 35–36 (Fed. Cir. 2010) (order granting en banc review). After vacating the initial panel decision, The Court of Appeals for the Federal Circuit heard en banc oral arguments on November 10, 2010 and has not yet issued an opinion. *Therasense, Inc. v. Becton, Dickinson, & Co. (Therasense En Banc)*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1595 (Fed. Cir. argued en banc Nov. 10, 2010), *on appeal from* 565 F. Supp. 2d 1088 (N.D. Cal. 2008).

<sup>2</sup> See Abbott Diabetes Care, Inc. and Abbott Laboratories' Reply Brief on Rehearing En Banc at 2, *Therasense En Banc*, 2010 WL 4622532, at \*2 (Fed. Cir. Oct. 21, 2010).

<sup>3</sup> See Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 8–9, *Therasense En Banc*, 2010 WL 3390234 (Fed. Cir. Aug. 2, 2010).

<sup>4</sup> 37 C.F.R. § 1.56(b)(1)–(2) (2010).

<sup>5</sup> See discussion *infra* Part II.B.

the duty of disclosure which strikes a workable balance between over disclosure and under disclosure.

It is far from clear just how the current version of Rule 56 reduces the extent of information which is to be considered “material” from that considered “material” under the “reasonable examiner” standard recited in the 1977 version and used in most of the post 1977 cases involving inequitable conduct.<sup>6</sup> It was the clear explicit intent of the United States Patent and Trademark Office (“PTO”) in promulgating the 1992 version of Rule 56 with the (b)(1) and (b)(2) tests for materiality to narrow the definition.<sup>7</sup> While the (b)(1) test certainly appears to have that effect, it is almost certain that the (b)(2) test will end up encompassing as much if not more information as “material” than the “reasonable examiner” standard once it is applied on its own.<sup>8</sup>

### I. BENEFITS OF 56(B)(1)

Rule 56(b)(1) defines information as material if “[i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim.”<sup>9</sup> Rule 56 goes on to provide a careful definition of just what a prima facie case of unpatentability of a claim means.<sup>10</sup> There could be a minor concern about just how to apply the definition to the record of a granted patent in view of the injunction to determine materiality “before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability,” but it is unlikely to be of any practical significance.<sup>11</sup> If the file of the patent at issue contains any evidence in support of patentability such as a declaration under 37 C.F.R. § 1.131 or § 1.132, it will almost certainly also contain an identification of the information (typically, but not necessarily, prior art) to which such evidence is directed.<sup>12</sup> Perhaps Rule 56 would be clearer if it had been drafted to say “which could be submitted” as it seems to be directed to the situation in which an applicant is in possession of evidence, that in his view, obviates the materiality of certain information and on that basis submits neither the information nor the evidence of non-materiality. For instance, an applicant may have evidence of invention before the effective date of a reference which is prior art on the basis of 35 U.S.C. § 102(a) and therefore decides to submit neither the reference nor the evidence.<sup>13</sup> While it is theoretically possible to submit the evidence but not the information, it is hard to imagine a real world case in which this would occur. In my professional experience, applicants do not gratuitously submit evidence of patentability not called for by the

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<sup>6</sup> See, e.g., *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314–16 (Fed. Cir. 2006) (discussing the 1977 “reasonable examiner” standard and its subsequent history).

<sup>7</sup> Duty of Disclosure, Notice of Final Rulemaking, 57 Fed. Reg. 2021, 2022 (Jan. 17, 1992); see *Digital Control*, 437 F.3d at 1314 (recognizing the new rule’s narrower standard).

<sup>8</sup> Indeed, as discussed herein, in at least one reported case there is a clear explicit indication that this is what will occur. See *infra* Part II.B (discussing *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 822–23 (N.D. Ill. 2007)).

<sup>9</sup> 37 C.F.R. § 1.56(b)(1).

<sup>10</sup> *Id.* § 1.56(b)(2)(ii).

<sup>11</sup> *Id.*

<sup>12</sup> See, e.g., *In re Mulder*, 716 F.2d 1542, 1543 (Fed. Cir. 1983).

<sup>13</sup> See 35 U.S.C. § 102(a) (2006); U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.02(b) (8th ed. Rev. 8, July 2010).

progress of the prosecution of the application. If the evidence had been submitted to rebut a different reference or other information which was of record, that of record reference or information would most probably render any undisclosed but rebutted information cumulative and therefore non-material.

Rule 56(b)(1) thus represents a genuine and substantial narrowing of the definition of materiality and therefore is in accord with the direction urged by many of the amici in the *Therasense* case.<sup>14</sup> Some of the amici, notably including the ABA and the AIPLA, have urged the adoption of a “but for” test.<sup>15</sup> It is not entirely clear whether the “but for” test is to be applied to the record created in the PTO before the issuance of the patent at issue or to the record before the court at the time the inequitable conduct evaluation is conducted.<sup>16</sup> Language to the effect that “but for the failure to disclose, the patent would not have issued” suggests that the focus is on the record before the PTO while language with regard to claim “validity” suggests a focus on the record before the court including any additional evidence of patentability, such as evidence of commercial success which was submitted during the court proceedings.<sup>17</sup> But regardless of whether these amici agree with the Rule’s focus on the PTO record, they do endorse the direction in which 56(b)(1) moves the materiality analysis.

