



THE INEQUITABLE CONDUCT DEFENSE LIVES ON:  
2003 FEDERAL CIRCUIT DECISIONS AND THEIR IMPACT

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ABSTRACT

The inequitable conduct defense remains a viable defense in patent litigation today, as illustrated in four 2003 Federal Circuit decisions. Though an alleged patent infringer must establish the elements of materiality and intent for a valid inequitable conduct defense, recent Federal Circuit decisions indicate that certain factual underpinnings bearing on materiality can raise an inference of intent. To most effectively counter this inference of intent, a plausible explanation for the questioned conduct should be provided by the patentee. However, in providing such plausible explanation, the patentee runs the risk of waiving privileged communications, which in turn may result in far more intrusive and costly discovery.

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INTRODUCTION

In 1988, the Federal Circuit characterized the practice of charging inequitable conduct in patent cases as “an absolute plague.”<sup>1</sup> Despite the court's admonition, inequitable conduct battles continue to rage in patent litigation as evidenced in four Federal Circuit decisions issued in 2003.

In *Hoffmann-La Roche, Inc. v. Promega Corp.*, the Federal Circuit upheld a district court's summary judgment finding of inequitable conduct where, among other things, the inventors of the patented invention falsely represented to the United States Patent and Trademark Office (“Patent Office”) that they had performed a protocol procedure and achieved the result described in its patent specification.<sup>2</sup> Shortly thereafter, in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, the Federal Circuit affirmed a district court's summary judgment inequitable conduct decision where the inventors intentionally withheld material information in the form of a prior art article during the prosecution of the patent applications.<sup>3</sup>

The *Hoffmann-La Roche* and *Bristol-Myers* decisions were followed by decisions in *Dayco Products, Inc. v. Total Containment, Inc.*<sup>4</sup> and *Ulead Systems, Inc. v. Lex Computer & Management Corp.*<sup>5</sup> In both *Dayco* and *Ulead*, the Federal Circuit vacated and remanded summary judgment findings of inequitable conduct. In *Dayco*, the Federal Circuit determined that the materiality of a withheld reference presented a question of fact requiring a trial.<sup>6</sup> The court also found error in the district court's finding of an intent to deceive the Patent Office because the plaintiff submitted declarations explaining why the reference was not given to the Patent Office.<sup>7</sup> Similarly, in *Ulead*, the Federal Circuit found a trial was required to determine whether an intent to deceive the Patent Office existed because the patentee presented testimony from its general counsel and its patent counsel, that they had acted innocently when they mistakenly claimed small entity status under 35 U.S.C. § 1.9(f).<sup>8</sup>

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<sup>1</sup> *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

<sup>2</sup> 323 F.3d 1354 (Fed. Cir. 2003).

<sup>3</sup> 326 F.3d 1226 (Fed. Cir. 2003).

<sup>4</sup> 329 F.3d 1358 (Fed. Cir. 2003).

<sup>5</sup> 351 F.3d 1139 (Fed. Cir. 2003).

<sup>6</sup> *Dayco*, 329 F.3d at 1367.

<sup>7</sup> *Id.* at 1366–67.

<sup>8</sup> *Ulead*, 351 F.3d at 1148.

These four cases exemplify the fact-specific nature of inequitable conduct disputes. The ultimate decision of whether inequitable conduct occurred can turn on documentary evidence and the veracity of witnesses, including experts and participants, in obtaining the challenged patent. Decisions as to what exculpatory evidence and testimony are needed can be critical to maintaining a successful defense. While the Federal Circuit may not favor the inequitable conduct defense, these most recent decisions indicate that alleged infringers will continue to rely on this costly, time-consuming and contentious defense.

### I. THE INEQUITABLE CONDUCT STANDARD

Inequitable conduct refers to intentional acts and omissions of a patent applicant or representative of a patent applicant during the course of obtaining a patent from the Patent Office.<sup>9</sup> Inequitable conduct consists of an “affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.”<sup>10</sup> The party alleging inequitable conduct must prove the threshold elements of materiality of the misstatement or omission and intent to deceive the Patent Office by clear and convincing evidence.<sup>11</sup> The district court then weighs the threshold findings of materiality and intent in light of all the circumstances to determine whether the patent applicant's conduct warrants a conclusion that the patent should be held unenforceable.<sup>12</sup>

The determination of inequitable conduct is committed to the district court's discretion.<sup>13</sup> To be overturned, “the appellant must establish that the ruling is based on clearly erroneous findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court.”<sup>14</sup> The district court's decision will not be disturbed on appeal unless the court has a definite and firm conviction that a mistake has been committed.<sup>15</sup>

Both intent and materiality are questions of fact that must be proven by clear and convincing evidence.<sup>16</sup> However, once a threshold of materiality has been established, the inquiry focuses upon whether the patentee intended to mislead the patent examiner.

The evidence of intent to mislead the Patent Office can rarely be demonstrated with direct evidence. Thus, “smoking gun” evidence is not required to establish an intent to deceive.<sup>17</sup> Rather, an accused infringer can prove intent by the acts of the applicant and the presumption that the natural consequences of those acts were

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<sup>9</sup> *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988); 37 C.F.R. § 1.56 (2002).

<sup>10</sup> *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

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

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 (Fed. Cir. 2003).

