# THE INEQUITABLE CONDUCT GYRE WIDENS\*

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On several occasions of late, I have been unable to resist the temptation to introduce my remarks relating to developments in the doctrine of inequitable conduct with a warning to the patent practitioners in the audience: "Get out! Get out while you still can!" The resulting nervous laughter and the comments and questions I have received from concerned practitioners after those presentations and in other contexts reflect a significant level of anxiety among members of the patent bar about a number of recent developments. In particular, this anxiety relates to the law of inequitable conduct and the disclosure obligations of practitioners.

These recent inequitable conduct developments include the decision by the U.S. Court of Appeals for the Federal Circuit to re-affirm the applicability of the "reasonable examiner" materiality standard, a decisional trend in the direction of expanding disclosure obligations relating to co-pending applications, and proposed U.S. Patent and Trademark Office ("USPTO") rules imposing unprecedented information disclosure requirements.

Is there any "good news" for practitioners? Are concerns about practitioner violations of the duty of candor legitimate? What are the practice implications of the recent developments relating to the disclosure obligations of patent applicants and the doctrine of inequitable conduct?

These developments and questions are considered below, following a brief "recap" of the legal standards relating to the duty of candor and the inequitable conduct doctrine.

W.B. Yeats, The Second Coming

<sup>\*</sup> Turning and turning in the widening gyre
The falcon cannot hear the falconer;
Things fall apart; the centre cannot hold....

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#### I. INEQUITABLE CONDUCT "BASICS"

The relevant USPTO rule, 37 C.F.R. § 1.56 ("Rule 56"), sets forth the duty of candor as follows:

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.<sup>1</sup>

At the time the USPTO adopted the current rule, it explained that the duty of candor "is broader than the duty to disclose material information." Yet clearly the duty to disclose material information is a significant aspect of the duty of candor.

Rule 56 further defines "information . . . material to patentability" as follows:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- It establishes, 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:
  - Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.<sup>3</sup>

An earlier version of Rule 56 provided a different definition of materiality. Under the version first promulgated in 1977, "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

Although Rule 56 governs duty of candor violations in the USPTO,<sup>5</sup> the issue of whether an applicant breached the duty of candor arises most frequently

Duty of Disclosure, 57 Fed. Reg. 2021, 2025 (Jan. 17, 1992) (to be codified at 37 C.F.R. pts. 1, 10) (stating that Rule 56 was "modified to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information").

<sup>&</sup>lt;sup>1</sup> 37 C.F.R. § 1.56(a) (2009).

<sup>&</sup>lt;sup>3</sup> 37 C.F.R. § 1.56(b).

<sup>&</sup>lt;sup>4</sup> 37 C.F.R. § 1.56(a) (1991).

See 37 C.F.R. § 1.313(b)(2) (2009) (providing that "[o]nce the issue fee has been paid, the Office will not withdraw the application from issue at its own initiative for any reason except [reasons including a] violation of § 1.56 or illegality in the application"); 37 C.F.R.

and prominently in the context of enforceability challenges to issued patents.<sup>6</sup> "[A] breach of [the duty of candor], when coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct, which, when proven, renders the patent unenforceable."<sup>7</sup>

The basic legal principles governing inequitable conduct determinations are now well-settled. Inequitable conduct is the "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." The patent challenger must establish the materiality of the omission or misrepresentation, and the requisite intent to deceive the USPTO, by clear and convincing evidence. Materiality and intent are fact determinations, reviewable under the clearly erroneous standard of Federal Rule of Civil Procedure 52(a). 10

If the patent challenger establishes both materiality and intent, then the trial court must decide whether the patent applicant's conduct was so culpable as to justify a holding of unenforceability.<sup>11</sup> The court is to weigh the levels of materiality and intent for this purpose: a high level of materiality will balance a lower level of intent, and vice versa.<sup>12</sup> A determination of inequitable conduct renders all of the claims of the subject patent unenforceable.<sup>13</sup> The Federal Circuit reviews district court determinations on the issue of inequitable conduct for abuse of discretion.<sup>14</sup> "'To overturn a discretionary ruling of a district court, the appellant must establish that the ruling is based upon clearly erroneous findings

<sup>\$10.23(</sup>c)(10) ("Conduct which constitutes a violation of [this rule] includes . . . [k]nowingly violating or causing to be violated the requirements of \$1.56...").

See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1242 (Fed. Cir. 2003) (affirming a judgment that an allegedly infringed patent was unenforceable on grounds of inequitable conduct).

<sup>&</sup>lt;sup>7</sup> *Id.* at 1233.

<sup>&</sup>lt;sup>8</sup> Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

<sup>&</sup>lt;sup>9</sup> Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 719 (Fed. Cir. 1998) (citing Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1556–57 (Fed. Cir. 1995)).

Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998) (citing Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc)).

Baxter, 149 F.3d at 1327; see also ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546–47 (Fed. Cir. 1998) (noting "the court's exercise of discretion") (citing Kingsdown, 863 F.2d at 872).

Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997); N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987), cited in Baxter, 149 F.3d at 1327.

<sup>&</sup>lt;sup>13</sup> Baxter, 149 F.3d at 1332 (citing Kingsdown, 863 F.2d at 874).

Elk Corp. v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999) (citing *Kingsdown*, 863 F.2d at 876).

of fact or a misapplication or misinterpretation of applicable law or that the ruling evidences a clear error of judgment on the part of the district court."<sup>15</sup>

# II. THE EXPANSIVE (AND EXPANDING) INEQUITABLE CONDUCT DOCTRINE

In the last several years, the Federal Circuit has expanded the doctrine of inequitable conduct. One important aspect of that growth relates to the nature and scope of the information the applicant must disclose; recent Federal Circuit decisions reaffirmed an expansive materiality standard and added to the list of sources of potentially material information. The resulting combination has the potential to significantly increase the burdens of compliance with the duty of candor as well as the risks associated with inequitable conduct charges.

# A. The "Reasonable Examiner" Is Alive and Well (a.k.a. Everything Old Is New Again!)

The materiality standard governing Federal Circuit determinations was at issue for approximately the past decade. As the court explained in a 2003 decision:

For many years this court held that materiality for purposes of an inequitable conduct determination required a showing that "a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application." . . . This interpretation of materiality was based, in part, on 37 C.F.R. § 1.56(a) (1991), which defined materiality using a "reasonable examiner" standard.

In 1992, however, the Patent Office amended its rules to provide a different standard for materiality. . . . The new rule reiterated the preexisting "duty of candor and good faith," but more narrowly defined materiality, providing for disclosure where the information establishes either "a prima facie case of unpatentability" or "refutes, or is inconsistent with a position the applicant takes."

Since the 1992 revision took effect, the court approached the issue of the applicable materiality standard in a variety of ways. In some cases, it applied the

Kingsdown, 863 F.2d at 876 (quoting PPG Indus., Inc. v. Celanese Polymer Specialties Co., 840 F.2d 1565, 1572 (Fed. Cir. 1988) (Bissell, J., stating additional views)).

Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1363 (Fed. Cir. 2003) (citations omitted).

version of Rule 56 that was in effect at the time the conduct at issue occurred.<sup>17</sup> In others, it declined to decide which standard applied, holding that the outcome of the appeal was the same under either.<sup>18</sup>

Recently, the court appeared to flirt with adopting the new Rule 56 standard. In a January 2005 opinion, a Federal Circuit panel said its application of the new standard reflected its "deference to the PTO's formulation at the time an application is being prosecuted before an examiner of the standard of conduct it expects to be followed in proceedings in the Office." And in a sincewithdrawn opinion issued in June 2005, the court stated, "In evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56."

The issue of what materiality standard applies at the Federal Circuit is important for several reasons. First, as the court itself noted, the new Rule 56 standard is narrower than the "reasonable examiner" standard.<sup>21</sup> Second, in several respects, the new Rule 56 standard—at least on its face—is more susceptible to objective application.

The Federal Circuit has now purported to resolve the issue; it not only declined to adopt the "new" Rule 56 materiality standard, thus denying accused practitioners and parties the comfort of its relative clarity, but also expressly reaffirmed its 1984 decree that no "single standard" will govern materiality determinations in the court's inequitable conduct analysis.<sup>22</sup> On February 8, 2006, in its unanimous panel opinion in *Digital Control, Inc. v. Charles Machine* 

Compare Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352–53 (Fed. Cir. 2005) ("[T]he new rule was applicable during the prosecution of the [subject] patent, and we evaluate the materiality of the [prior art product] under the standard set forth in the applicable amended rule."), with Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1379 (Fed. Cir. 2000) (applying the "reasonable examiner" standard to pre-1992 conduct).