If the focus of 56(b)(1) were on the prosecution record before the PTO, such a focus would be in accord with the goal of the inequitable conduct doctrine of assuring that the examiner has all the information available to the patent applicant which bears meaningfully on the patentability on the claims before him.<sup>18</sup> On the other hand, if the focus were on the litigation record, such a focus would allow applicants to delay or avoid the consideration of some issues of patentability, depending on whether the patent was litigated. Given that many more patents have a commercial impact than are litigated and that some litigated patents have a substantial irreversible commercial impact before they are litigated, it is important that an incentive exist for assuring that the prosecution record before the PTO be as complete as practically possible.<sup>19</sup>

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<sup>14</sup> See, e.g., Brief of Washington Legal Foundation as Amicus Curiae in Support of Plaintiffs-Appellants, Urging Reversal at 26, *Therasense En Banc*, 2010 WL 3390237, at \*26 (Fed. Cir. Aug. 2, 2010).

<sup>15</sup> E.g., Brief of Amicus Curiae the American Intellectual Property Law Association in Support of Neither Party at 2, *Therasense En Banc*, 2010 WL 3390242, at \*2 (Fed. Cir. Aug. 2, 2010); Brief and Appendix of the ABA as Amicus Curiae at 16–17, *Therasense En Banc*, 2010 WL 2751537, at \*16–17 (Fed. Cir. June 17, 2010).

<sup>16</sup> See Brief of Amicus Curiae Apotex, Inc. Not Supporting Any Party at 16, *Therasense En Banc*, 2010 WL 3390240, at \*16 (Fed. Cir. July 30, 2010).

<sup>17</sup> Given the opposition of the IP Section of the ABA to allowing a purge of inequitable conduct once the patent at issue has been granted, perhaps it can be assumed that it endorses a focus on the record before the PTO. See Brief and Appendix of the ABA as Amicus Curiae at 16–17, *Therasense En Banc*, 2010 WL 2751537, at \*16–17 (Fed. Cir. June 17, 2010). A focus on the record before the court would allow an applicant to fail to cite a “material” reference and then render it non-material by submitting evidence (like comparative data) in the court proceeding, essentially purging the “inequitable conduct” that occurred before the examiner.

<sup>18</sup> See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (2006) (stating that the purpose of the duty of candor is to provide relevant information to a PTO examiner).

<sup>19</sup> One substantial concern is that there may be some doubt that the evidence a patent applicant holds back is sufficient to negate the impact on patentability of the undisclosed

## II. DEFECTS IN 56(B)(2)

*A. Introduction*

Rule 56(b)(2) with its incorporation of an “inconsistency” standard does nothing to narrow and sharpen the definition of material information and might even be characterized as a disaster waiting to happen. The term “inconsistent” is not well defined, the “information” to which it is applied potentially encompasses a wide universe of information not the least helpful to a determination of patentability, the position taken by the applicant to which the undisclosed information is to be compared has been expanded by case law to include the mere presentation of a claim, no consideration is given to the reliability of the undisclosed information and the intent element of the inequitable conduct analysis may have for all practical purposes been vitiated.<sup>20</sup> One can reasonably hypothesize that the only reason the disaster has not yet come to fruition is that for all practical purposes subpart (b)(2) is only applied by the courts as part of an inequitable conduct analysis and to date such application has always been with an overlay of the “reasonable examiner” standard, i.e. while courts have applied the (b)(2) “inconsistency” standard, none has yet found inequitable conduct without also finding the undisclosed information material under the “reasonable examiner” standard.

*B. The Ambiguity of “Inconsistent”*

The meaning of “inconsistent” in subpart (b)(2) is simply ambiguous and neither the comments accompanying the adoption of the rule nor the subsequent case law has done much to clarify it. In normal English usage, the term is applied to a wide range of discrepancies from mere differences in emphasis to flat out contradiction.<sup>21</sup> For instance, a first prior art reference might caution that a certain process “must” not be performed in the presence of moisture while a second reference might caution that a certain process “should” not be performed in the presence of moisture. If an inventor discovers that the process need not be anhydrous and seeks a patent application on this discovery, is he required by Rule 56(b)(2) to call the second reference to the attention of the examiner if he has based arguments of patentability on the first reference? One might argue that “inconsistent” should be applied to any information which would make it more likely that an examiner would enter a

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information. Thus, a focus on the record before the court could allow patent applicants to delay the day of reckoning and, in some cases, have a commercial impact with invalid claims.

<sup>20</sup> As explored in some depth later, many court decisions and commentators can be read to say if an appreciation of materiality can be established, then the intent to deceive prong of the inequitable conduct analysis is satisfied. *See infra* Part II.C. But if all one needs to appreciate is an “inconsistency,” it can be expected that establishing an appreciation of materiality can, in the substantial majority of cases, become pro forma.

<sup>21</sup> THE OXFORD ENGLISH DICTIONARY 818 (James A. H. Murray et al. eds., Clarendon Press 2d ed. 1989) (defining various meanings of the word “inconsistent”).

rejection.<sup>22</sup> But this would mean encompassing even more information than that called for by the superseded 1977 “reasonable examiner” standard.

The meaning of “inconsistent” clearly cannot be limited to contradictory in the context of (b)(2) of Rule 56 because the text recites “refutes, or is inconsistent with.” The canons of statutory and regulatory construction do not allow one to read the two terms as redundant.<sup>23</sup> Therefore, “inconsistent” must be read to encompass something more than contradictory. An interesting philosophical argument can be made as to whether “inconsistent” should be fairly construed as encompassing information which “refutes.” Patent attorneys who are used to the rules governing claim construction will find fault with language that includes a specific term and a broader term that encompasses the specific term in the same list, and even lay readers will have some difficulty with a phrase which is analogous to saying “on Tuesday or on any weekday.” But for present purposes, this is far less significant than the question of just how far beyond contradictory the term “inconsistent” should extend.