<sup>17</sup> *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189–90 (Fed. Cir. 1993); *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992).

presumably intended by the actor.<sup>18</sup> Generally, the courts will infer intent from the facts and circumstances surrounding the applicant's conduct.<sup>19</sup>

An accused infringer cannot rely solely on undisclosed prior art's materiality to prove the intent element.<sup>20</sup> However, the more material the omission or the misstatement, the lower the level of evidence required to show the requisite intent, and vice versa.<sup>21</sup> As asserted in *Rohm & Haas Co. v. Crystal Chemical Co.*, an affirmative misrepresentation by the patentee, in contrast to a misleading omission, is more likely to be regarded as material.<sup>22</sup>

A finding of inequitable conduct can lead to the devastating consequence of rendering a patent unenforceable.<sup>23</sup> Therefore, despite the Federal Circuit's stated distaste for such charges, the accused infringers and their attorneys continue to develop novel bases for making allegations of misconduct.<sup>24</sup>

## II. THE RECENT FEDERAL CIRCUIT INEQUITABLE CONDUCT CASES

### *A. Hoffmann-La Roche, Inc., v. Promega Corp.*<sup>25</sup>

Hoffmann-La Roche, Inc., ("Hoffmann") sued Promega Corporation ("Promega") for alleged infringement of Hoffmann's United States Patent No. 4,889,818 ("the '818 patent").<sup>26</sup> The '818 patent is directed to the isolation of a purified thermostable enzyme ("Thermus aquaticus" or "Taq") used in DNA synthesis.<sup>27</sup> In response, Promega counterclaimed, asserting that the '818 patent was unenforceable due to inequitable conduct.<sup>28</sup>

After conducting a bench trial, the district court found for Promega, identifying three categories of material misrepresentations and related omissions made by the patentee with intent to deceive the Patent Office that constituted inequitable conduct, rendering the '818 patent unenforceable.<sup>29</sup> The categories of the district

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<sup>18</sup> *Molins*, 48 F.3d at 1180 (Fed. Cir. 1995).

<sup>19</sup> *Id.* at 1180–81.

<sup>20</sup> *Braun, Inc. v. Dynamics Corp.*, 975 F.2d 815, 822 (Fed. Cir. 1992).

<sup>21</sup> *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

<sup>22</sup> 722 F.2d 1556, 1571 (Fed. Cir. 1983).

<sup>23</sup> *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988).

<sup>24</sup> See Lisa A. Dolick, *The Inequitable Conduct Doctrine: Lessons From Recent Cases*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719, 719 (2002).

<sup>25</sup> 323 F.3d 1354 (Fed. Cir. 2003).

<sup>26</sup> Cetus Corporation was the original patentee and filed United States Application Serial No. 07/063,509 that ultimately issued as the '818 patent. *Id.* at 1358. Cetus licensed the '818 patent to Promega in June of 1990. *Id.* at 1359. Cetus subsequently sold the '818 patent to Hoffmann. *Id.* Following the sale of the '818 patent to Hoffmann, Promega allegedly breached the license agreement. *Id.* Hoffmann filed suit, alleging patent infringement and breach of contract. *Id.*

<sup>27</sup> *Id.* at 1358.

<sup>28</sup> *Id.* at 1359.

<sup>29</sup> *Id.* Initially, Promega moved for summary judgment of inequitable conduct. *Id.* The district court granted Promega's motion relating to whether material misrepresentations or omissions were

court's findings were: (1) misrepresentations regarding the difference in molecular weight between the claimed and prior art Taq enzymes; (2) misrepresentations that the inventors had performed Example VI (one of the procedures described in the specification) and that they had achieved the described results; and (3) misrepresentations concerning the comparative fidelity and template dependence of the claimed enzyme and the prior art enzymes.<sup>30</sup>

As described below, the Federal Circuit reversed the district court's findings on the first category ("Molecular Weight"), but upheld the second ("Example VI") and third ("Comparison of Fidelity") findings.<sup>31</sup>

### *1. Molecular Weight*

In the prosecution of the '818 patent, the inventors distinguished their invention from the prior art by asserting that their enzyme had a higher molecular weight than the prior art enzyme.<sup>32</sup> The district court found that the inventors had made two material omissions to the Patent Office regarding the molecular weight of the claimed and prior art enzymes.<sup>33</sup> First, an undisclosed experiment conducted by one of the inventors (the Soffel experiment) was believed by the district court to cast doubt on the inventors' representations that the claimed invention had a higher molecular weight than the prior art enzyme.<sup>34</sup> Second, the district court believed the inventors failed to disclose that the technique used by the prior art scientist to determine the molecular weight of the prior art enzyme was inaccurate and produced an underestimate of the true weight of the prior art.<sup>35</sup>

The original claims of the '818 patent were rejected based upon prior journal publications by Chien, et al. ("Chien") and Kaledin, et al. ("Kaledin"), which disclosed a DNA polymerase derived from *Thermus aquaticus* or "Taq" bacterium.<sup>36</sup> In explaining the rejection, the examiner stated that "it is not clear whether or not the molecular weight . . . claimed by applicants for the instant enzyme is a result of experimental parameters or an enzyme activity different than the [enzyme] previously described in the literature."<sup>37</sup> The patentee responded by presenting a new independent claim setting forth a molecular weight range for a Taq enzyme significantly higher than the ranges reported by Chien and Kaledin.<sup>38</sup> In remarks,

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made to the Patent Office and then conducted a bench trial on the issue of the patentee's intent to deceive the Patent Office. *Id.*

<sup>30</sup> *Id.* at 1359–60.

