

## **Question Presented**

What actions led to a holding of inequitable conduct in McKesson v. Bridge Medical?

## **Summary of Facts**

McKesson Information Solutions, Inc. (“McKesson”) filed a patent infringement suit in the United States District Court for the Eastern District of California (“District Court”) against Bridge Medical, Inc. (“Bridge”) based on U.S. Patent No. 4,857,716 (“the ‘716 patent”). Bridge answered McKesson's complaint by pleading the affirmative defenses of unenforceability due to inequitable conduct, equitable estoppel, and unclean hands. Bridge also brought counterclaims against McKesson for declaratory judgment.

The District Court found that inequitable conduct occurred during the prosecution of the ‘716 patent and accordingly entered judgment against McKesson declaring the patent unenforceable for that reason.

McKesson appealed the decision. However, the U.S. Court of Appeals for the Federal Circuit (“CAFC”) affirmed the District Court’s ultimate finding of unenforceability of the ‘716 patent due to inequitable conduct before the USPTO.

## **Summary of Actions leading to Holding of Inequitable Conduct**

*The CAFC affirmed that the following three actions by the patentee’s prosecuting attorney rose to the level of inequitable conduct:*

1. *Failure to disclose a prior art reference*, identified by an Examiner in a similar prosecution, to the Examiner of the patent at issue.
2. *Failure to disclose rejections*, made by an Examiner in a similar prosecution, to the Examiner of the patent at issue.
3. *Failure to disclose the allowance of claims* in a continuation-in-part (CIP) application to the Examiner of the patent at issue.

The District Court held that “each of the nondisclosures ... individually would support [a] judgment of unenforceability.”<sup>1</sup>

On appeal, the CAFC affirmed this holding and stated that: “It is not necessary to decide whether any one of the three nondisclosures, standing alone, would have been sufficient to justify a judgment of unenforceability; in light of the district court’s finding that there was inequitable conduct in all three instances, we hold that the court did not abuse its discretion in holding the patent unenforceable.”<sup>2</sup>

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<sup>1</sup> *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 2006 U.S. Dist. LEXIS 76517, at \*70 (D. Cal. Jun. 13, 2006).

<sup>2</sup> *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007).

## Parties and Patents Involved

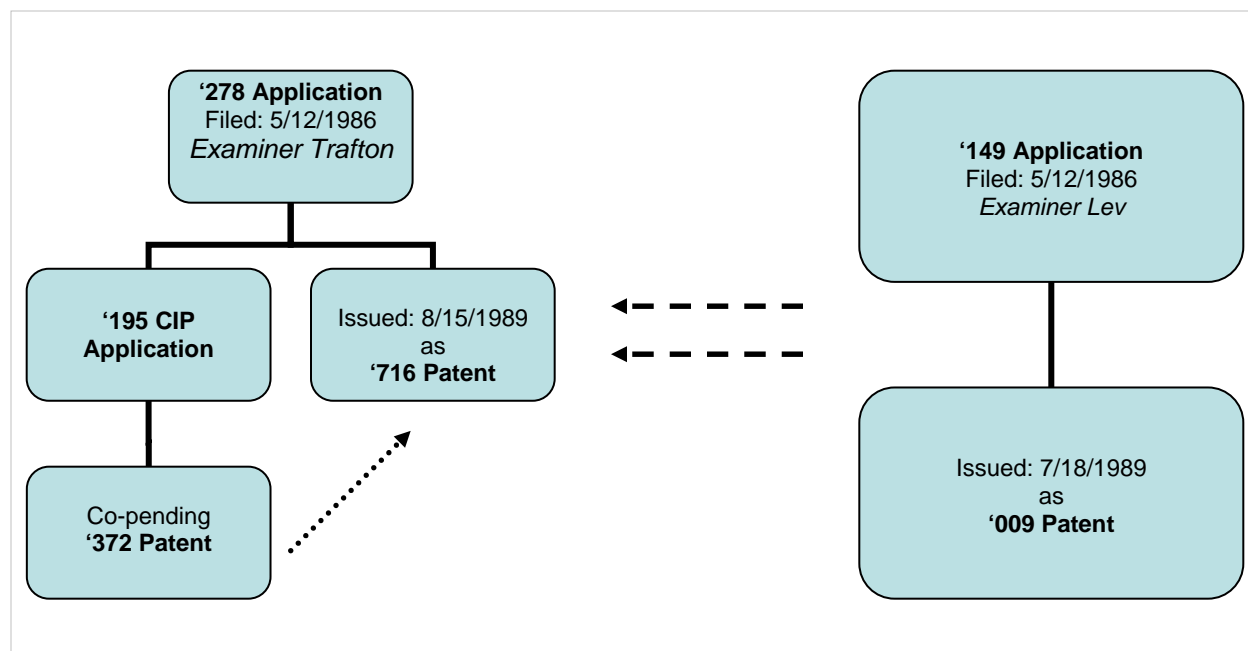
To facilitate discussion, a graphical illustration identifying the patents and their respective applications is provided below. The applications and their resulting patents in the illustration were prosecuted by the patentee's prosecuting attorney, Michael Schumann ("Schumann").