For a term that is clearly intended to provide guidance as to what information is significant enough to merit an inequitable conduct sanction, the “inconsistent” of Rule 56(b)(2) provides precious little guidance. Clearly, when exactly the same language in one source is repeated in another source, the two sources should not be construable as “inconsistent,” even if found in vastly different contexts and at various depths of treatment. But putting aside context and depth of treatment, just how great a deviance in content is required to render information “inconsistent”? If a patent applicant poses his arguments relating to temperature in degrees Celsius and a reference reports temperature in degrees Fahrenheit, can it be reasonably argued that the reference provides “inconsistent” information on the basis that in the relevant art area the Examiner is more likely to be familiar with the Fahrenheit temperature scale? If the required deviance is fairly minor, for all practical purposes, the “inconsistency” test merges with the cumulative test which applies to both (b)(1) and (b)(2).

### *C. Historical Criticisms of the Scope of “Inconsistent” Information*

The problems with the “inconsistent” standard were recognized as long ago as 1992, the year the “new” Rule 56 was adopted, but the Federal Circuit’s decision to continue to apply the “reasonable examiner” standard from the 1977 version of Rule 56 has meant that the case law on inequitable conduct has not explicitly highlighted these deficiencies. In 1992 the AIPLA Quarterly Journal did an enlarged issue to reflect upon the newly adopted Rule 56 containing the “inconsistent” standard in which both John F. Lynch and Rene D. Tegtmeier reflected upon deficiencies in this

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<sup>22</sup> As explored in more depth hereinafter, even this minimal tie to patentability is lacking in this standard of materiality. See *infra* Part II.C.2.

<sup>23</sup> See, e.g., *Huntleigh USA Corp. v. United States*, 525 F.3d 1370, 1382 (Fed. Cir. 2008) (“[T]he words of a statute are not to be rendered superfluous if such a construction can be avoided.”). One might argue that “refutes” is being used in its narrower, more formal sense to mean “proves the opposite,” but it is a somewhat strained construction to then proceed to the conclusion that “inconsistent” should be limited to “a contradiction which is not self proving,” i.e., it is not persuasive on its own.



standard.<sup>24</sup> Both were highly prescient about the issues that would arise. Instead of addressing these potential issues, the Court has avoided a rigorous analysis of inequitable conduct allegations under the new standard and has continued to evaluate the materiality of undisclosed information against the “reasonable examiner” standard.

### *1. Inclusion of Flawed Data*

Rene Tegtmeier, who was Assistant Commissioner of Patents in the days when a fraud squad existed at the PTO, focused on the problem of “failed test results.”<sup>25</sup> He noted that the PTO had specifically declined to address the vagueness inherent in the “inconsistent” standard in promulgating the new rule and he made specific reference to “Comment 22” and the PTO reply which were as follows:

*Comment 22.* One comment stated that the definition of materiality in proposed § 1.56(b) imposes substantial new burdens on applicants who would be required to disclose failed experiments, papers published less than one year prior to filing and experimental public uses even if they clearly are refutable and will not affect patentability. One comment stated that the proposed rule would require applicants to incur added expense for affidavits and comparison tests. Five comments stated that the Office should not require applicants to present results from clearly invalid tests since this would be contrary to usual scientific practice. One comment argued that information should not be required to be submitted if there was no doubt that it would not preclude patentability, e.g., where common ownership existed so that the exception of 35 U.S.C. 103, second paragraph, would apply.

*Reply:* The definition of materiality in § 1.56 does not impose substantial new burdens on applicants, but is intended to provide the Office with the information it needs to make a proper and independent determination on patentability. It is the patent examiner who should make the determination after considering all the facts involved in the particular case. The comments reflect that the Office objective of clarifying what information the Office considers to be material has been accomplished by the amendment of the rules.<sup>26</sup>

Mr. Tegtmeier expressed concern that a court might interpret the “new” rule to actually require disclosure not called for by the “old” rule.<sup>27</sup> It might well be that a

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<sup>24</sup> John F. Lynch, *New Rule 56: The Second Time Around*, 20 AIPLA Q.J. 144 (1992); Rene D. Tegtmeier, *A Refocusing on Inequitable Conduct in New Rule 56*, 20 AIPLA Q.J. 191 (1992).

<sup>25</sup> See Tegtmeier, *supra* note 24, at 203.

<sup>26</sup> Duty of Disclosure, Notice of Final Rulemaking, 57 Fed. Reg. 2021, 2025–26 (Jan. 17, 1992) (responding to and analyzing specific comments in response to the proposed changes to Rule 56).

<sup>27</sup> See Tegtmeier, *supra* note 24, at 203, 207. Tegtmeier states: “It could be construed that these PTO statements go beyond the requirements of the existing law,” and “[t]his is an area in

“reasonable examiner” would not want to know about flawed unrepresentative experimental data, but it would nonetheless be “inconsistent” information if it were not redundant of data presented to the examiner.