<sup>31</sup> *Id.* at 1360.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 1360–63.

<sup>34</sup> *Id.* at 1360.

<sup>35</sup> *Id.* at 1361.

<sup>36</sup> *Id.* at 1358. The Chien reference described an enzyme with a molecular weight of 63,000–68,000 daltons; the Kaledin reference described an enzyme with a molecular weight of 60,000–62,000 daltons. *Id.* at 1360.

<sup>37</sup> *Id.* at 1358.

<sup>38</sup> *Id.* at 1358–59. Claim 1 of the '818 patent claimed: "Purified thermostable *Thermus aquaticus* DNA polymerase that migrates on a denaturing polyacrylamide gel faster than phosphorylase B and more slowly than does bovine serum albumin and has an estimated molecular

the patentee pointed to the differences in molecular weight of the prior art enzyme and the claimed enzymes, and that Chien and Kaledin had identified “a crude preparation of degraded Taq polymerase” in their journal articles.<sup>39</sup>

*a. The Undisclosed Soffel Experiment*

On summary judgment, the Soffel experiment was found to suggest that the prior art enzyme was not a degraded form of Taq.<sup>40</sup> The failure to describe the Soffel experiment to the Patent Office was thus determined by the district court to be a material omission on the part of the inventors.<sup>41</sup> However, the Federal Circuit reversed, holding that there were genuine issues of fact regarding both materiality and intent of the inventors regarding the non-disclosure.<sup>42</sup>

The Federal Circuit agreed with Hoffmann's argument that the Soffel experiment was not material to patentability, determining that the Soffel experiment was conducted under conditions very different than those described in the Chien prior art experiment.<sup>43</sup> Therefore, it was not clear whether the withheld experiment was material to determining the correct molecular weight of the patentee's enzyme.<sup>44</sup>

In reversing the district court's finding that the inventors had intentionally failed to disclose the Soffel experiment, the Federal Circuit pointed to un rebutted testimony that the inventors considered the salt concentration significant to the failure of the Taq enzyme to bind.<sup>45</sup> The court indicated that because the salt concentration used in the Soffel experiment was significantly different than in the experiments conducted by Chien, the inventors would not have considered the result

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weight of 86,000-90,000 daltons when compared with a phosphorylase B standard assigned a molecular weight of 92,500 daltons.” U.S. Patent No. 4,889,818 (issued Dec. 26, 1989).

<sup>39</sup> *Hoffman-La Roche*, 323 F.3d at 1359–60.

<sup>40</sup> *Id.* Co-inventor, Susanne Soffel, performed an experiment in which she applied a protein sample to a phosphocellulose column. *Id.* “She observed that a Taq fragment with a molecular weight of 62,000 daltons did not bind to the phosphocellulose column.” *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 1360–61.

<sup>43</sup> *Id.* Specifically, the Federal Circuit found that the ability of a particle to bind to the phosphocellulose column is dependent upon the salt concentration of the buffer in which the phosphocellulose is suspended. *Id.* at 1360. The salt concentration of the buffer used in the Soffel experiment was significantly higher than it was in the buffer used in the Chien experiment. *Id.* at 1361.

<sup>44</sup> *Id.* at 1361.

<sup>45</sup> *Id.* There was testimony that when a difficulty with an enzyme sticking to the column was encountered, Dr. Gelfand suggested reducing the salt concentration to around 40 mM. *Id.* The consequence of Dr. Gelfand's suggestion “was that the salt concentration of the load in this column was probably too high . . . [a]nd . . . to get that material to stick to the column, one needed to lower the salt concentration . . . .” *Id.* In addition:

Ms. Stoffel testified that experiments showed that the fragment did not bind when it was loaded at a salt concentration of 80 mM, but that “it stuck but it eluted earlier in the gradient” at a salt concentration of 10 mM—the concentration in Chien's experiment. When the inventors noted that the proteolyzed enzyme did not bind to phosphocellulose, they included a reference to the restriction “at 80 mM salt,” indicating that they considered the salt concentration significant to the failure to bind.

*Id.*

of the Soffel experiment to have any bearing on whether Chien had isolated a fragment of the Taq enzyme.<sup>46</sup>

*b. The Undisclosed Information Relating to Inaccuracy of Size Exclusion Chromatography*

The district court also found that the inventors had improperly withheld information suggesting that the technique Chien used to determine molecular weight of his Taq enzyme was inaccurate and resulted in an underestimate of the true weight.<sup>47</sup> The district court believed that disclosure of that information to the Patent Office would have weakened the inventors' argument that the claimed invention was different than the prior art enzyme.<sup>48</sup> The Federal Circuit disagreed with the district court's conclusion on materiality, concluding that none of the evidence cited proved that the molecular weight recorded by Chien was too low.<sup>49</sup> The Federal Circuit reversed the district court's inequitable conduct finding to the extent the district court relied on the representations and omissions regarding the molecular weights of the prior art and claimed Taq enzymes.<sup>50</sup>

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<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 1361. Chien used size exclusion chromatography to measure the weight of the Taq enzyme produced. *Id.* In the size exclusion chromatography procedure at issue, the sample of the protein to be weighed is placed in a column filled with porous beads (sometimes referred to as a "matrix"). *Id.* Then:

A buffer solution is run through the column. The proteins in the sample that are larger than the pore size of the beads will flow around the beads and out the bottom of the column. The smaller proteins will enter the pores between the beads, thus retarding their progress through the column. As a result, the speed at which a protein "elutes," or moves through the column, corresponds to its molecular weight. The faster a protein moves through the column, the greater its molecular weight. If, however, a protein ... has a chemical affinity for the matrix, it may move through the column more slowly than would be expected, resulting in an underestimation of its molecular weight.