Dayco, 329 F.3d at 1364 ("[W]e leave for another day a final disposition of this [materiality] issue."); PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322 n.2 (Fed. Cir. 2000) ("As the district court found, the intentional falsehoods and omissions in this case would be plainly material under the newer PTO rule as well.").

<sup>&</sup>lt;sup>19</sup> *Bruno*, 394 F.3d at 1353.

Purdue Pharma L.P. v. Endo Pharms. Inc. (*Purdue I*), 410 F.3d 690, 696 (Fed. Cir. 2005), withdrawn, 438 F.3d 1123 (Fed. Cir. 2006).

<sup>&</sup>lt;sup>21</sup> Dayco, 329 F.3d at 1363–64.

See Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (noting that "there is no reason []to be bound by any single standard" (quoting Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984))) (alteration in the original).

Works,<sup>23</sup> the court traced at length the history of the law of materiality and concluded that "[e]ven though the PTO's 'reasonable examiner' standard became the dominant standard invoked by this court, in no way did it supplant or replace the case law precedent."<sup>24</sup> Similarly, the court in *Digital Control* said:

[T]he PTO's recent adoption of an arguably narrower standard of materiality does not supplant or replace our case law. Rather, it merely provides an additional test of materiality. That is, if a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the "reasonable examiner" standard or under the older three tests, it is also material.<sup>25</sup>

Accordingly, at least as far as the language of the operative standard in the Federal Circuit goes, patent practitioners are now right back where they were before "new" Rule 56 came into being. As recently as its opinion in *Digital Control*, the court acknowledged that the "new" Rule 56 standard is at least "arguably narrower" than the "reasonable examiner" standard. Accordingly, conduct that does not violate "new" Rule 56 may well violate the "reasonable examiner" standard and be material for purposes of inequitable conduct. Therefore, a challenger need only satisfy the "reasonable examiner" standard to prevail on the issue of materiality.

Thus, the court confirmed that both the "new" and "old" materiality standards—and the objective and subjective "but for" standards, for that matter—are in play in inequitable conduct litigation; in so doing, the court confirmed that the duty of candor springs not only from Rule 56, but also from case law relating to the doctrine of inequitable conduct.<sup>27</sup> The *Digital Control* panel did note that "to the extent that one standard requires a higher showing of materiality than another standard, the requisite finding of intent may be lower."<sup>28</sup> This tenet—a reaffirmation of the rationale for the "no single standard" rule—will, if faithfully observed by the court, ameliorate the court's recent expansive holding regarding materiality. Presumably, litigants with little or no evidence of intent will be forced to demonstrate relatively higher materiality, whether via

<sup>&</sup>lt;sup>23</sup> 437 F.3d 1309 (Fed. Cir. 2006).

<sup>&</sup>lt;sup>24</sup> *Id.* at 1315–16.

<sup>&</sup>lt;sup>25</sup> *Id*.

<sup>&</sup>lt;sup>26</sup> Ia

See id. (acknowledging the different standards and declaring: "Even though the PTO's 'reasonable examiner' standard became the dominant standard invoked by this court, in no way did it supplant or replace the case law precedent. Rather, it provided an additional test of materiality.").

<sup>&</sup>lt;sup>28</sup> *Id.* at 1316.

satisfaction of the "new" Rule 56 standard or otherwise. As discussed below,<sup>29</sup> the court recently renewed its commitment to the balancing aspect of the analysis—in very colorful fashion.

## B. The Ever-Expanding Scope of Potentially Inequitable Acts

The cases show that a variety of acts have been alleged to constitute violations of the duty of candor.<sup>30</sup> Several recent decisions provide sobering illustrations of the Federal Circuit's current view of the scope of the duty to disclose and investigate material information.

#### 1. Co-Pending Applications: The Ratchet Turns

Several years ago, the Federal Circuit expressly recognized that the *existence* of a co-pending, co-owned patent application could be material information for inequitable conduct purposes. According to the court, the two applications at issue in *Akron Polymer Container Corp. v. Exxel Container, Inc.*<sup>31</sup> covered "quite similar subject matter," but were examined by different examiners.<sup>32</sup> The responsible attorneys knew of the "existence and details" of both applications, which were identified in the decision as the "Venus application" and the "Katz application." While the Katz application was disclosed to the Venus application examiner during prosecution of the Venus application, "the Venus application was not disclosed to the Katz application examiner until after the PTO had issued a notice of allowance for the Katz application." Reversing the district court's conclusion that the facts supported a determination of inequitable conduct, the Federal Circuit relied heavily on the disclosure of the Katz application to the Venus application's examiner as evidence inconsistent with an intent to deceive the PTO.<sup>35</sup> It is possible that "but for" this disclosure, the district

See infra Part IV.A.

<sup>30</sup> See Lisa A. Dolak, The Inequitable Conduct Doctrine: Lessons from Recent Cases, 84 J. PAT. & TRADEMARK OFF. Soc'Y 719, 723–25 (2002) (listing various acts alleged by infringement defendants to constitute inequitable conduct).

<sup>&</sup>lt;sup>31</sup> 148 F.3d 1380 (Fed. Cir. 1998).

<sup>&</sup>lt;sup>32</sup> *Id.* at 1381.

<sup>&</sup>lt;sup>33</sup> Id.

<sup>&</sup>lt;sup>34</sup> *Id.* at 1381–82.

<sup>35</sup> See id. at 1383–84 (noting that the applicant's disclosure of the copending application was convincing evidence against deceptive intent).

court's finding of inequitable conduct on these facts would have been sustained.<sup>36</sup>

Since *Akron*, the court extended the reach of these principles. What is material about a co-pending application may be not only its *existence*, but also the specific *rejections* issued by the examiner during its prosecution.

The applicant in *Dayco Products, Inc. v. Total Containment, Inc.*<sup>37</sup> had two application families simultaneously pending before the PTO—the applications for the patents-in-suit and "the '196 family" of applications. The PTO assigned the two application families to different examiners, and the applicant did not advise the examiner assigned to the patents-in-suit of the pendency of the applications in the '196 family.<sup>39</sup> The Federal Circuit upheld the district court's determinations of materiality (on summary judgment) for both "[t]he pendency of the '196 applications"<sup>40</sup> and a "rejection of claims in the '196 application that were substantially similar in content and scope to claims pending in the applications that issued as the patents-in-suit."<sup>41</sup>

After noting that the question was one of first impression, the court held "that a contrary decision of another examiner reviewing a substantially similar claim meets the *Akron Polymer* 'reasonable examiner' threshold materiality test of 'any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent."<sup>42</sup> It further held that the rejection was material under "new" Rule 56.<sup>43</sup>

The court set forth specific rationales for holding rejections of substantially similar claims in co-pending applications to be material under both standards. With respect to the "old" Rule 56 ("reasonable examiner") standard, the court said:

Patent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ when interpreting such documents. Although examiners are not bound to fol-

<sup>37</sup> 329 F.3d 1358 (Fed. Cir. 2003).

<sup>&</sup>lt;sup>36</sup> *Id.* at 1384.

See id. at 1360–61 (identifying that "[t]he patents-in-suit all claim priority through a string of continuation applications to U.S. Application No. 408,161," and that "Dayco is also the assignee of a separate family of applications that claim original priority to U.S. Application No. 993,196").

<sup>&</sup>lt;sup>39</sup> *Id.* at 1361.

<sup>&</sup>lt;sup>40</sup> *Id.* at 1366.

<sup>41</sup> *Id.* at 1367–68.

<sup>42</sup> Id. at 1368 (quoting Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998)).

<sup>&</sup>lt;sup>43</sup> Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1368 (Fed. Cir. 2003).

low other examiners' interpretations, knowledge of a potentially different interpretation is clearly information that an examiner could consider important when examining an application.<sup>44</sup>

### Regarding "new" Rule 56, the court said:

We also hold that the information meets the threshold level of materiality under new Rule 56, in that "it refutes, or is inconsistent with, a position the applicant takes in . . . asserting an argument of patentability." 37 C.F.R. § 1.56(b)(2) (2002). When prosecuting claims before the Patent Office, 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. 45

Both of these explanations are notable for their expansiveness. With respect to "old" Rule 56, the court apparently would require the disclosure of even erroneous or meritless rejections. All that is required to trigger the duty to disclose is a "potentially different interpretation" with regard to "substantially similar claims" by another examiner. The court's treatment of "new" Rule 56 is even more noteworthy, both because the court has had little opportunity, as yet, to interpret its language, and because it regards the mere presentation and prosecution of patent claims as at least an implicit assertion of the patentability of those claims. Since "new" Rule 56 provides that information "inconsistent with" such an assertion is material, <sup>46</sup> the court's premise results in a very broad definition of materiality.