Though I am not aware of any case in which inequitable conduct was found as a result of failure to disclose “inconsistent” information which was not material under the “reasonable examiner” standard, there is at least one case in which the “inconsistent” standard was explicitly found to apply to information which did not meet the “reasonable examiner” standard. In *Abbott Laboratories v. Sandoz, Inc.*,<sup>28</sup> the district court found that the failure to disclose certain test data was a violation of Rule 56(b)(2) but that the undisclosed information was not material under the “reasonable examiner” standard and therefore declined to find a reasonable probability of inequitable conduct.<sup>29</sup> The court accepted Abbott’s arguments that a “reasonable examiner” would not have wanted to know about the inconsistencies because they were not probative of patentability.<sup>30</sup> The Federal Circuit explicitly endorsed this reasoning on appeal.<sup>31</sup>

While one may quibble with the court’s determination that the undisclosed information was not probative of patentability, and indeed this very court later had second thoughts with regard to some of the undisclosed information in *Abbott Laboratories v. Sandoz, Inc.*, the key point remains that Mr. Tegtmeyer’s fear was confirmed that the “inconsistent standard” could be untethered from any considerations of patentability.<sup>32</sup> Thus, it is no longer speculation that the “inconsistent standard” of 56(b)(2) may be read by courts as extending to information never before considered material.

## 2. Inclusion of Opinions and Arguments

John F. Lynch, in the same issue of the AIPLA Quarterly Journal, went on to express even broader concerns about the vagueness of the “inconsistency standard.”<sup>33</sup> He commented:

the fact that materiality may be triggered by a vague notion of “inconsistency” promises to expand the litigation witch hunt in large

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which a court might well interpret the new rules, albeit improperly, as requiring more than a fair and balanced presentation of data supporting the applicant’s position.” *Id.*

<sup>28</sup> 544 F.3d 1341 (Fed. Cir. 2008).

<sup>29</sup> *Id.* at 1354–56.

<sup>30</sup> *Id.* at 1356.

<sup>31</sup> *Id.*

<sup>32</sup> See Tegtmeyer, *supra* note 24, at 202. The initial determination in *Abbott Labs.* had been on a motion for preliminary injunction while the later determination was on motions for summary judgment in which the court was unwilling to hold some “inconsistent” information immaterial without a trial on the merits, which was never had because the case settled before trial. See *Abbott Labs. v. Sandoz, Inc.*, No. 05-cv-05373 (Apr. 16, 2007) (order granting preliminary injunction), ECF No. 302; *Abbott Labs. v. Sandoz, Inc.*, No. 05-cv-05373 (Dec. 4, 2007) (order denying Sandoz’ motion for summary judgment and granting in part and denying in part Abbott’s motion for summary judgment), ECF No. 454.

<sup>33</sup> Lynch, *supra* note 24, at 144–45.

corporate patentees to find anything contrary to the statements made during patent prosecution.<sup>34</sup>

He went on to note that there was no requirement that the “inconsistent” information even be important and that any judgment with regard to patentability is removed from the determination of materiality under this standard.<sup>35</sup> He also observed that the “inconsistent” information need not be factual but could extend to arguments and opinions regarding patentability as well as the full text of rejections by foreign patent offices on corresponding patent applications.<sup>36</sup>

Some of Mr. Lynch’s fears may have been realized in the recent *Therasense* case, in which arguments made by counsel for the patentee in another proceeding were found to be “inconsistent” information and therefore material pursuant to Rule 56(b)(2).<sup>37</sup> The district court held, and the Federal Circuit panel affirmed, that the characterization in the other proceeding of a sentence appearing in a key prior art reference was inconsistent with what had been said about this sentence in the prosecution of the patent at issue.<sup>38</sup> In fact, the district court found the arguments in the other proceeding to be flatly contradictory of what had been said in the U.S. proceeding but the standard itself does not specify any particular degree of inconsistency.<sup>39</sup> More importantly, the district court found that the “information” contemplated by Rule 56(b)(2), which sets forth the “inconsistency” standard, was not limited to factual information, such as experimental results, but extended to opinions and arguments.<sup>40</sup>

The district court may have been influenced by the fact that the arguments had been made by a predecessor of the assignee of the patent at issue, but there is nothing in the Rule 56(b)(2) “inconsistency” standard which speaks to the identity of the author of the opinion or argument. If the “information” to which this standard applies includes opinions or arguments and a given opinion or argument is “inconsistent” with positions that the patent applicant took in obtaining his patent, then it is material for the purpose of an inequitable conduct analysis using the “inconsistency” standard.

There is no apparent reason why the “inconsistent” standard would not extend to the opinions of third parties regarding patentability of the claims at issue. For

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<sup>34</sup> *Id.* at 150.

<sup>35</sup> *Id.* at 161.

<sup>36</sup> *Id.*

<sup>37</sup> See *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088, 1112–13 (N.D. Cal. 2008) (holding that arguments made to a European Patent Office proceeding were inconsistent with the representations made to the PTO), *aff’d*, 593 F.3d 1289 (Fed. Cir. 2010) (panel), *vacated for en banc review*, 374 Fed. App’x 35 (Fed. Cir. 2010).

<sup>38</sup> *Id.* The district court seems to have found the undisclosed information also material under the “reasonable examiner” standard, but only the dissenter on the panel made reference to this finding. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1313 n.1 (Fed. Cir. 2010) (panel) (Linn, J., dissenting), *vacated for en banc review*, 374 Fed. App’x 35 (Fed. Cir. 2010).

<sup>39</sup> *Therasense*, 565 F. Supp. 2d at 1112–13.