*Id.*

<sup>48</sup> *Id.* at 1361.

<sup>49</sup> *Id.* at 1362. The information relied upon by the district court consisted of the results of purification and sizing experiment by the inventors, data concerning Taq's tendency to avoid interacting with water, and an internal memorandum indicating Taq "migrates differently on Zorbax." *Id.* In reversing, the Federal Circuit held that the experiments by the inventors would not show that the Sephadex G-100 chemical product used by Chien would bind with the matrix. *Id.* The inventors used a wholly different chemical product (Zorbax and Ultrogel) in their experiments. *Id.* The Federal Circuit also concluded that the district court failed to consider the chemical properties of Sephadex when it concluded that Taq's tendency to avoid interacting with water resulted in an underestimation of its molecular weight. *Id.* Finally, the internal memo was not conclusive on whether Taq would interact with Sephadex used by Chien. *Id.* at 1363.

<sup>50</sup> *Id.* The Federal Circuit did not address the issue of intent to deceive the Patent Office with regard to the failure to disclose information suggesting the underreporting of the molecular weight of Chien's Taq. *Id.*



## 2. Example VI

The district court also made findings related to misrepresentations made by the inventors concerning the performance of and results achieved in a purification protocol (“Example VI”) described in the ‘818 patent.<sup>51</sup> Specifically, the district court found that the inventors intentionally misrepresented to the Patent Office that they had performed the procedure described in the Example VI protocol and achieved the represented results.<sup>52</sup> Example VI in the patent specification concluded as follows:

Active fractions with no detectable nuclease(s) were pooled and run on a silver stained SDS-page mini gel. The results show a single 88 kd band with a specific activity of 250,000 units/mg. This specific activity is more than an order of magnitude higher than that claimed for the previously isolated Taq polymerase and is at least an order of magnitude higher than that for *E. coli* polymerase I.<sup>53</sup>

The district court found that use of the past tense falsely suggested to the examiner that the Example VI protocol had been performed when it had not.<sup>54</sup> The statements regarding purity, specifically, that Example VI resulted in a “nuclease-free preparation,” that the inventors had achieved a specific activity of “250,000 units/mg,” and that the claimed specific activity of the “produced” enzymes was significantly higher than in the prior art, were considered material to the issue of patentability.<sup>55</sup> The district court also concluded that the representations were knowingly false.<sup>56</sup>

### a. Hoffmann's Misrepresentations

The district court found that the inventors used the past tense in describing the steps of the Example VI protocol on more than seventy-five occasions.<sup>57</sup> Use of the past tense implied to the reader that the inventors performed the Example VI protocol and achieved the described results.<sup>58</sup> However, at trial, the inventors admitted that they had never performed the Example VI protocol and never achieved the results they claimed.<sup>59</sup>

Hoffmann attempted to explain that it was not necessary that the Example VI protocol be performed from start to finish exactly as written.<sup>60</sup> Hoffmann claimed the actual steps in the procedure were part of two separate procedures which had been

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

<sup>52</sup> *Id.*

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

<sup>54</sup> *Id.* at 1364.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 1367.

<sup>57</sup> *Id.* at 1364.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

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

performed by the inventors.<sup>61</sup> The district court rejected Hoffmann's argument that Example VI was, in effect, performed through the combination of steps from two different preparations.<sup>62</sup> The Federal Circuit agreed and found the representation concerning performance of the Example VI protocol was false.<sup>63</sup>

Significant to the Federal Circuit's decision was the disparity in evidence presented by Promega and Hoffmann.<sup>64</sup> The accused infringer, Promega, offered expert testimony that doing the preparations Hoffmann relied upon would not provide an accurate representation of the results of a procedure conducted according to Example VI.<sup>65</sup> Hoffmann offered no evidence contradicting this expert testimony regarding the importance of the order of the steps, or leading to the conclusion that the results of two separate tests give an accurate representation of the entire experiment.<sup>66</sup>

The district court also found that the patentee misrepresented to the Patent Office that the Example VI protocol resulted in: a nuclease-free preparation, an enzyme with a specific activity of 250,000 units/mg, and an enzyme with a specific activity 10 times that of the prior art enzyme.<sup>67</sup> At trial, the inventors admitted that they had relied upon the results of a different protocol test and that the resulting enzyme from that step was not nuclease-free.<sup>68</sup> The Federal Circuit upheld the district court's finding that affirmative misrepresentations were made to the Patent Office regarding the Example VI protocol.<sup>69</sup>

#### *b. Intent to Deceive*

In upholding the district court's finding that Hoffmann had made statements to deceive the Patent Office, the Federal Circuit pointed out that “[m]isrepresentations by themselves are not enough to render a patent unenforceable; the misrepresentations must be intentional and they must be material to

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<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 1365.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* Specifically, Dr. Mosbaugh testified that one “cannot fuse these [separate preparations] together and get any prediction as to what the outcome would be.” *Id.*

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

<sup>67</sup> *Id.* at 1365–67. The patentee misrepresented to the Patent Office that “active fractions with no detectable nuclease(s) were pooled and run on a silver stained SDS PAGE mini-gel” and that “the Taq polymerase purified as described above in Example VI was found to be free of any contaminating Taq endonuclease and exonuclease activities.” *Id.* at 1365–66.