The applications and patents are related as follows:

- Application '149, before Examiner Lev, led to U.S. Patent No. 4,850,009 ("the '009 Patent").
- Application '278, before Examiner Trafton, led to both a CIP application ("the '195 Application") as well as U.S. Patent No. 4,857,716 ("the '716 Patent").
- The '195 Application, also before Examiner Trafton, led to U.S. Patent No. 4,835,372 ("the '372 Patent").

The three actions by Schumann which rose to the level of inequitable conduct are illustrated below using dash and dot arrows. Two dash arrows signify Schumann's failure to inform Examiner Trafton in the '716 prosecution of either of Examiner Lev's rejections in the '009 prosecution or of the prior art reference. The dot arrow signifies Schumann's failure to disclose the allowance of claims of the '372 patent to Examiner Trafton in the '716 prosecution. The aforementioned "actions" are examined in greater detail on pages 5-9 of this memo.

### Illustration: Relationship between Relevant Applications & Patents



## **Legal Standard for Inequitable Conduct: Materiality & Intent**

In its detailed opinion, the CAFC first provided, in broad terms, the legal standard for inequitable conduct:

A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006); see also 37 C.F.R. § 1.56(a) ("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>3</sup>

The CAFC then provided further guidance for each of the two elements (materiality and intent) identified in the broad definition:

The materiality of information withheld during prosecution may be judged by the "reasonable examiner" standard. See id. at 1316. That is, "[m]ateriality . . . embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent." Akron Polymer, 148 F.3d at 1382 (citations omitted). Moreover, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." Li Second Family, 231 F.3d at 1380. "However, a withheld otherwise material [piece of information] is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner." Digital Control, 437 F.3d at 1319. "As this court has previously noted, the scope and content of prior art and what the prior art teaches are questions of fact."<sup>4</sup>

"The intent element of the offense is . . . in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." Akron Polymer, 148 F.3d at 1384. "However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible." Dayco, 329 F.3d at 1367. In addition, "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).<sup>5</sup>

Finally, the CAFC explained that, in order to determine whether the questioned conduct amounts to inequitable conduct, the court must balance levels of materiality and intent, "with a greater showing of one factor allowing a lesser showing of the other."<sup>6</sup>

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<sup>3</sup> McKesson, 487 F.3d at 913.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* (quoting Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001)).

## Detailed Analysis of Actions leading to Holding of Inequitable Conduct

### Action 1: Non-disclosure of the Baker Patent

On 10/23/1987, during a telephonic interview in the '009 prosecution, Examiner Lev brought U.S. Patent 4,456,793 to Baker et al. ("Baker") to Schumann's attention. Until this point, the same 38 prior art references had been cited in the '716 and '009 prosecutions (i.e. the '278 and '149 applications respectively).