<sup>40</sup> *Id.* This could create quite a dilemma for a party who acquires a patent application after initially obtaining an opinion of counsel reflecting negatively on the patentability of one or more claims. If he did not share this opinion in the course of his acquisition negotiations it would be protected by attorney client privilege. However, 56(b)(2) would require its disclosure to the examiner.

instance, a patent applicant might seek a declaration in support of patentability from an independent expert and find that the first expert that he approached was not favorably disposed toward the patentability of the invention. Even if he did not present the declaration of a more favorably disposed expert, there are certainly good grounds to argue that the first expert's negative reaction was "inconsistent" information whose disclosure is required by Rule 56(b)(2). Or suppose the patent applicant engages in license negotiations with a third party who takes an interest in the applicant's published patent application, but as part of his negotiating strategy denigrates the patentability of one or more of the pending claims. As discussed in Part II.C.3 below, there is a solid basis for concluding that the denigrating comments communicated to the patent applicant would be subject to the "inconsistency" standard of Rule 56(b)(2). Indeed, the language of Rule 56(b)(2) provides no basis for distinguishing such denigrating comments from a patent examiner's comments made during rejection of a substantially similar claim.<sup>41</sup>

### 3. "Inconsistency" with the Specification and Claims

But Mr. Lynch further expressed concern that it was not clear just what constitutes a "position the applicant takes" for purposes of Rule 56(b)(2), and he suggested that it could extend to information included in the patent application itself as opposed to the formal "argument" portion of a prosecution history.<sup>42</sup> Once again, case law has proven Mr. Lynch quite prescient as the court in *Abbott Laboratories v. Sandoz, Inc.* looked to data and assertions regarding taste perversion which appeared in the application itself in conducting a 56(b)(2) analysis.<sup>43</sup>

And *Abbott Laboratories v. Sandoz, Inc.*, is not the only case to find a position against which to measure "inconsistency" in areas other than the formal arguments of the applicant. In *Sigram Schindler Beteiligungsgesellschaft mbH v. Cisco Systems, Inc.*,<sup>44</sup> the court held that "[w]hen prosecuting claims before the PTO, a patent applicant is, at least implicitly, asserting that those claims are patentable" and then found that rejections in reexaminations of related claims constituted "inconsistent" information to this implicit assertion, thus making these rejections material under 56(b)(2).<sup>45</sup> In response to the patentee noting that he had made no arguments during the prosecution, the court in *Lusa Lighting, International, Inc. v. America Elex, Inc.*,<sup>46</sup> stated that "Rule 56 does not pertain solely to arguments made to the PTO after an application has been submitted. It also covers the claims contained in the

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<sup>41</sup> See *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367–68 (Fed. Cir. 2003) (holding that "a contrary decision of another examiner reviewing a substantially similar claim meets the . . . threshold materiality test" under both the "reasonable examiner" standard and the new Rule 56(b)(2) standard).

<sup>42</sup> Lynch, *supra* note 24, at 158–59.

<sup>43</sup> See *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1353–56 (Fed. Cir. 2008).

<sup>44</sup> 726 F. Supp. 2d 396 (D. Del. 2010).

<sup>45</sup> *Id.* at 421. The court also found the rejections material under the "reasonable examiner" standard, quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380 (Fed. Cir. 1998).

<sup>46</sup> No. 07-00674, 2008 WL 4350741 (C.D. Cal. Sept. 22, 2008).

patent application itself.”<sup>47</sup> And these cases were following the lead of the Federal Circuit in *Dayco*:

We also hold that the information meets the threshold level of materiality under new Rule 56, in that “[i]t refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability.” 37 C.F.R. § 1.56(b)(2) (2002). When prosecuting claims before the PTO, a patent applicant is, at least implicitly, asserting that those claims are patentable. A prior rejection of a substantially similar claim refutes, or is inconsistent with the position that those claims are patentable. An adverse decision by another examiner, therefore, meets the materiality standard under the amended Rule 56.<sup>48</sup>

But if the mere presentation of claims is the taking of a position in favor of patentability and any evidence tending to show unpatentability is “inconsistent” information and therefore material, then 56(b)(2) entirely swallows 56(b)(1). One cannot logically contemplate a prior art reference which would create a prima facie case of unpatentability of a claim in accordance with 56(b)(1) without also qualifying as information “inconsistent” with the patentability of that claim.

It is not entirely clear why this inherent internal contradiction of the “new” Rule 56 has not been widely recognized. Initially, it may have been believed from just a reading of the text of the rule that subpart (b)(2) was limited to specific arguments actually presented in the prosecution and indeed this is the position taken in some of the briefing in the en banc *Therasense* case, including the brief of the appellee Bayer and the amicus brief of the PTO.<sup>49</sup> But since *Dayco* in 2003 it should have been apparent that a “position the applicant takes” is not so limited.<sup>50</sup> Perhaps the delayed recognition lies in the fact that only the Federal Circuit and courts subject to its supervision actually apply the “new” Rule 56 and to date they almost always have done so in conjunction with the “reasonable examiner” standard.<sup>51</sup> Thus, to the extent that (b)(2) would have designated information as material not so designated by an application of (b)(1), the “reasonable examiner” standard did the same thing.

In this regard, *Abbott Laboratories v. Sandoz, Inc.*, and its affirmation by the Federal Circuit, is of particular importance.<sup>52</sup> In this case, the court explicitly limited the reach of Rule 56(b)(2) in an inequitable conduct analysis to information meeting the “reasonable examiner” standard and explicitly found any “inconsistent” information not meeting this standard to be non-material.<sup>53</sup>

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<sup>47</sup> *Id.* at 11 (C.D. Cal. Sept. 22, 2008).