<sup>68</sup> *Id.* at 1365. The patentee also falsely represented they achieved an enzyme with a specific activity of 250,000 units/mg. *Id.* at 1366. On summary judgment, the court determined that using the definition of “unit” set forth in the Example VI protocol, only a magnitude of 100,000 units/mg was achieved. *Id.* The district court also found that the patentee's comparison of the specific activity of the claimed enzyme and the prior art enzyme was deceptive. *Id.* The inventors had twice represented to the Patent Office that the claimed enzyme had a specific activity 10 times that of the prior art enzyme. *Id.* However, Promega's expert testified that the prior art and claimed enzymes were not assayed under the same conditions. *Id.* The district court found the contrary testimony of Hoffmann's expert not credible. *Id.*

<sup>69</sup> *Id.* at 1363–66.

patentability.”<sup>70</sup> Nonetheless, the Federal Circuit upheld the finding that the inventors' affirmative misrepresentation was deceptive, and that Hoffmann had the requisite intent.<sup>71</sup> The Federal Circuit noted that the inventors attested that all statements made in their patent application were true.<sup>72</sup> Hoffmann did not provide any evidence suggesting that the use of the past tense language was merely an oversight and not knowingly false.<sup>73</sup> Rather, Hoffmann argued that Example VI was included as simply a best mode disclosure.<sup>74</sup> The Federal Circuit countered that “the best mode requirement, however, does not entitle the inventor to suggest that the best mode has been performed when it has not . . . .”<sup>75</sup>

Hoffmann also argued that the inventors believed they had discovered a novel enzyme.<sup>76</sup> However, the Federal Circuit responded that a good faith belief “does not permit [an applicant] to make misrepresentations in seeking to persuade the examiner to issue a patent . . . .”<sup>77</sup> Because the inventors knew that past tense language indicates that the experiment had actually been performed, intent to deceive was inferred from its use in the patent.<sup>78</sup> Furthermore, Hoffmann failed to adequately explain why past tense language was utilized.<sup>79</sup>

### *c. Materiality of the Misrepresentations*

The Federal Circuit also upheld the district court's finding that the inventors' mischaracterizations to the Patent Office regarding the purity comparison of the fidelity and template dependency of the claimed enzyme and the prior art enzymes were material to patentability.<sup>80</sup> Hoffmann argued that the representation was not material because the patent did not include claim limitations directed to purity.<sup>81</sup> The Federal Circuit rejected that argument stating that “[m]ateriality . . . is not limited to matters reflected in the claims of a patent.”<sup>82</sup> Further, the Federal Circuit, citing its decision in *Rohm & Haas Co. v. Crystal Chem. Co.*, indicated that

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<sup>70</sup> *Id.* at 1366–67.

<sup>71</sup> *Id.* at 1367.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* In addition:

There was no suggestion by Roche that the use of the past tense in Example VI was an oversight—Dr. Gelfand admitted he understood that, at least in a scientific publication, the use of the past tense means that an experiment was actually performed. He provided no reasonable explanation as to why a different principle would apply in a patent application.

*Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 1368.

<sup>81</sup> *Id.* at 1367.

<sup>82</sup> *Id.*

affirmative misrepresentations are more likely regarded as material than mere omissions.<sup>83</sup>

Moreover, the Federal Circuit noted that in response to the initial rejection by the Patent Office, the patentee asserted that the claimed enzyme's purity was different from the prior art enzyme as an alternative argument to support patentability.<sup>84</sup> Because the patentee had argued that the patent could have issued based upon the asserted purity, a reasonable examiner would have considered information about the purity in Example VI and referenced in the office action to be material.<sup>85</sup>

### 3. Comparison of Fidelity

The Federal Circuit also affirmed the district court's finding that the inventors had made misrepresentations in comparing the fidelity and template dependence of the claimed enzyme and prior art enzyme.<sup>86</sup> In the application and during prosecution of the application, the inventors claimed that their enzyme exhibited a high fidelity, while the prior art enzyme did not.<sup>87</sup> Although the statements regarding their own enzyme were correct, the statements characterizing the activity of the prior art enzymes and comparing it to that of the claimed enzyme were inaccurate.<sup>88</sup> Promega's expert testified "the differing results referred to by the inventors in the office action response related to differences in experimental conditions (specifically, differences in the DNA templates used) and not to differences in the properties of the enzymes."<sup>89</sup> Hoffmann offered no expert testimony to refute the testimony of Promega's expert.<sup>90</sup> Rather, Hoffmann countered by arguing that Promega's expert and the inventors differed over how to interpret the experimental results relied on by the inventors.<sup>91</sup> The court found, however, that Hoffmann "failed to make a persuasive showing that there was a legitimate difference of scientific opinion on that issue."<sup>92</sup>

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<sup>83</sup> *Id.* at 1367 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)).