On 12/1/1987, Examiner Lev rejected claims 20 and 22-24 as obvious in light of Baker in combination with other prior art. On 6/17/1988, in response to Examiner Lev's rejections of 12/1/1987, Schumann cancelled claims 19-24. However, **Schumann did not inform Examiner Trafton in the '716 prosecution of either of Examiner Lev's rejections in the '009 prosecution or of the Baker patent.**

### MATERIALITY

The District Court stated that "[a]n examiner's reliance on a prior art reference in a related prosecution supports a finding of materiality."<sup>7</sup>

The District Court noted how the prior art references in the '278 and '149 applications had been identical until the Baker patent was identified in the telephonic interview between Schumann and Examiner Lev. Indeed, Schumann himself testified that Examiner Lev's reliance on the Baker patent supports a finding of materiality. Moreover, Examiner Lev not only brought the Baker patent to Schumann's attention, he ultimately rejected claims 20 and 22-24 in the '009 prosecution because of Baker. Taking these facts into consideration, the District Court found that the Baker patent met the "reasonable examiner" materiality standard and should have been disclosed to Examiner Trafton. Additionally, the District Court found the Baker patent material because it contradicted the position that Schumann took in arguing for the issuance of the '716 patent.

### INTENT

The District Court then found that the overwhelming circumstantial evidence, combined with Schumann's failure to provide a credible explanation for the nondisclosure, proved intent by clear and convincing evidence on multiple alternative grounds. First, Schumann had disclosed the Baker patent to an examiner in another pending prosecution but had withheld it from Examiner Trafton. Second, Schumann was made aware (by Examiner Lev) of Baker only seventeen days after he had made arguments to Examiner Trafton which he could not have made had the art (Baker) been disclosed. Third, although he knew that his duty to disclose material information continued until issuance, Schumann continued to actively prosecute the '716 patent for another 22 months until his duty of disclosure expired. Fourth, Schumann was unable to proffer any credible explanation for his failure to disclose the Baker patent to Examiner Trafton.

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<sup>7</sup> *McKesson*, 2006 U.S. Dist. LEXIS 76517 at \*28.

## ON APPEAL

On appeal McKesson argued that the Baker reference was not material. McKesson also argued that Baker was merely cumulative because another reference, Hawkins, which was before Examiner Trafton, also disclosed the feature in question.

During the prosecution of the '716 patent, Schumann had argued in favor of patentability based on the use of three-node communication. Baker disclosed a three-node system. "However, unlike the Baker patent, only two nodes [were] described in any significant detail in the Hawkins patent."<sup>8</sup> Therefore, Hawkins was not on "equal footing as Baker."<sup>9</sup>

To further demonstrate that Baker is cumulative, McKesson argued that the art of record showed at least twelve three-node systems. However, the CAFC found that, aside from Hawkins, only two such systems (Pejas and Koenig) were specifically pointed to by McKesson. The CAFC dismissed Pejas because Baker provided a significantly lengthier and more detailed description of the preferred embodiment than Pejas.<sup>10</sup> The CAFC then dismissed Koenig because one of the three nodes in the three-node system in Koenig did not appear to be distinct. This led the CAFC to question whether Koenig actually disclosed a three-node system. Furthermore, the CAFC found that Koenig did not disclose anything analogous to the programmable unique identifier limitation of the '716 patent.

McKesson also contended that irrespective of Baker's materiality, the District Court erred in finding that Schumann intended to deceive Examiner Trafton. However, the CAFC rejected all arguments advanced by McKesson. The CAFC then affirmed the District Court's finding that "the overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure of Baker, supports the finding of deceptive intent."<sup>11</sup>

### Action 2: Non-disclosure of the rejections in the '009 Prosecution.

**The District Court held that although non-disclosure of the Baker reference alone supported unenforceability, this finding was further supported by Schumann's failure to inform Examiner Trafton of two adverse Office Actions by Examiner Lev in the '009 prosecution.**<sup>12</sup>

## MATERIALITY

The District Court pointed out that "[t]he law requires that material rejections in one prosecution be disclosed to the examiner in a copending case."<sup>13</sup> The District Court, further explained that "[a]n adverse decision by another examiner ... meets the

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<sup>8</sup> *McKesson*, 487 F.3d at 914.