A recent Federal Circuit decision not only re-affirms, but also extends, the *Dayco* holding. In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,<sup>47</sup> a divided panel upheld materiality and intent findings relating to undisclosed rejections from a co-owned, co-pending case, even though the prosecuting attorney (for both applications) disclosed the co-pending application itself—twice!<sup>48</sup> Also, the majority refused to excuse the practitioner's failure to disclose a Notice of Allowance from yet another co-pending application—a continuation-in-part (CIP) of the patent at issue—even though the CIP and the pa-

<sup>&</sup>lt;sup>44</sup> *Id*.

<sup>45</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>46</sup> Id.

<sup>&</sup>lt;sup>47</sup> 487 F.3d 897 (Fed. Cir. 2007).

<sup>&</sup>lt;sup>48</sup> See id. at 922 (noting that the attorney, in two separate instances, disclosed the co-pending application's existence to the other examiner during prosecution of the other patent).

tent at issue were assigned to the same examiner.<sup>49</sup> The fact that the examiner had issued the undisclosed Notice of Allowance in the CIP only "a few months" before allowing the claims of the challenged patent did not dissuade the court.<sup>50</sup>

The patent held unenforceable in *McKesson* (referred to in the course of this discussion as "the McKesson patent") issued from a continuation application.<sup>51</sup> The continuation was filed for the purpose of accepting the offer of the Examiner, Examiner Trafton, to allow a particular claim in the parent if rewritten in independent form.<sup>52</sup> That offer appeared in a December 8, 1987 office action in the parent application.<sup>53</sup>

Meanwhile, the applicant, and the same prosecuting attorney, had a separate application pending—Application 2—that was assigned to Examiner Lev.<sup>54</sup> According to the majority, "The invention of this simultaneous application was similar to the invention of [the McKesson patent]—so similar, in fact, that [the prosecuting attorney] initially disclosed the same body of prior art with both applications."<sup>55</sup> The district court and the Federal Circuit majority agreed that three specific events in the course of the Application 2 prosecution generated information material to the claims of the McKesson patent:

- (1) Examiner Lev's February 26, 1987 office action included an obviousness rejection over Blum and Pejas.<sup>56</sup> In response, the prosecuting attorney amended the rejected claims (15–16), and added new claims (19–24);<sup>57</sup>
- (2) On October 23, 1987, Examiner Lev had a telephone conversation with the prosecuting attorney "to discuss [Examiner Lev's] discovery of" Baker, a prior art patent.<sup>58</sup>

<sup>51</sup> *Id.* at 904.

<sup>49</sup> See id. at 925 ("If this argument goes to materiality, it must fail because, as stated above, the allowance of the '372 claims is material. The most McKesson can argue is that the allowance is cumulative by virtue of the fact that Examiner Trafton, as the '278 examiner, probably remembered allowing the '372 claims. . . . However, . . . we cannot conclude that the allowance is cumulative.").

<sup>&</sup>lt;sup>50</sup> *Id*.

<sup>&</sup>lt;sup>52</sup> *Id* 

McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 904 (Fed. Cir. 2007).

<sup>&</sup>lt;sup>54</sup> *Id*.

<sup>&</sup>lt;sup>55</sup> *Id*.

<sup>&</sup>lt;sup>56</sup> *Id.* at 904–05.

<sup>&</sup>lt;sup>57</sup> Id

<sup>&</sup>lt;sup>58</sup> *Id.* at 906.

The Examiner suggested that the new claims be cancelled in light of Baker's teachings;<sup>59</sup>

- (3) Examiner Lev issued several rejections in his December 1, 1987 office action, including:
  - a. Claim 19 as anticipated by Sunstedt; and
  - b. Claims 15, 16, and 21–23 as obvious in view of "several new combinations of prior art references," including Blum, Sunstedt, and Baker.<sup>60</sup>

One further application, filed by the applicant while the McKesson patent and Application 2 were pending, was also held to have yielded information material for purposes of the inequitable conduct analysis.<sup>61</sup> Specifically, the majority affirmed the district court's finding that the Notice of Allowance issued in a CIP of the McKesson patent's parent was material to the claims of the parent and the McKesson patent.<sup>62</sup>

The inequitable conduct determination—made by the district court and affirmed by the Federal Circuit panel majority—was based on the prosecuting attorney's failure to disclose to Examiner Trafton, during the course of the McKesson patent prosecution: (1) the Baker reference, (2) Examiner Lev's rejections in the two Application 2 office actions identified above, and (3) Examiner Trafton's Notice of Allowance in the CIP, which had the same parent as the McKesson patent.<sup>63</sup>

Baker was affirmed as material on the ground that the district court did not clearly err in concluding that it was not cumulative of the other references before Examiner Trafton.<sup>64</sup> In particular, the Federal Circuit panel majority rejected the patentee's contention that the district court misinterpreted an argu-

61 See id. at 925 (finding that the Sunstedt application possessed material information when combined with another reference).

<sup>&</sup>lt;sup>59</sup> McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 906 (Fed. Cir. 2007).

<sup>60</sup> Id

See id. (concluding that the district court's basis for finding materiality was not incorrect given Examiner Lev's conclusions regarding the '149 patent's obviousness in light of Sunstedt and Baker).

<sup>63</sup> See infra notes 64–73 and accompanying text.

McKesson, 487 F.3d at 913–16 (refusing to reverse the district court's ruling of "materiality" when the applicant, whose only assertion against Baker's materiality was that it was cumulative, failed to undercut the district court's holding that Baker was not cumulative).

ment the attorney made during prosecution.<sup>65</sup> According to the district court, the attorney's patentability argument would have been futile had Examiner Trafton had the opportunity to consider Baker,<sup>66</sup> and the panel majority agreed that Baker should have been disclosed.<sup>67</sup>

The panel majority similarly, and in significant detail, analyzed and rejected the patentee's argument that Examiner Lev's rejections were cumulative of information otherwise before Examiner Trafton, 68 and disagreed that the Notice of Allowance in the CIP could only be material if "there was a substantial likelihood a reasonable examiner would have issued a double patenting rejection." 69

In affirming the district court's finding that Baker was withheld with deceptive intent, the majority pointed to Baker's high materiality as found by the district court, and the "mere seventeen-day gap" between when the attorney made the above-referenced patentability argument to Examiner Trafton (October 6) and when he learned of Baker (October 23).70 The majority also pointed to the fact that the attorney responded to Examiner Lev's citation of Baker by canceling the rejected claim, and the district court's finding that the attorney's testimony as to "the conclusions he must have drawn at the time with respect to Baker's materiality" was not credible.71 Regarding the nondisclosure of Examiner Lev's rejections and the CIP Notice of Allowance, respectively, the majority held that the district court correctly turned away the patentee's effort to distinguish the claims rejected in Application 2 from those of the McKesson patent,72 and held that the patentee's reliance on the fact that the McKesson patent examiner and the CIP examiner were the same person "fails as a factual

McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 915–16 (Fed. Cir. 2007) (concluding that Schumer had not in fact disclosed Baker to the examiner, but was instead "plainly referring to the differences between the three-node communication system of the '716 claims and non-three-node communication systems of the prior art . . . . ").

<sup>66</sup> *Id.* at 908.

See id. at 926 (affirming the district court's decision).

See id. at 920–22 (analogizing that if Baker was found to be not cumulative despite obvious differences between it and the other references, then "we must likewise hold here that any citation to Examiner Trafton regarding Examiner Lev's February 26 rejection would not have been cumulative.").

<sup>&</sup>lt;sup>69</sup> *Id.* at 925.

<sup>&</sup>lt;sup>70</sup> *Id.* at 916, 918.

McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 916–18 (Fed. Cir. 2007).