<sup>84</sup> *Id.* at 1367–68.

<sup>85</sup> *Id.* at 1368.

<sup>86</sup> *Id.* at 1369–72.

<sup>87</sup> In the application that became the '818 patent, "the inventors posited that their claimed enzyme exhibited high fidelity while the prior art enzyme experienced misincorporation." *Id.* at 1369. The inventors stated:

[W]hen only one or more nucleotide triphosphates were eliminated from a DNA polymerase assay reaction mixture, very little, if any, activity was observed using the enzyme herein, and the activity was consistent with the expected value, and with an enzyme exhibiting high fidelity. In contrast, the activity observed using the Kaledin et al. (*supra*) enzyme is not consistent with the expected value, and suggests misincorporation of nucleotide triphosphate(s).

*Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 1370.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

As with the purity issue, the affirmative misrepresentation to the Patent Office regarding fidelity was deemed material.<sup>93</sup> The inventors made the assertions regarding fidelity to support their contention that the claimed enzyme was different from the prior art enzyme cited by the examiner.<sup>94</sup> The claim of greater fidelity was therefore intended to demonstrate, along with the purported difference in molecular weight, that the claimed enzyme was not the same as the enzyme described in the prior art references and, accordingly, was patentable.<sup>95</sup>

The Federal Circuit found the statements the patentee made regarding fidelity were intentionally deceptive as well.<sup>96</sup> The court stated that “[i]ntent . . . is typically proved inferentially,” and the Promega expert witness testified that “he did not believe that a scientist aware of the information . . . in the records could truthfully make the statements found in the specification and office action response and that [the inventors were] knowledgeable about that information.”<sup>97</sup> Hoffmann did not put forward evidence to contradict Promega’s expert witness statements about whether the inventors’ interpretation, although inaccurate, was reasonable.<sup>98</sup> Nor did the inventors testify about their knowledge in the field or whether they believed their statements in the office action response to be truthful.<sup>99</sup> For these reasons, both threshold requirements were met, and the Federal Circuit upheld the district court’s finding of inequitable conduct.<sup>100</sup>

The Federal Circuit indicated that an important step in the judicial resolution of inequitable conduct claims is the court’s determination of “whether the material misrepresentations or omissions in question are sufficiently serious in light of the evidence of intent to deceive, under all the circumstances, to warrant the severe sanction of holding the patent unenforceable.”<sup>101</sup> Because the district court had not previously performed this step in the inequitable conduct analysis, the case was vacated and remanded to determine whether the two incidents of inequitable conduct affirmed by the Federal Circuit were sufficient to render the patent unenforceable.<sup>102</sup>

*B. Bristol-Myers Squibb Co., v. Rhone-Poulenc Rorer, Inc.*<sup>103</sup>

Bristol-Meyers Squibb, Co. (“Bristol”), the accused infringer, sued Rhone-Poulenc Rorer, Inc. (“RPR”), seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of RPR’s United States Patent No. RE 34,277 (“the ‘277 patent”).<sup>104</sup> The ‘277 patent related to a semi-synthesis of Taxol®, a cancer chemotherapeutic agent.<sup>105</sup> One of the problems the invention overcame in the semi-

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<sup>93</sup> *Id.* at 1371.

<sup>94</sup> *Id.* at 1369.

<sup>95</sup> *Id.* at 1371.

<sup>96</sup> *Id.* at 1368–72.

<sup>97</sup> *Id.* at 1371.

<sup>98</sup> *Id.* at 1372.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> 326 F.3d 1226 (Fed. Cir. 2003).

<sup>104</sup> *Id.* at 1229.

<sup>105</sup> *Id.*

synthesis of Taxol® was preventing unwanted products from bonding to the main chemical structure (known as the “10-DAB”).<sup>106</sup> The inventors of the '277 patent developed a method of using “protecting groups” to prevent the unwanted side reactions on the 10-DAB, clearing the way for the formation of Taxol®.<sup>107</sup>

The district court held an evidentiary hearing on the issue of claim construction and the inventor's failure to disclose a prior art article to the Patent Office.<sup>108</sup> The district court then found by clear and convincing evidence that the RPR inventors had committed inequitable conduct by not providing the prior art article to the Patent Office.<sup>109</sup> Thereafter, the Federal Circuit affirmed the district court's finding of materiality and intent to deceive.<sup>110</sup>

### *1. History of the Journal of the American Chemical Society Article Disclosure*

At the core of Bristol's inequitable conduct claim was a scientific article published by several of the inventors in the *Journal of the American Chemical Society* (“JACS Article”).<sup>111</sup> This article was not disclosed to the Patent Office despite being known by the inventors and the patent agent involved in the prosecution of the application that became the '277 patent.