<sup>9</sup> *Id.*

<sup>10</sup> *See Id.* at 915.

<sup>11</sup> *Id.* at 919.

<sup>12</sup> *See McKesson*, 2006 U.S. Dist. LEXIS 76517 at \*47-48.

<sup>13</sup> *Id.* at \*48.

materiality standard.”<sup>14</sup> Although McKesson repeatedly asserted that the 2003 *Dayco* decision created a new disclosure requirement that did not apply to the prosecution of the ‘716 patent in the 1980s, the District Court rejected this argument. The District Court held that this duty of disclosure was already in existence based on the rules set forth in MPEP § 2001.06(b), which is based on 37 C.F.R. 1.56.

Under *Dayco*, the rejections would be found material if the rejected claims were “substantially similar” to the claims pending before Examiner Trafton.<sup>15</sup> McKesson argued that *Dayco* requires claims to be ‘substantially similar” in content and scope. However, the District Court pointed out that this language was not present in the *Dayco* holding and that McKesson had not provided any persuasive explanation of how this language would alter the result. Accordingly, the District Court found the claims to be “substantially similar” and found that Schumann should have disclosed the adverse Office Actions. The District Court also pointed out that the two rejections by Examiner Lev were material also because they contradicted certain arguments for patentability made by Schumann in the ‘716 prosecution.<sup>16</sup> That is, the “rejections in the ‘009 prosecution were material because (1) they involved claims substantially similar to those pending in the ‘716 application, and (2) they directly addressed the point of novelty Mr. Schumann had advanced to Examiner Trafton.”<sup>17</sup>

### INTENT

The District Court stated that “a patentee aware of material information but who fails to disclose it to the PTO ‘can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead.”<sup>18</sup> Schumann advanced two excuses for nondisclosure. First Schumann stated that he probably did not believe activity in the ‘009 application to be material because it involved only a terminal and the ‘716 involved an entire system. Second, Schumann attempted to justify his conduct by explaining that he acted in conformance with his firm’s policy at the time. The District Court found that such conduct constituted “studied ignorance” and “supports, rather than defeats, an inference of deceptive intent.”<sup>19</sup>

### ON APPEAL

On appeal, McKesson argued that the District Court misapplied *Dayco* because it used a lesser, “in some respects identical,” test which failed to account for differences between the compared sets of claims.<sup>20</sup> The CAFC explained that materiality may be proven in numerous ways, including via the “reasonable examiner” standard which is satisfied “if the rejected claims are substantially similar to the claims at issue.”<sup>21</sup> The

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<sup>14</sup> *Id.* (quoting *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003).

<sup>15</sup> *Id.* at \*51.

<sup>16</sup> *See Id.* at \*53.

<sup>17</sup> *Id.* at \*55.

<sup>18</sup> *Id.* at \*57 (quoting *Bristol-Myers Squibb*, 326 F.3d at 1239).

<sup>19</sup> *Id.* at \*61.

<sup>20</sup> *McKesson*, 487 F.3d at 919.

<sup>21</sup> *Id.*

CAFC then stated that “[i]n other words, a showing of substantial similarity is sufficient to prove materiality. It does not necessarily follow, however, that a showing of substantial similarity is necessary to prove materiality. Indeed, in the same way that prior art need not be substantially similar in order to be material, ... rejected claims in a co-pending application also need not be substantially similar in order to be material.”<sup>22</sup> Since the test of materiality was met under the “reasonable examiner” standard, the CAFC then restricted itself to determining whether the finding was clearly erroneous.