See id. at 922 ("[A] comparison of the [Application 2] claims to the [McKesson] claims reveals that both sets of claims relate to the use of three-node communication and a unique address in the context of bar code reading.").

matter" on the issue of intent because the attorney "specifically testified that he did not consider the identity of the examiner in deciding whether to disclose information about co-pending applications."<sup>73</sup>

A number of aspects of this case are noteworthy. Most important are (1) the court's holding—in the context of examiner rejections—that disclosing the *existence* of a co-pending application does not effectively disclose *the material information in* that application file,<sup>74</sup> and (2) its holding that the duty to disclose material information from co-pending applications applies even when the two applications are in the hands of the same examiner (and even when they have a common parent).<sup>75</sup>

With regard to the former, the majority expressly addressed and regarded as untenable the patentee's argument that "given the state of the law in the mid-1980s, 'there was no awareness' that the further disclosure of rejections in co-pending applications was necessary." The majority quoted extensively from the "then-current Fifth Edition of the [Manual of Patent Examining Procedure (MPEP)]" to conclude that "the MPEP to which [the attorney] would have referred while the [McKesson patent parent] was pending leaves no doubt that material rejections in co-pending applications fall squarely within the duty of candor." The majority also relied on the court's decision in *Li Second Family L.P. v. Toshiba Corp.*, where the court held that an applicant's disclosure of a "genealogy chart" showing a chain of related patent applications "[did] not adequately disclose the relevant information" and "was not evidence of good faith."

<sup>&</sup>lt;sup>73</sup> *Id.* at 925–26.

See id. at 922 (rejecting McKesson's argument that, according to "the state of the law" at the time, attorneys were not aware "that the further disclosure of rejections in co-pending applications was necessary").

<sup>&</sup>lt;sup>75</sup> See id. at 925–26 ("[The attorney] thus was not entitled to assume that Examiner Trafton would recall his decision to grant the claims of the '372 patent when he was examining the '278 application in the absence of a written disclosure to that effect.").

<sup>&</sup>lt;sup>76</sup> *Id.* at 922.

McKesson Info. Solutions, Inc. v. Bridge Med., Inc.(McKesson II), 487 F.3d 897, 922–23 (Fed. Cir. 2007) (citing U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COM., MANUAL OF PATENT EXAMINING PROCEDURE §§ 2001.04, 2001.06, 2001.06(b) (5th ed. 3d rev. 1986)) [hereinafter M.P.E.P.].

<sup>&</sup>lt;sup>78</sup> 231 F.3d 1373 (Fed. Cir. 2000).

McKesson II, 487 F.3d at 924 (citing Li Second Family, 231 F.3d at 1379–81 (involving a Board decision refusing to accord an application an asserted priority date)). The McKesson majority also noted that Dayco itself involved "patents claiming a priority date of 1989." McKesson, 487 F.3d at 922.

Elsewhere in the opinion, the majority noted its agreement with the district court's observation that the prosecuting attorney deserved some "credit" for disclosing the co-pendency of Application 2, but observed that the district court concluded that the resulting "favorable inference... 'does not overcome the inference of an intent to deceive established by the [other] facts." Thus, the *McKesson* majority held that while the disclosure of the existence of a copending application can serve as the basis for inferring good faith, it does not—at least not necessarily—constitute disclosure of material information contained in that prosecution file, and will not necessarily suffice to overcome evidence of bad faith. It

The second significant extension of *Dayco*—the indication that it may not matter whether the same examiner is responsible for the co-pending applications at issue—is particularly noteworthy given that each of the prior cases relating to the obligation to disclose co-owned, co-pending applications and information therein (*Akron Polymer*, *Li Second Family*, and *Dayco*) involved copending applications assigned to different examiners. Here again, the majority cited the MPEP for its teaching that "a prosecuting attorney should not 'assume that [a PTO examiner] retains details of every pending file in his mind when he is reviewing a particular application." Thus, said the majority, the McKesson patent prosecuting attorney "was not entitled to assume that Examiner Trafton would recall his decision to grant the claims of the [CIP] when he was examining the [McKesson patent parent] in the absence of a written disclosure to that effect." This holding is particularly significant given that the period of time between the allowance of the CIP claims and the allowance of the McKesson patent was only "a few months."

A third notable aspect of the *McKesson* majority opinion relates to *Day-co*'s "substantially similar claim" standard for triggering the obligation to disclose rejections in co-pending applications. In the course of turning back the patentee's argument that the claims of Application 2 and the McKesson patent

Id. at 917 (quoting McKesson Info. Solutions, Inc. v. Bridge Med., Inc. (McKesson I), No. CIVS022669FCDKJM, 2006 WL 1652518, at \*22 (E.D. Cal. June 13, 2006)) (alteration in the original).

See McKesson II, 487 F.3d at 917 (noting the district court's ruling "that the favorable inference drawn from disclosure of the second application 'does not overcome the inference of an intent to deceive established by the [other] facts." (quoting McKesson I, 2006 WL 1652518, at \*22) (alteration in the original).

McKesson Info. Solutions, Inc. v. Bridge Med., Inc. (*McKesson II*), 487 F.3d 897, 925 (Fed. Cir. 2007) (alteration in original) (quoting M.P.E.P. § 2001.06(b) (5th ed. 3d rev. 1986)).

<sup>83</sup> *Id.* at 925–26.

<sup>&</sup>lt;sup>84</sup> *Id.* at 925.

were insufficiently similar to necessitate the disclosure of the Application 2 rejections, the majority appears to have expanded the disclosure obligation relating to such rejections. McKesson argued that "a 'substantially similar' claim is a claim having substantial similarity 'in content and scope' to the claim at issue." The district court noted that the Federal Circuit "found substantial similarity in *Dayco* among claims that 'were *in some respects substantially identical.*" The majority refused to quibble about the various formulations, emphasizing that the relevant standard is "materiality in one of the accepted ways." The majority did, however, specifically note that while "substantial similarity is *sufficient* to prove materiality[,] [i]t does not necessarily follow . . . that a showing of substantial similarity is *necessary* to prove materiality." Thus, although the majority did not provide meaningful guidance as to what constitutes "substantial similarity," it apparently would not limit the obligation to disclose rejections in co-pending cases to situations involving such claims.

There is plenty to criticize in the majority opinion. For example, the majority reports—and effectively credits—the district court's apparent misinter-pretation (or mischaracterization) of the prosecuting attorney's "testimony that his firm at the time did not have procedures in place for citing office actions in co-pending applications." The district court inappropriately equated *not* having such procedures with "instituting policies that prevent [the attorneys] from complying with the law." The majority's analysis of the patentee's argument that Baker was cumulative is also less than compelling, in that the majority relied, in part, on the fact that the relevant text in Baker spanned "over eleven columns" while the relevant disclosure of Pejas—a reference in the possession of Examiner Trafton—was "just under two columns." Most significantly, the evidence of deceptive intent—at least as it was described by the majority—is not particularly persuasive. Nor did it persuade Judge Newman, who dissented

<sup>85</sup> Id. at 919 (quoting McKesson Info. Solutions, Inc. v. Bridge Med., Inc. (McKesson I), No. 02-2669, 2006 WL 1652518, at \*17 n.7 (E.D. Cal. June 13, 2006)).

Id. (emphasis added) (quoting Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1361 (Fed. Cir. 2003)).

<sup>&</sup>lt;sup>87</sup> *McKesson II*, 487 F.3d at 920.

McKesson Info. Solutions, Inc. v. Bridge Med., Inc. (McKesson II), 487 F.3d 897, 919 (Fed. Cir. 2007).

<sup>89</sup> *Id.* at 911 (citing *McKesson I*, 2006 WL 1652518, at \*15).

McKesson II, 487 F.3d at 911–12 (alteration in the original) (quoting McKesson I, 2006 WL 1652518, slip op. at \*21).

<sup>91</sup> *McKesson II*, 487 F.3d at 915.

on the ground that "invalidation based on the charge of withholding material information for purposes of deception requires more than was here shown."<sup>92</sup>

McKesson and Dayco have unsettling implications for practitioners who struggle to discern which applications and claims are "similar enough" to require disclosure, and who must cope with the logistical complications associated with trying to meet their disclosure obligations without risking a charge of "burying" relevant information amidst too much irrelevant disclosure. Yet, at least as materiality is currently defined, the basic rationale underlying these decisions is entirely sound. It is the case, for example, that a reasonable examiner would want to know that another examiner, evaluating a substantially similar claim, had rejected that claim, and why. Moreover, co-pending applications, and the information they contain, are no less subject to potential misuse and improper suppression than other types of information, such as prior art, pre-filing sales information, and test data.<sup>93</sup> Regardless, unless or until the definition of materiality is significantly narrowed, practitioners have no alternative but to develop procedures for appropriately reckoning with the holdings in these cases.