<sup>48</sup> *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003).

<sup>49</sup> Defendant-Appellee Bayer Healthcare LLC’s Brief on Rehearing En Banc at 4, *Therasense En Banc*, 2010 WL 4310671, at \*4 (Fed. Cir. Oct. 8, 2010); Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 23, *Therasense En Banc*, 2010 WL 3390234, at \*9–12 (Fed. Cir. Aug. 2, 2010).

<sup>50</sup> *Dayco Prods.*, 329 F.3d at 1365.

<sup>51</sup> *Id.* at 1363.

<sup>52</sup> *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807 (N.D. Ill. 2007), *aff’d*, 544 F.3d 1341 (Fed. Cir. 2008).

<sup>53</sup> *Id.* at 825.

*D. Unreliable “Inconsistent” Information*

But the concerns with the Rule 56(b)(2) standard extend beyond the very broad reach of the term “inconsistent” and its untethering from any concepts of patentability to the fact that there is no limitation with regard to the reliability of the information. For the most part, the cases to date have focused on information whose reliability was not subject to serious question, such as office actions in related cases, although there have been some potential exceptions. For instance, in *Cargill, Inc. v. Canbra Foods, Ltd.*,<sup>54</sup> the patentee attempted unsuccessfully to argue that a portion of the undisclosed experimental data was unreliable because it was generated with the wrong starting materials and another portion of data was unreliable because the experimental conditions were inadequately specified.<sup>55</sup> However, there is nothing in the text of Rule 56(b)(2) which speaks to reliability.<sup>56</sup>

In stark contrast to both the “reasonable examiner” standard and Rule 56(b)(1), there is nothing in the Rule 56(b)(2) “inconsistency” standard which would allow a court to find information not material on the basis of unreliability.<sup>57</sup> Both of these other standards implicitly or explicitly require that material information be meaningful to patentability.<sup>58</sup> But information which is not of interest to a reasonable examiner in deciding whether to allow a claim because of its unreliability and information on which an examiner would not base a rejection because of its unreliability could be material under the “inconsistency” standard. Perhaps the “refutes” prong of Rule 56(b)(2) provides the basis for a court evaluating the reliability of undisclosed information in making a materiality determination,<sup>59</sup> but the “inconsistent” prong does not.<sup>60</sup>

The fact that the “inconsistency” test does not allow for any evaluation of reliability has very serious implications in a modern technological age. For example, assume a diligent patent attorney wants to support his arguments for patentability with the principle that water reliably boils at 100°C, so he resorts to Google to identify a few supporting technical publications. Among the publications he reviews is a crackpot posting taking issue with this well known scientific principle, arguing that the boiling point of water is dramatically affected by the phases of the moon. Under the “inconsistency” standard, the court would have no discretion to find this information/posting not material.

The inability to evaluate reliability creates particularly grave concerns with regard to technologies which involve the generation of great amounts of experimental data. As Mr. Lynch noted, some fields of endeavor, such as the development of products which must be reviewed by the FDA or the EPA, involve the generation of enormous amount of experimental data.<sup>61</sup> But as any scientifically trained person knows, the generation of any experimental data carries with it the probability of

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<sup>54</sup> 476 F.3d 1359 (Fed. Cir. 2007).

<sup>55</sup> *Id.* at 1365–66.

<sup>56</sup> See 37 C.F.R. § 1.56(b)(2) (2010).

<sup>57</sup> See *id.*

<sup>58</sup> *Cargill, Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007).

<sup>59</sup> This would be the case if “refutes” is read in accordance with its narrower, formal meaning of “proves the contrary.” See 37 C.F.R. § 1.56(b)(2).

<sup>60</sup> *Id.*

<sup>61</sup> Lynch, *supra* note 24, at 161–62.

generating “bad” or unreliable data.<sup>62</sup> This is demonstrated on a daily basis by high school students studying chemistry or physics who fail to obtain experimental results consistent with universally accepted scientific principles as a result of defects in their experimental technique. In highly complex fields such as the evaluation of pharmaceuticals in human clinical trials, the probability of generating unreliable experimental data is reasonably high.<sup>63</sup> But under the “consistency” standard, this unreliable experimental data would be material if it was not in accord with the patentability of a patent application claim at issue. In *Abbott Laboratories v. Sandoz, Inc.*, Abbott was able to argue the immateriality of certain undisclosed taste perversion data on the basis that it was done at a different dosage than the data relied upon before the examiner and therefore did not provide a reliable (meaningful) comparison.<sup>64</sup> But these arguments were made under the “reasonable examiner” standard and would have no place in an analysis using the “inconsistency” standard. In *Cargill v. Canbra*, there was an attempt to argue that the “inconsistent” data was unreliable because in one instance the wrong starting material was used and in another the experimental conditions were not fully specified.<sup>65</sup> While the court in that case did not find these arguments persuasive, under an “inconsistency” standard those arguments could not have even been advanced.<sup>66</sup>

Hypothetically, the reliability issue could be dealt with under the “intent” prong of an inequitable conduct analysis, but such an approach would be highly impractical. One could argue that an actor lacked the intent to deceive the PTO to obtain a patent if all he did was fail to disclose unreliable inconsistent data; if he felt the information was unreliable, he could fairly feel it would have no impact on patentability.<sup>67</sup> But the case law to date has generally held that intent is established if the actor appreciated the materiality of the undisclosed information during the period that the patent application was under prosecution. Most inequitable conduct cases in which intent was contested have focused on whether the actor under examination had a subjective appreciation of the materiality of the undisclosed information. It is far from clear whether a court would feel confident that existing precedent allowed the court to exonerate an actor who appreciated the materiality of undisclosed information on the basis that he honestly believed it to be unreliable and therefore to have no impact on patentability. It remains an open question whether the courts would incorporate reliability considerations into an intent analysis in cases in which materiality had been established using an “inconsistency” standard which was untethered from any considerations of patentability.