McKesson had argued that the District Court ignored four differences between the claims in the ‘149 application and the ‘716 patent. However, the CAFC found this argument to be unpersuasive and found that the District Court did not ignore these differences; rather, the District Court had explicitly mentioned the differences and explained the rationale for rejecting the differences as insufficient to undermine a finding of materiality. The CAFC then went so far as to say that “even if the district court’s opinion had not adequately addressed the differences pointed to by McKesson, we would not be inclined to find clear error as a result.”<sup>23</sup> The CAFC then concluded its materiality analysis by stating “[n]evertheless, we do not believe that the possibility of one small piece of evidence being cumulative is sufficient to undermine the legitimacy of the district court’s otherwise error-free finding of materiality.”<sup>24</sup>

The CAFC also found that Schumann had intended to deceive the PTO because “(1) the examiner of one application (Trafton) was not apprised of the adverse decisions by another examiner (Lev) in a closely-related application; (2) the applicant disclosed the closely-related application only in the context of prior art cited in that application, but failed to mention the adverse decisions; and (3) the applicant made statements to the examiner inconsistent with the other examiner’s decisions, i.e., that nothing in the prior art disclosed three-node communication.”<sup>25</sup>

### Action 3: Non-disclosure of allowance of ‘372 Patent.

**Schumann had also failed to disclose the allowance of claims of the ‘372 patent to Examiner Trafton in ‘716 prosecution.**

### MATERIALITY

**The District Court determined that a finding of unenforceability was further supported by Schumann’s conduct in failing to disclose the Notice of Allowability of the ‘372 patent in the ‘716 prosecution.** In reaching this result, the District Court relied on rules established in the MPEP and *Dayco* which instruct that “information relating to co-pending U.S. patent applications ‘in which similar subject matter but patentably indistinct claims are present’ must be disclosed to the examiner of each of the involved applications.”<sup>26</sup> McKesson argued that *Dayco* created new law and that the

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<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 920.

<sup>24</sup> *Id.* at 922.

<sup>25</sup> *Id.* at 924.

<sup>26</sup> *McKesson*, 2006 U.S. Dist. LEXIS 76517, at \*64.

law required disclosure only of the existence of the co-pending application, not the allowance of those claims. The District Court rejected both of these contentions. McKesson also argued that the '372 and '716 claims were not "substantially similar." However, the District rejected this argument as well.

### INTENT

The District Court found that the '372 allowance was withheld with deceptive intent. The District Court held that "[g]iven the high level of materiality, as with Mr. Schumann's other non-disclosures, Mr. Schumann face[d] 'great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead.'"<sup>27</sup> Although the District Court found that Schuman's disclosure of the co-pendency of the '372 application was "some evidence of a lack of intent to deceive, ... weighing all the evidence, said disclosure [did] not overcome the inference of an intent to deceive established by the above facts."<sup>28</sup>

### ON APPEAL

On appeal, McKesson argued that the District Court erred in its materiality analysis by failing to determine whether the difference between the allowed '372 claims and the '716 patent were "so inconsequential [that] there was a substantial likelihood a reasonable examiner would have issued a double patenting rejection."<sup>29</sup> In other words, McKesson proposed that the allowance of the '372 could only be material to Examiner Trafton if he would have been likely to reject the '716 patent for double patenting. The CAFC disagreed and stated that "the test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability."<sup>30</sup>

McKesson also pointed out that both the '372 and '716 prosecutions were before the same examiner. The CAFC explained that:

[T]he MPEP at the time explained 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," MPEP § 2001.06(b) (5th ed. rev. 3, 1986) (quoting *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779 (7th Cir. 1972)), and PTO regulations required all disclosures to be in writing, 37 C.F.R. § 1.2; see also MPEP § 2002.02 (5th ed. rev. 3, 1986). Schumann 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>31</sup>

Rejecting as duplicative all other arguments made by McKesson, the CAFC found no clear error in the District Court's finding of materiality and intent.

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<sup>27</sup> *Id.* at \*67 (quoting *Bristol-Myers*, 326 F.3d at 1239).

<sup>28</sup> *Id.*

<sup>29</sup> *McKesson*, 487 F.3d at 925.

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

<sup>31</sup> *Id.* at 925-926.