### 2. Known Materiality: A Limited Protection

A few years ago, the court delivered a message to patent practitioners who rely on the information their clients provide: where there's smoke, there may be fire. In *Brasseler*, *U.S.A. I, LP v. Stryker Sales Corp.*, <sup>94</sup> the Federal Circuit upheld an award of attorney fees to a prevailing infringement defendant based on the patentee's inequitable conduct. <sup>95</sup> The alleged inequitable conduct stemmed from a sale of the claimed invention that occurred more than a year before the application was filed. <sup>96</sup> The patentee had developed the invention, a surgical saw blade, in collaboration with a manufacturer, and had agreed that the manufacturer would be its exclusive supplier for the blades. <sup>97</sup> The first sale

<sup>&</sup>lt;sup>92</sup> *Id.* at 926 (Newman, J., dissenting).

Under certain circumstances, for example, co-pending applications qualify as prior art or can support a provisional double patenting rejection. See, e.g., M.P.E.P. § 2127 (8th ed. 3d rev. 2005). In these and other situations, see, e.g., M.P.E.P. § 2004 (8th ed. 3d rev. 2005) (providing other examples of situations where applicants should consider disclosing copending applications), the intentional failure to disclose the existence of such applications could undermine the integrity of the prosecution process.

<sup>&</sup>lt;sup>94</sup> 267 F.3d 1370 (Fed. Cir. 2001).

<sup>95</sup> See id. at 1386 (holding that the district "court's decision to award attorney fees in accordance with 35 U.S.C. § 285 was not an abuse of discretion in this exceptional case.").

<sup>&</sup>lt;sup>96</sup> See id. at 1374.

<sup>&</sup>lt;sup>97</sup> *Id*.

from the manufacturer to the patentee occurred on April 13, 1992.<sup>98</sup> On April 27, 1993, the prosecuting attorney—an associate in the firm representing the patentee—received instructions from his supervisor to file a patent application covering the blade by April 30, 1993, "to avoid 'a potential on-sale bar of May, 1992." Neither the associate nor his supervisor investigated the facts surrounding the on-sale event. <sup>100</sup>

The Federal Circuit agreed with the district court's conclusion that, under the circumstances, the attorneys had a duty to investigate the materiality of the sale. Those circumstances included the following facts: (1) "someone" representing the patentee told the supervising attorney that a potential bar event had occurred, (2) the associate was told "to file the application within three days, which he recognized to be an extremely short period of time in which to file an application," and (3) although the associate "was in direct contact with an inventor[-principal]" of the patentee, he never asked about the event. The same contact with an inventor [-principal]" of the patentee, he never asked about the event.

The court emphasized that a duty to investigate does not arise in a vacuum, stating that:

There is no need for an attorney to pursue a fishing expedition to obtain information. Counsel can reasonably rely on information provided by the client, unless, as here, there is reason to question the accuracy or completeness of the information or to doubt the adequacy of the client's own investigation into material facts. Thus, no duty to inquire arises unless counsel is on notice of

The patent attorneys in *Brasseler* had knowledge of a potential on-sale bar by their client, had no rational basis to support their contention of when the sale had occurred, and offered no credible evidence or explanation for their failure to inquire about the sale before or after an application was filed.

Flex-Rest, 455 F.3d at 1363.

<sup>&</sup>lt;sup>98</sup> *Id*.

<sup>&</sup>lt;sup>99</sup> Ia

Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1374 (Fed. Cir. 2001).

See id. at 1382–83 (stating that attorneys can rely on information given to them by clients unless there is reason to doubt the accuracy or adequacy of the client's information).

Id. at 1382. The Federal Circuit also approved the district court's conclusion that the associate's testimony "lacked candor" and was "evasive." Id. at 1384. In contrast, in a recent opinion, the Federal Circuit agreed that the district court properly distinguished Brasseler in a situation where an attorney, having not disclosed to the USPTO photographs sent to the patentee by a competitor, had testified that he did not regard the photographs as credible evidence of a prior art device and that he believed the photographs were largely cumulative. Flex-Rest, LLC v. Steelcase, Inc., 455 F.3d 1351, 1363 (Fed. Cir. 2006). In contrast, said the Federal Circuit:

the likelihood that specific, relevant, material information exists and should be disclosed.  $^{103}$ 

Additionally, the court rejected the patentee's argument that it could not have known—without its attorneys' assistance—that the sale was material, and that its failure to fully apprise its attorneys of the facts surrounding the sale absolves them. 104 Referring to the patentee's argument as "circular logic," the court emphasized that "inventors represented by counsel are presumed to know the law." 105 *Brasseler* thus not only teaches that attorneys cannot hide from their clients' potentially damaging revelations, but also that counsel must educate their clients regarding the duty of disclosure.

# 3. Information Immaterial to Patentability, but Material Nonetheless

As *Dayco* and *McKesson* illustrate, the duty to disclose material information extends beyond the prior art.<sup>106</sup> Two Federal Circuit decisions are notable, however, for their holdings that even information completely unrelated to substantive patentability can be material for purposes of inequitable conduct.

The patent applicant in *General Electro Music Corp. v. Samick Music Corp.* <sup>107</sup> had filed a "petition to make special" during prosecution of the patent-in-suit. <sup>108</sup> The MPEP required applicants to support such petitions with an oath or declaration showing "that he or she has made or caused to be made a careful and thorough search of the prior art or has a good knowledge of the pertinent prior art." <sup>109</sup> The applicant's declaration, made by his attorney, stated that the "prior art search conducted on the subject matter of this design application has uncovered . . . Decker." <sup>110</sup> At trial, however, the jury found this statement to be material and intentionally false based on evidence that the applicant's "search"

<sup>&</sup>lt;sup>103</sup> Brasseler, 267 F.3d at 1382–83.

<sup>&</sup>lt;sup>104</sup> *Id.* at 1380.

<sup>&</sup>lt;sup>105</sup> *Id.* at 1380, 1385.

See GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) (upholding a determination of inequitable conduct based on the inventor's failure to disclose a third party's non-prior art patent application and model of the product at issue to the PTO); PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322–23 (Fed. Cir. 2000) (affirming an inequitable conduct determination based on "intentional falsehoods, misrepresentations, and omissions" relating to inventorship).

<sup>&</sup>lt;sup>107</sup> 19 F.3d 1405 (Fed. Cir. 1994).

<sup>&</sup>lt;sup>108</sup> *Id.* at 1407.

<sup>&</sup>lt;sup>109</sup> *Id.* (quoting M.P.E.P. § 708.02 (5th ed. 9th rev. 1988)).

<sup>&</sup>lt;sup>110</sup> Id.

involved its attorney "ask[ing] numerous individuals in the piano design industry whether they knew of pertinent prior art designs and . . . search[ing] his own files for prior art."<sup>111</sup>

The Federal Circuit upheld the jury finding of materiality because "there is no room to argue that submission of false affidavits is not material," and that "a false statement in a petition to make special is material if, as in the case here, it succeeds in prompting expedited consideration of the application." The court thus signaled its willingness to regard as material for purposes of inequitable conduct misrepresentations made to secure some benefit during prosecution other than claim allowance.

The patent at issue in *General Electro* was presumably issued sooner than it might otherwise have been, a result that could significantly benefit a patentee. And although not the case in *General Electro*, unjustifiable early issuance in a 20-year-term case would result in an undeserved extension of the potential effective patent term. Truly remarkable, however, was the subsequent extension of the rationale of *General Electro* to practitioner conduct that was not only unrelated to patentability, but which occurred *after the patent issued*. In *Ulead Systems, Inc. v. Lex Computer & Management Corp.*, <sup>113</sup> a split panel of the court held that an unjustifiable claim of entitlement to small entity status and accompanying payment of insufficient maintenance fees was material as a matter of law:

While [the patentee] is correct that the affidavit did not induce issuance of the patent, the misrepresentation that [it] qualified as a small entity was material to the PTO's acceptance of reduced maintenance fees, and thus, survival of the patent. As such, at least a threshold level of materiality has been established as a matter of law. 114

Thus, *Ulead* and *General Electro* support the general proposition that inequitable conduct can be based on gaining a material advantage before the PTO if the gain is based on a deceitful misrepresentation. However, the Federal Circuit declined to hold that a knowingly false representation was "material" for inequitable conduct purposes when the representation was made to gain an advantage before a non-PTO governmental agency and was unrelated to patentability,

<sup>&</sup>lt;sup>111</sup> Id

See id. at 1411 ("There was thus no error in the jury's finding of materiality.").