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<sup>62</sup> See *id.*

<sup>63</sup> See Hans Peter Fischer, *Mathematical Modeling of Complex Biological Systems: From Parts List to Understanding Systems Behavior*, 31 ALCOHOL RES. & HEALTH 49, 55 (2008).

<sup>64</sup> *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 825–26 (N.D. Ill. 2007), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008).

<sup>65</sup> *Cargill, Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1365–66 (Fed. Cir. 2007).

<sup>66</sup> See *id.*

<sup>67</sup> One should not lose sight of the ultimate goal of the inequitable conduct doctrine which is to ensure the examiner is provided with all the information available to the applicant which is relevant to patentability. See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (noting that the purpose of the duty of candor is to provide relevant information to a PTO examiner).

## III. POLICY DEFECT OF THE “INCONSISTENCY” STANDARD

Any modification of the duty of disclosure which broadens the definition of what should be disclosed from what is required by the “reasonable examiner” standard is detrimental to the functioning of the U.S. patent system, and Rule 56(b)(2) does just that. The briefing in the en banc *Therasense* case and other statements by both the PTO and others have made it clear that a balance must be struck between the breadth of disclosure required of patent applicants and the amount of information an examiner can meaningfully deal with in examining a patent application and that the “reasonable examiner” standard itself has been interpreted to call for excessive disclosure.<sup>68</sup> The PTO explicitly stated that one of its goals in replacing “old” Rule 56 with “new” Rule 56 was to narrow the scope of disclosure required of patent applicants and address the overload of disclosure faced by the Examining Corps.<sup>69</sup> No current commentator on inequitable conduct and no brief filed in the en banc *Therasense* case has advocated broadening the scope of required disclosure beyond that called for by the “reasonable examiner” standard.<sup>70</sup> Yet, there seems to be no basis for concluding that Rule 56(b)(2) does not call for the disclosure of information whose disclosure was not called for by the “reasonable examiner” standard.

Undisclosed information which is “inconsistent” with a position on patentability taken by a patent applicant in seeking his patent is not necessarily information which would be of interest to a reasonable examiner in deciding whether to allow a patent claim. As discussed above, this was explicitly recognized in *Abbott Laboratories v. Sandoz, Inc.*, and it is supported by the text of Rule 56(b)(2). There is nothing in the language of Rule 56(b)(2) which ties “inconsistent” information which should be disclosed to any impact of this information on the patentability of the claims at issue.

Thus, even without consideration of the ambiguity of the term “inconsistent” and concerns about making unreliable information material, adoption of the “inconsistent” standard of Rule 56(b)(2) in an inequitable conduct analysis is a poor policy choice. These two additional infirmities make it a particularly bad policy choice. One persistent theme in the current commentary on inequitable conduct is the difficulty in ascertaining just what information is material and therefore utilizing the particularly ambiguous term “inconsistent” can only exacerbate the problem.<sup>71</sup> And it is illogical to burden the examiner with considering information on which he could place no reliance in his consideration of patentability.

Because what is at issue is the potential of the “inconsistency” standard of 56(b)(2) as a definition of materiality in inequitable conduct analyses, the fact that this standard has been applied to cases in which the court felt the undisclosed information did impact patentability is not a good measure of its adequacy as a materiality standard. The key concern is not that the standard misses any wheat but rather that it is likely to capture a great deal of chaff as well.

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<sup>68</sup> En Banc Brief of Defendants-Appellees at 52–53, *Therasense En Banc*, 2010 WL 4310685, at \*52–53 (Fed Cir. Oct. 8, 2010).

<sup>69</sup> Duty of Disclosure, Notice of Final Rulemaking, 57 Fed. Reg. 2021, 2022–23 (Jan. 17, 1992).

<sup>70</sup> See discussion *supra* Part I.

<sup>71</sup> En Banc Brief of Defendants-Appellees at 13–14, *Therasense En Banc* (Fed Cir. Oct. 8, 2010), 2010 WL 4310685, at \*13–14.