<sup>&</sup>lt;sup>113</sup> 351 F.3d 1139 (Fed. Cir. 2003).

<sup>&</sup>lt;sup>114</sup> *Id.* at 1146.

even though the false representation was repeated in the patent specification.<sup>115</sup> The panel in *Regents of the University of California v. Eli Lilly & Co.*<sup>116</sup> distinguished *General Electro* on the ground that the advantage gained in *General Electro* was in a procedure within the PTO (though not related to patentability).<sup>117</sup>

#### III. THE USPTO'S PROPOSED RULES

On July 10, 2006, the USPTO published proposed new rules relating to information disclosure statements. The rules would impose new disclosure requirements on applicants, including—depending on the nature, length, and number of references submitted and the stage of the prosecution—requiring specific reference to and explanations regarding particular portions of prior art references. Under some circumstances, applicants would be required to assert that claims are or are not patentable over submitted references, and why. 120

#### According to the USPTO:

[T]he proposed changes will enhance the examination process for both examiners and applicants. Ensuring a focused and thorough examination is a joint responsibility of the examiner and the applicant.... The proposed changes provide an incentive... to cite only the most relevant documents, and are designed to provide the examiner with useful and relevant information early in the examination process. All parties involved with, or affected by, the patent system want the patent examination system to "get it right" the first time. Concentrating the patent examiner's review on the information most

See Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569–70 (Fed. Cir. 1997) (reversing the district court because the misrepresentations were made to the National Institute of Health and Congress, but not to the USPTO).

<sup>116 119</sup> F.3d 1559 (Fed. Cir. 1997).

<sup>117</sup> Id. at 1570.

Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808 (July 10, 2006) (to be codified at 37 C.F.R. pt. 1).

See id. at 38,813-16 (proposing, for example, to require explanations identifying the relevance of submitted documents in situations where the applicant submits more than twenty total documents in a given application or submits documents having more than twenty-five pages, and proposing additional disclosure requirements depending on when applicants submit information disclosure statements).

See id. at 38,815 (explaining that after payment of the issue fee, "information may be submitted only if a claim is unpatentable over the information being submitted either considered alone or in combination with information already of record" and proposing to require, in such circumstances, the applicant to admit such unpatentability).

pertinent to patentability prior to a first Office action on the merits will significantly help in achieving this goal. <sup>121</sup>

Enhancing the quality of the examination process is a laudable goal, to be sure. And, in isolation, encouraging applicants to provide only the most relevant information at an early stage of the patentability evaluation process makes a great deal of sense, as, at least in many cases, the applicant will know more about both the claimed invention and the relevant information bearing on its patentability than anyone else. The problem, of course, is that once a patent is asserted, every action the applicant took during prosecution—and every word an applicant submitted—will be scrutinized in a search for something on which to ground an inequitable conduct assertion.<sup>122</sup>

The USPTO proposed a "safe harbor" of sorts to deal with this dilemma. Specifically, it would amend Rule 56 to add a new section designed to benefit those who make disclosure in accordance with the new rules after "reasonable inquiry" and who "act[] in good faith... by having a reasonable basis for [their] statements":

(f) The additional disclosure requirements for documents... would be deemed satisfied where a § 1.56(c) individual has made reasonable inquiry of the relationship of the documents cited in an information disclosure statement to the claimed invention, including the supporting specification, and the individual has acted in good faith to comp-

The USPTO has observed that applicants sometimes provide information in a way that hinders rather than helps timely, accurate examination. For example, some applicants send a very large number of documents to the examiner, without identifying why they have been submitted, thus tending to obscure the most relevant information. Additionally, some applicants send very long documents without pointing out what part of the document makes it relevant to the claimed invention. Sometimes applicants delay sending key information to the examiner. These practices make it extremely difficult for the patent examiner to find and properly consider the most relevant information in the limited time available for examination of an application.

U.S. Patent & Trademark Office, Proposed Rule Changes to Focus the Patent Process in the  $21 \mathrm{st}$  Century,

http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html (last visited Jan. 14, 2010).

<sup>&</sup>lt;sup>121</sup> *Id.* at 38,810.

That is not to say that every inequitable conduct allegation is baseless. In fact, some practitioners have told me that they believe that inequitable conduct occurs with some frequency. Additionally, the USPTO asserted that the proposed information disclosure statement rules are necessary to discourage practices that undermine the USPTO's efforts to improve patent quality:

ly with the disclosure requirements by having a reasonable basis for the statements made in such disclosure. <sup>123</sup>

#### The USPTO acknowledged that:

[T]he proposed amendment to § 1.56 may not act as a complete defense in all situations, particularly as the court is not bound by any one duty of disclosure standard established by the Office, [but] the Office is hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account.<sup>124</sup>

Given the current trend in the Federal Circuit's inequitable conduct jurisprudence, practitioners cannot reasonably be expected to find much solace in the proposed "safe harbor." However, the USPTO's recognition of the risk that additional disclosure requirements pose to practitioners is laudable.

### IV. THE GOOD NEWS?

# A. Balancing Materiality and Intent: A Reinvigorated Requirement?

In its recitations of the "black letter" law governing inequitable conduct determinations, the Federal Circuit routinely, but not always, includes a requirement that the district court undertake an equitable balancing of the materiality and intent factors "to determine whether a finding that inequitable conduct occurred is warranted." On many occasions, the court has explained how such balancing can affect the ultimate conclusion on the issue of inequitable

<sup>123</sup> Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. at 38,820.

Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808, 38,811–12 (July 10, 2006) (to be codified at 37 C.F.R. pt. 1).

Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359 (Fed. Cir. 2005); see also Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (describing the two steps of the inequitable conduct analysis to include, "first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent 'in light of all the circumstances' to determine 'whether the applicant's conduct is so culpable that the patent should be held unenforceable." (alteration in the original) (quoting Baxter Int'l, Inc. v. McGraw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998))); Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed. Cir. 1990) ("A threshold showing of both materiality and intent to mislead or deceive must be first established, and then those fact-findings are balanced to make the determination whether 'the scales tilt to a conclusion that inequitable conduct occurred." (quoting J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1560 (Fed. Cir. 1984))).

conduct, namely, that where the materiality of the omission or misrepresentation is high, a lesser showing of intent is required. 126

Yet appellate rulings reversing or vacating district court holdings of inequitable conduct are usually based on clear error in a district court's finding on the elements of materiality or intent, as opposed to some error in the court's balancing analysis.<sup>127</sup> This is not surprising. Fact-findings on materiality and intent are subject to less deferential (clear error) review than is the district court's equitable determination on the ultimate issue of enforceability, which includes the intent-materiality balancing step.<sup>128</sup> Accordingly, materiality and intent are more fertile territories for the appellant and the reviewing court, and the court's conclusions on one or both of those issues often moots the issue of whether the district court's balancing included reversible error.<sup>129</sup>

Thus, it is fair to say that it is news when the Federal Circuit reverses or vacates a district court determination of inequitable conduct based even in part on the district court's failure to adequately balance materiality versus intent. It is even bigger news when the decision the court is reversing or vacating on this basis is its very own, as was the case with its two recent decisions in *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*<sup>130</sup>

In the *Purdue* litigation, the district court held that generic drug manufacturer Endo infringed three Purdue patents relating to Purdue's best-selling drug product, OxyContin, by filing an abbreviated new drug application

See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003) ("Moreover, when balanced against high materiality, the showing of intent can be proportionally less."); Baxter, 149 F.3d at 1327 ("Once the threshold levels of materiality and intent have been established, the trial court is required to weigh materiality and intent. The more material the omission, the less evidence of intent will be required in order to find that inequitable conduct has occurred." (internal citation omitted)).

See, e.g., Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1370 n.11 (Fed. Cir. 2008) (reversing a "holding of inequitable conduct . . . due to the clearly erroneous finding of deceptive intent" regarding the subject patent); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1185 (Fed. Cir. 1995) (vacating an inequitable conduct determination because the underlying finding of materiality was clearly erroneous).

Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359 (Fed. Cir. 2005) ("We review the district court's factual findings with respect to materiality and intent for clear error. We review the ultimate determination of inequitable conduct, however, under an abuse of discretion standard." (citing Perseptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1319 (Fed. Cir. 2000))).

<sup>129</sup> See CFMT, Inc. v. YieldUp Int'l Corp., 349 F.3d 1333, 1343 (Fed. Cir. 2003) (reversing the district court's inequitable conduct determination because the district court clearly erred in finding materiality and intent).

Purdue Pharma L.P. v. Endo Pharms. Inc. (*Purdue I*), 410 F.3d 690 (Fed. Cir. 2005), *vacated*, 438 F.3d 1123 (Fed. Cir. 2006).

(ANDA) seeking FDA approval to market its own generic version of the drug; however, the court held that the three Purdue patents were unenforceable because of Purdue's inequitable conduct.<sup>131</sup> In June 2005, the Federal Circuit affirmed the district court on the following grounds:

- Materiality was established based on Purdue's assertions in the specifications of the patents at issue, as well as in an attachment to a declaration submitted during prosecution, "to have made a surprising medical discovery without disclosing the evidentiary basis for it, i.e., that the alleged 'discovery' under these circumstances was based on insight and was without an empirical basis."
- "[I]ntent to mislead the PTO can be inferred from Purdue's statements and the context in which they were made. [That is,] Purdue's carefully chosen language suggest[ing] that it had obtained clinical results . . . unclarified by any disclosure that discovery . . . was based on insight . . . [and t]he consistent and repetitive nature of Purdue's communications with the PTO . . . ."<sup>133</sup>
- "Weighing materiality and intent is a matter of judgment. On the record before us we cannot say that the trial court abused its discretion in weighing these findings to conclude that the patents-in-suit are unenforceable due to Purdue's inequitable conduct."<sup>134</sup>

On petition for rehearing, however, the panel withdrew its original opinion, and issued a new opinion vacating the district court judgment.<sup>135</sup> The court reiterated its conclusion that materiality had been established, emphasizing this time that the conduct at issue was Purdue's "failure to tell the PTO that the discovery

Purdue Pharma L.P. v. Endo Pharms. Inc., Nos. 00 CIV. 8029(SHS), 01 CIV. 2109(SHS), 01 CIV. 8177(SHS), 2004 WL 26523, at \*1, 27 (S.D.N.Y. Jan. 5, 2004).

See Purdue I, 410 F.3d at 699–700 ("The trial court examined the entire record and found materiality because Purdue repeatedly argued to the PTO that the four-fold dosage range distinguished the invention over prior art and, while using language that implied, if not suggested, experimental results had been obtained, failed to tell the PTO its discovery was based only on [an inventor's] insight.").

<sup>133</sup> *Id.* at 701.

<sup>&</sup>lt;sup>134</sup> Id

<sup>&</sup>lt;sup>135</sup> Purdue Pharma L.P. v. Endo Pharms. Inc. (*Purdue II*), 438 F.3d 1123, 1137 (Fed. Cir. 2006).

was based only on the inventor's insight after suggesting during prosecution that the discovery was based on the results of clinical studies."<sup>136</sup> However, the Federal Circuit significantly revised the other aspects of its decision on inequitable conduct.

First, in its explication of the applicable law the second time around, the court elaborated on the "careful balancing" of materiality and intent, noting that "when the misrepresentation or withheld information is highly material, a lesser quantum of proof is needed to establish the requisite intent. In contrast, the less material the information, the greater the proof must be."<sup>137</sup> This was a prelude to the court's new conclusion that the district court "may have erred to the extent it relied on a high level of materiality," emphasizing that Purdue was guilty of an omission as opposed to an affirmative misrepresentation. <sup>138</sup>

Second, the Federal Circuit reversed its prior conclusion that the district court had not clearly erred in finding deceptive intent, in part because it now took a different view of the evidence on which the district court relied, and also because the district court's misperception regarding the level of materiality contributed to its intent finding.

The court's focus here on the *level* of materiality—especially given its resolute and thoroughly supported conclusion that the conduct at issue was material—and its express reminder that the district court's job is not finished once it finds materiality and intent are both noteworthy here.<sup>141</sup> It appears that the court could have reached the same result—vacatur of the district court judgment—without either, given its re-evaluation of the intent evidence, although of course for purposes of remand, it was necessary to fully instruct the district court.

<sup>136</sup> Id. at 1133 (emphasis added).

<sup>137</sup> *Id.* at 1128–29 (internal citation omitted).

Id. at 1133 ("This omission of information was material, but not as material as an affirmative misrepresentation would have been.").

On rehearing, the panel concluded that the district court erred in the amount of weight it gave to internal memoranda evidencing Purdue's inability to prove a proposed labeling claim to the satisfaction of the FDA. *Id.* at 1134.

See id. at 1134–35 (instructing the district court to re-evaluate its finding on intent, and then, if it still found a threshold level of intent, to "reweigh its materiality and intent findings to determine whether the sanction of unenforceability due to inequitable conduct is warranted").

See Purdue Pharma L.P. v. Endo Pharms. Inc. (*Purdue II*), 438 F.3d 1123, 1135 (Fed. Cir. 2006) ("If the trial court still finds that a threshold level of intent to deceive has been established, the court should reweigh its materiality and intent findings to determine whether the sanction of unenforceability due to inequitable conduct is warranted.").

Furthermore, soon after *Purdue II*, the court signaled that the decision's attentiveness to relative materiality was not an isolated event. A week after the decision in Purdue II, an entirely different Federal Circuit panel in Digital Control similarly vacated a district court inequitable conduct determination. 142 This was, in part, because the district court's summary ruling of high materiality, and therefore its ultimate conclusion on inequitable conduct, was based on two allegedly inequitable acts—a misrepresentation and an omission—the materiality of only one of which (the misrepresentation) the Federal Circuit upheld on appeal. 143 And, as in *Purdue II*, the Federal Circuit also vacated the district court's finding of deceptive intent as grounded, in part, on that court's partially erroneous summary determination that the inventor had committed two material inequitable acts. 144 Here, too, the Federal Circuit systematically dissected the district court's determination of inequitable conduct and illustrated the fundamental analytical interdependence of its facets. Notably, the court's fine-grained examination of the district court's ruling in *Digital Control* resulted in the restoration, at least temporarily, of patents the Federal Circuit agreed were procured via material misrepresentation.<sup>145</sup>

# B. The Court Insists on Particularized Allegations

In recent years, the Federal Circuit has expressly enforced a requirement for specificity in inequitable conduct pleadings. For example, the court held insufficient an allegation that a patentee "was motivated to extend its patent monopoly beyond the . . . patent term by patenting [a structurally similar compound], and it needed to conjure up "unexpected" results." Also held insuffi-

<sup>&</sup>lt;sup>142</sup> Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1322 (Fed. Cir. 2006).

<sup>&</sup>lt;sup>143</sup> *Id.* at 1321–22.

See id. at 1321 ("[B]oth the district court's determination that the failure to disclose the Rorden patent was made with intent to deceive the PTO and its determination that the misstatements in the Rule 131 declaration were made with intent to deceive the PTO were based in part on the court's improper determination at summary judgment that the failure to disclose the Rorden patent was a material omission.").

See id. at 1316–22 (affirming the district court's decision to grant summary judgment on the materiality of misstatements in a submitted declaration, but reversing its partial summary judgment grant on the materiality of an undisclosed reference, and vacating the district court's inequitable conduct determination).

See, e.g., Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (upholding the district court's claim dismissal for inequitable conduct "because it was not properly raised").

Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1381 (Fed. Cir. 2006) (quoting Apotex brief).

cient was a charge that "during prosecution . . . , the patentee failed to disclose all of the relevant prior art known to it' and . . . 'by manipulation of various measurements and units, the patentee sought to mislead the [USPTO] regarding the relationship between the claimed invention and the prior art." While the district courts, for the most part, and for some time, have insisted on heightened specificity for inequitable conduct allegations, <sup>149</sup> the Federal Circuit's affirmation of this principle is worth noting.

In this regard, a recent panel decision has the potential to dramatically alter the inequitable conduct landscape. In *Exergen Corp. v. Wal-Mart Stores, Inc.*, <sup>150</sup> the court affirmed a district court decision denying an infringement defendant's motion to amend its answer to allege inequitable conduct on the ground that the amendment allegations were insufficiently particular under Federal Rule of Civil Procedure 9(b). <sup>151</sup> The court held that "simply aver[ring] the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." <sup>152</sup>

Standing alone, this holding is not particularly remarkable, given that in recent years the Federal Circuit has expressly enforced a requirement for specificity in inequitable conduct pleadings. What is noteworthy about the panel ruling in *Exergen* is the degree and nature of the specificity it demands. According to the court, "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the

Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1356 (Fed. Cir. 2007) (quoting Advanced Cardiac Solutions pleading).