One could fairly ask if the problem is ameliorated by limiting 56(b)(2) to information which “refutes” and this would indeed narrow the focus considerably. One might argue that, in fact, it narrows the focus too much and requires that the information at issue be persuasive of unpatentability. Perhaps this is why the PTO did not formulate the 56(b)(2) with just the word “refutes.” But it seems that it would have been better to have said “refutes or is contradictory to.” However, such an approach would reintroduce the reliability problem. “Refutes” at least has the virtue of requiring the information at issue have some authority.<sup>72</sup>

Unfortunately, the problem has been made worse by the case law that has divorced “takes a position” from any specific argument made by the patent applicant. This appears to have been at least partially driven by the courts desire to bring rejections in related cases within the ambit of 56(b)(2), but has resulted in a loss of focus and definition to an already ambiguous standard.<sup>73</sup>

#### CONCLUSION

In my view, the en banc court in *Therasense* would do well to adopt 56(b)(1) as the sole measure of materiality in inequitable conduct analyses and leave the application of 56(b)(2) to the PTO. The courts should not demand that an examiner be provided with more information than the expert agency, the PTO, feels is appropriate, but they can certainly provide that the sanction of inequitable conduct will only be imposed upon the failure to provide particularly significant and well defined information. Indeed, a great deal of the criticism of the “reasonable examiner” standard has been based on the conclusion that since the 1992 adoption of the “new” Rule 56 the courts have been mandating more disclosure than the PTO felt it needed or would find usefully, and in fact this is reflected in the PTO amicus brief in the en banc proceedings in *Therasense*.<sup>74</sup>

Rule 56(b)(1) will designate sufficient information as material to reasonably ensure the integrity of the patent examining process. If undisclosed information would not have changed the examiner’s conclusions with regard to patentability, then its non-disclosure should not invoke the severe penalty of an inequitable conduct finding. Rule 56(b)(1) should, in most cases, capture information which truly refutes

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<sup>72</sup> At least when “refutes” is read in its formal sense.

<sup>73</sup> This perceived need to bring the substance of U.S. PTO Office Actions within the ambit of Rule 56(b)(2) appears to be inconsistent with the current examining procedures of the PTO, which are based upon electronic files. Today, if an examiner has been informed of the existence of a related case, he is just a few key strokes from the current status and full prosecution history of that case. Visit the PTO, <http://www.uspto.gov/patents/process/status/index.jsp>, for more information on electronic application files.

<sup>74</sup> Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 9–12, *Therasense En Banc*, 2010 WL 3390234, at \*9–12 (Fed Cir. Aug. 2, 2010). These criticisms were apparently made without a recognition of the defects in Rule 56(b)(2) outlined by Rene Tegtmeyer and John Lynch. See discussion *supra* Part II.C.

an argument in favor of patentability or against unpatentability.<sup>75</sup> And it adequately deals with the issue of undisclosed experimental data which does not support patentability in accordance with the way scientifically trained persons deal with experimental data. It is rare that all the data in a given experimental program supports the hypothesis of the experimenter, but it is accepted scientific practice to simply weigh all the data to come to a conclusion as to whether or not the hypothesis is supported. Similarly, a court would evaluate all the data including the undisclosed data to come to a conclusion as to whether all the data taken together supports a conclusion of patentability.<sup>76</sup> A similar weighing approach would be applied to arguments or opinions of unpatentability regardless of the author. If the undisclosed argument or opinion revealed a different way of viewing the claims or prior art at issue that was persuasive of unpatentability, it would establish a prima facie case of unpatentability and therefore be material. If a court, evaluating an inequitable conduct claim based on undisclosed arguments or opinions of unpatentability, did not find them to be persuasive, they would not be found to be material (there is no apparent justification for requiring an applicant to provide an examiner with the arguments or opinions of authors “who got it wrong” in the court’s view).<sup>77</sup>

It would be a particularly bad policy choice for the Federal Circuit to adopt 56(b)(2) as a test for materiality in inequitable conduct analyses both because: (1) the “inconsistency” standard is deeply flawed and the “refutes” standard is only meaningful when it substantially overlaps with the 56(b)(1) standard; and (2) it would frustrate the widely recognized need to narrow the scope of material information from that called for by the “reasonable examiner” standard. “Inconsistent” can be fairly applied to anything from simply different to flatly contradictory and there is nothing in the language of 56(b)(2) which limits the meaning of this term to anything within this broad spectrum when using it as a standard for materiality. Furthermore, the case law has developed in such a way that the undisclosed information is appropriately compared for “inconsistency” to the mere presentation of a claim as opposed to a specific focused argument presented by the patent applicant in prosecution. Finally, there is nothing in 56(b)(2) which requires material undisclosed information to be at all reliable, so that, for instance, obviously deeply flawed experimental data can be material. Even if the undisclosed information did refute an argument of patentability such a result is only meaningful

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<sup>75</sup> In the case in which an applicant has two independent bases for establishing patentability (for instance, evidence of prior invention allowing him to swear behind a reference and arguments or evidence establishing a patentable distinction over the reference), undisclosed information which refutes only one basis would not be found material by the prima facie standard of Rule 56(b)(1), but then it would not be found material by the “reasonable examiner” standard which is now fairly widely acknowledged as too broad.

<sup>76</sup> If one accepts the proposition that Rule 56(b)(1) governs the disclosure of prior art references (though there is some basis to question this proposition), then Rule 56(b)(2) creates a more inclusive standard of materiality for “inconsistent” experimental data than Rule 56(b)(1) creates for prior art references. A reference which does not establish a prima facie case of unpatentability is not material but data which is insufficient to establish a prima facie case of unpatentability is material if it is merely “inconsistent” with data in the case.

<sup>77</sup> This would avoid the unfortunate situation that occurred in *Larson Manufacturing Co. of South Dakota, Inc. v. Aluminart Products Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009), in which a rejection which was later withdrawn by the same examiner who issued it, was found to be material to the prosecution of a related case.

if that refutation would render at least one claim prima facie unpatentable, in which case the information would also be material under 56(b)(1). Lastly, both simple logic and the case law lead to the conclusion that the “inconsistent” standard of 56(b)(2) will designate a broader scope of information material than will the “reasonable examiner” standard.