See, e.g., Heraeus Electro-Nite Co. v. Midwest Instrument Co., No. 06-355, 2006 U.S. Dist. LEXIS 76452, at \*14 (E.D. Pa. Oct. 18, 2006) (noting that the Federal Circuit stated in dicta that pleading inequitable conduct requires particularity).

<sup>&</sup>lt;sup>150</sup> 575 F.3d 1312 (Fed. Cir. 2009).

<sup>&</sup>lt;sup>151</sup> *Id.* at 1331.

<sup>&</sup>lt;sup>152</sup> *Id.* at 1326–27.

See, e.g., Cent. Admixture Pharmacy Servs., 482 F.3d at 1356 (holding insufficient a charge that "during prosecution . . ., the patentee failed to disclose all of the relevant prior art known to it" and "by manipulation of various measurements and units, the patentee sought to mislead the [USPTO] regarding the relationship between the claimed invention and the prior art." (quoting Advanced Cardiac Solutions pleading)); Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1381 (Fed. Cir. 2006) (rejecting as insufficiently particular an allegation that a patentee "was motivated to extend its patent monopoly beyond the [patent] term by patenting [a structurally similar compound], and it needed to conjure up "unexpected" results." (quoting Apotex brief)); Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (upholding the district court's dismissal of an accused infringer's inequitable conduct charge for lacking particularly because the accused infringer merely asserted that a patent revival was "improper").

material misrepresentation or omission committed before the [USPTO]."<sup>154</sup> Applying this standard, the court held that a recitation that "Exergen, its agents and/or attorneys" failed to identify the "who," and the pleading inadequately set forth the "what' and 'where' of the material omissions" by "fail[ing] to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found..."<sup>155</sup> It similarly held that generally stating that the withheld references "are 'material' and 'not cumulative to the information already of record" fails to "explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims."<sup>156</sup> The court indicated that "identify[ing] the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record" would be necessary in this regard.<sup>157</sup> It likewise held the defendant's allegations regarding deceptive intent to be insufficient.<sup>158</sup>

## C. Sometimes, the Patentee Prevails!

In the wake of attention-grabbing court decisions and USPTO actions that seem to increase the disclosure burdens on practitioners, it is worth noting that inequitable conduct charges do not always succeed! Recently, for example, the Federal Circuit affirmed district court determinations of no inequitable conduct<sup>159</sup> and reversed determinations that inequitable conduct occurred.<sup>160</sup>

Exergen, 575 F.3d at 1327.

<sup>&</sup>lt;sup>155</sup> *Id.* at 1329.

<sup>156</sup> *Id.* at 1329–30.

<sup>&</sup>lt;sup>157</sup> *Id.* at 1329.

<sup>&</sup>lt;sup>158</sup> *Id.* at 1331.

See, e.g., Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000 (Fed. Cir. 2007) (affirming the district court decision that the information at issue was cumulative to information in the examiner's possession, and noting that the accused infringer did not challenge the court's determination of no culpable intent); *In re* Omeprazole Patent Litig., 483 F.3d 1364, 1376 (Fed. Cir. 2007) (affirming the district court's conclusion that there was no inequitable conduct, fraud, or unclean hands during prosecution of one of the patents-insuit).

See, e.g., In re Metoprolol Succinate Patent Litig., 494 F.3d 1011, 1020–21 (Fed. Cir. 2007) (vacating a summary judgment of unenforceability on the ground that a genuine factual dispute existed regarding the issue of deceptive intent); Young v. Lumenis, Inc., 492 F.3d 1336, 1350 (Fed. Cir. 2007) (holding that the district court erred in holding the asserted patent unenforceable on summary judgment).

It is also worth noting that, even where materiality and deceptive intent are found, a holding of unenforceability is not inevitable. The Federal Circuit's recent opinion in *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*<sup>161</sup> provides another reminder of the importance of evaluating the levels of materiality and intent established in a given situation. The jury, acting in an advisory capacity, found that the president of the company that owned one of the patents-in-suit had withheld a reference with intent to deceive the USPTO. The Federal Circuit, though, affirmed the district court's determination that the patent was not unenforceable, and did so on the ground that the reference "was not highly material and that the showing of deceptive intent was not compelling." According to the court, "[e]ven when a court finds that the patentee failed to disclose material information to the PTO and acted with deceptive intent, the court retains discretion to decide whether the patentee's conduct is sufficiently culpable to render the patent unenforceable." <sup>164</sup>

Purdue II, Digital Control, and Kemin send an important signal to future inequitable conduct litigants. Whether making or defending charges of inequitable conduct, litigants—especially patentees—cannot afford to neglect the relative materiality and balancing aspects of the analysis, as the salvation of the patents at issue in these cases illustrate. Furthermore, in the wake of these cases we are likely to see the district courts and the Federal Circuit pay far greater attention to the relative weight of the evidence of materiality and intent as litigants place renewed emphasis on this issue.

#### V. THE FUTURE

The Office of Management and Budget (OMB) completed its review of the final information disclosure statement rules in December 2007. The particular contours of the final rules are unknown, but, as approved by the OMB, they apparently do increase the disclosure obligations of practitioners. The final rules are unknown, but, as approved by the OMB, they apparently do increase the disclosure obligations of practitioners.

<sup>&</sup>lt;sup>161</sup> 464 F.3d 1339 (Fed. Cir. 2006).

<sup>&</sup>lt;sup>162</sup> *Id.* at 1345.

<sup>&</sup>lt;sup>163</sup> *Id.* at 1346.

<sup>164</sup> Id.

Office of Mgmt. & Budget, Office of Info. & Reg. Aff., RIN 0651-AB95, OIRA Conclusion of EO 12866 Reg. Rev., http://www.reginfo.gov/public/do/eoDetails?rrid=114766.

See Office of Mgmt. & Budget, RIN 0651-AB95, Abstract, Changes to Information Disclosure Statement Requirements and Other Related Matters, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200710&RIN=0651-AB95.

To date, the new information disclosure statement rules have not been implemented, and their status is uncertain. It is also unclear whether additional disclosure-related burdens will be included in any patent reform legislation ultimately enacted. However, in recent years, Congress has entertained proposals to authorize the USPTO to require applicants to submit analyses of the pertinence of references found in prior art searches. Ion

That recent developments in the courts and potential new disclosure requirements increase not only the burdens, but also the risks, for patent practitioners cannot be denied.<sup>169</sup> Apparently, though, there is some sentiment among policymakers that this trend cannot continue. For example, on September 7, 2007, the House of Representatives passed the Patent Reform Act of 2007 (H.R. 1908).<sup>170</sup> If enacted, H.R. 1908 would have:

- codified the defense of unenforceability for inequitable conduct;
- narrowed the definition of materiality;
- required a patent challenger to prove "specific facts beyond materiality of the information submitted or not disclosed" in order to establish deceptive intent;
- authorized the district courts to grant remedies short of declaring the entire affected patent unenforceable, including "[d]enying equitable relief to the patent holder and limiting the remedy for infringement to damages"; and
- authorized the USPTO to "require that applicants submit a search report and other information and analysis relevant to patentability."

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See, e.g., Mercedes K. Meyer, Partner, Drinker Biddle & Reath LLP, Information Disclosure Statement Rules Package—Where Are the Rules? (Apr. 2008), http://www.aipla.org/Content/Microsites152/IP\_Practice\_in\_Japan/Committee\_Meetings/20

<sup>08-04</sup>\_Japan\_Trip/Presentations13/JPO-New-Rules-IDS-Rules-(Mercedes-Meyer).ppt.
Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12 (2007); Patent Reform Act of 2007, S. 1145, 110th Cong. § 11 (2007).

Judge Newman recently accused her colleagues of "resurrect[ing] the [inequitable conduct] plague of the past." Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1197 (Fed. Cir. 2006) (Newman, J., dissenting).

<sup>&</sup>lt;sup>170</sup> H.R. 1908, 110th Cong. (2007).

<sup>&</sup>lt;sup>171</sup> *Id*.

The bill died with the 110th Congress, and passage of legislative limits on the inequitable conduct doctrine is uncertain. Yet contraction in the law of inequitable conduct is inevitable. "[T]he centre cannot hold  $\dots$ " "172

W.B. YEATS, The Second Coming, in MICHAEL ROBARTES AND THE DANCER 19, 19 (Kessinger Publ'g 2003) (1921).