On November 3, 1987, the inventors submitted a draft of what became the JACS Article to their French patent agent, Jacques Pilard.<sup>112</sup> In the draft JACS Article, the inventors identified certain limitations regarding the use of several types of protecting groups.<sup>113</sup> Specifically, the draft JACS Article stated that the conversion of 10-DAB to Taxol® “could be successfully achieved only with *specific protecting groups and under unique reaction conditions*” and expressly identified limitations and problems with two protecting groups acronymized as “MOM” and “TMS.”<sup>114</sup>

Two weeks later, Pilard recommended to the inventors that the draft publication could be the subject of a patent application.<sup>115</sup> In January of 1988, RPR's licensing department wrote to Pilard and suggested that a patent application be drafted

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<sup>106</sup> *Id.*

<sup>107</sup> *Id.* The method specifically involved “modifying 10-deacetylbaccatin III (“10-DAB”) with an acetyl group adding a (2R 3S) 3-phenylisoserine side chain (“the side chain”) through an esterification reaction.” *Id.* “The inventors devised a method of utilizing “protecting groups” to prevent particular hydroxyl groups on the 10-DAB core and side chain molecules from reacting in side reactions and thereby preventing the formation of taxol.” *Id.*

<sup>108</sup> *Id.* at 1233.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at 1229.

<sup>111</sup> *Id.* at 1230. Entitled “A Highly Efficient, Practical Approach to Natural Taxol,” the JACS Article was written by four of the six inventors of the '277 patent. *Id.* The Article was submitted for publication on April 20, 1988, and was published on August 17, 1988. *Id.* at 1231.

<sup>112</sup> *Id.* at 1230.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.* (emphasis in original). The draft article explained the limitations of several of the protecting groups: 1) the Methoxymethyl (“MOM”) protecting group at C-2' could not be removed after esterification; 2) the trimethylsilyl (“TMS”) protecting group was unstable in the esterification process; and 3) the tert-butyldimethylsilyl (“TBDMS”) group could not be cleanly introduced at C-7. *Id.*

<sup>115</sup> *Id.*

covering the inventors' semi-synthesis of Taxol<sup>®</sup>.<sup>116</sup> On March 7, 1988, two of the inventors provided invention disclosures to Pilard entitled "Modes Operatoires" which described the semi-synthesis of Taxol<sup>®</sup>.<sup>117</sup> The "Modes Operatoires" reiterated the JACS Article's report of limitations regarding the use of MOM and TMS protecting groups.<sup>118</sup> Three days later, Pilard drafted a French patent application for the semi-synthesis of Taxol<sup>®</sup>.<sup>119</sup> In drafting the application, however, Pilard left out the limitations concerning the MOM and TMS protecting groups identified in the draft JACS Article and Modes Operatoires.<sup>120</sup> In fact, Pilard not only identified that MOM and TMS were permissible protecting groups, but that they were the preferred protecting groups.<sup>121</sup>

Pilard sent his draft patent application to the inventors on March 18, 1988, asking them to review it carefully, adding and modifying as they deemed necessary.<sup>122</sup> The inventors returned the application without substantive change to either the specification or claims.<sup>123</sup> Pilard filed the application on April 6, 1988.<sup>124</sup> Two weeks later, the *Journal of the American Chemical Society* received the draft JACS Article,<sup>125</sup> which was published on August 17, 1988.<sup>126</sup>

Pilard later contacted an American patent attorney, Ellsworth Mosher, to obtain a United States Patent. Pilard did not provide Mosher with either the JACS Article or the Modes Operatoires.<sup>127</sup> Mosher, using an English translation of Pilard's French patent application, filed an application on April 3, 1989 that became United States Patent No. 4,924,011 ("the '011 patent"). No one disclosed the JACS Article or the Modes Operatoires to the Patent Office during the prosecution of the '011 patent application.<sup>128</sup> In the prosecution, the Patent Office prepared a search report that identified the JACS Article; however, the examiner failed to place his initials next to

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<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* The "Modes Operatoires" states that in the invention: 1) the [TMS] group used in the regioselective process proved too fragile in the esterifying reaction with the protected side chain; 2) the protective reaction does not go forward with the TBDM chloride; and 3) Hydroxyl function of side chain was protected by use of protective groups such as MOM, but did not state MOM could be removed. *Id.*

<sup>119</sup> *Id.* at 1231.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* In claim 1 of the draft patent application, Pilard claimed the process as one:

'[I]n which R2 is a hydroxy-protecting group . . . [and] in which R3 is a hydroxy-protecting group,' without specifying any limitation as to the hydroxy-protecting groups that could be used in the process. In claim 2 of the draft application, Mr. Pilard claimed the process according to claim 1 'in which R2 is chosen from [MOM and other compounds] . . . and R3 is chosen from trialkylsilyl groups in which each alkyl portion contains one to three carbon atoms.'

*Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

the article indicating that he considered it in issuing the patent.<sup>129</sup> On May 8, 1990, the Patent Office issued the '011 patent.<sup>130</sup>

On June 11, 1991, Pilard contacted a different patent attorney, Frederick Caveletti, requesting legal assistance in filing a reissue patent application on the '011 patent.<sup>131</sup> Pilard attached a copy of the JACS Article to his letter.<sup>132</sup> Footnote 16 of the JACS Article, which discussed the limitation of using MOM in the semi-synthesis of Taxol<sup>®</sup>, was circled (by an unknown person).<sup>133</sup> Caveletti replied to Pilard on June 13, 1991, stating that the JACS Article would not affect the grant of the original '011 patent because the journal article was filed less than one year before the '011 application was filed.<sup>134</sup> Calvetti then filed the reissue '277 patent application on November 1, 1991.<sup>135</sup> In doing so, Calvetti did not disclose the JACS Article to the Patent Office.<sup>136</sup> On July 17, 1992, Pilard sent a letter to Calvetti identifying prior art including the JACS Article but stated in the letter, “[a]ccording to our evaluation these references are irrelevant.”<sup>137</sup> Calvetti never identified the JACS Article during any of his responses to the Patent Office actions.<sup>138</sup>

In December of 1992, Pilard instructed Calvetti to provide a copy of the JACS Article to the Patent Office.<sup>139</sup> The JACS Article was thus finally received by the Patent Office on January 14, 1993.<sup>140</sup> The Patent Office issued the '277 patent on June 8, 1993.<sup>141</sup>

## 2. Materiality of the JACS Article

On materiality, the Federal Circuit noted that the examiner had an obligation to review the application for enablement under 35 U.S.C. § 112.<sup>142</sup> Based upon what was submitted to the examiner, the examiner would have expected the use of MOM and TMS protecting groups in performing the invention.<sup>143</sup> However, the undisclosed JACS Article and Modes Operatoires conflicted with this recommendation. Specifically, the JACS Article reported that the TMS group was unstable and that the MOM group could not be removed.<sup>144</sup> This information was deemed to be highly

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<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 1232.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* Footnote 16 stated: “A methoxymethyl [(“MOM”)] protecting group at C-2' could not be removed following esterification.” *Id.* at 1230.

<sup>134</sup> *Id.* at 1232.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.* at 1232–33.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 1233.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.* at 1234. “The legal question of enablement involves an assessment of whether a patent disclosure would have enabled one of ordinary skill in the art at the time the application was filed to make and use the claimed invention without undue experimentation.” *Id.* (citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)).

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*



material because, had it been disclosed to the examiner, it would have cast doubt upon the invention's ability to produce Taxol®.<sup>145</sup> Bristol offered expert testimony that one skilled in the art would understand the JACS Article to mean that use of the MOM cannot produce Taxol®.<sup>146</sup> A reasonable examiner would have wanted to know whether the unsuccessful use of MOM and TMS affected the ability to perform the invention.<sup>147</sup>

On appeal, the Federal Circuit rejected arguments raised by RPR.<sup>148</sup> RPR argued that the examiner must have reviewed the JACS Article because it was included in the search report found in the file history.<sup>149</sup> The Federal Circuit agreed with the district court's finding that it could not be presumed that the examiner reviewed the JACS Article where he had not checked off and initialed the references.<sup>150</sup> No presumption of the Patent Office regularity arose in the absence of objective evidence that the examiner actually reviewed the JACS Article prior to issuing the '011 patent.<sup>151</sup>

RPR also argued that because the examiner actually considered the JACS Article during the '277 reissue prosecution and allowed the patent to issue, the JACS Article was not material to patentability.<sup>152</sup> The Federal Circuit disagreed, stating that the standard of materiality was: (a) not whether one particular examiner considered the reference to be important, but instead, a reasonable examiner;<sup>153</sup> and (b) a reference is not immaterial simply because the claims are eventually deemed by an examiner to be patentable over the reference.<sup>154</sup> The court noted that it was not enough that the withheld references were eventually provided to the examiner because they "were not cited when they should have been."<sup>155</sup>

The Federal Circuit was not persuaded that the district court gave insufficient weight to Pilard's statement that the JACS Article was "irrelevant."<sup>156</sup> The Federal Circuit affirmed the district court's finding that Pilard's statement was neither persuasive nor credible.<sup>157</sup> All of RPR's arguments were rejected, and the

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<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 1234–35.

<sup>147</sup> *Id.* at 1235.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* at 1236. Furthermore, as stated by the Federal Circuit:

The MPEP § 717.05 (5th ed. rev. 6 Oct. 1987) states that an examiner "should indicate which publications [on a search printout] were reviewed by initialing and dating the copy of the printout in the left margin adjacent to each reviewed publication." Thus, had the Examiner been performing his duties "regularly," he would have initialed and dated [next] . . . to the JACS article if he read it.

*Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* at 1236–37.

<sup>153</sup> *Id.* at 1237.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at 1237–38.

<sup>157</sup> *Id.* at 1238. In doing so, the Federal Circuit stated:

[G]iven Mr. Pilard's extensive chemical engineering background, he would have known that a person of ordinary skill in the art would read the statements in the JACS article either to apply to TMS and MOM at any yield or, at the very least, to be unclear. Specifically, the district court could not reconcile Mr. Pilard's

nondisclosure was found to be material from the standpoint of a reasonable patent examiner.<sup>158</sup>

### 3. Withholding JACS Article With Intent to Deceive

The Federal Circuit also affirmed the district court's finding of an intent to mislead the Patent Office by the withholding of the JACS Article.<sup>159</sup> The district court found: 1) Pilard intentionally drew the '011 patent overly broad; 2) Pilard was aware of the JACS Article at all times; and 3) Pilard was also aware of a patentee's duty of candor and disclosure to the Patent Office.<sup>160</sup> The district court further found that Pilard's justifications for nondisclosure of the JACS Article were insufficient and not credible.<sup>161</sup> The Federal Circuit deferred to the district court's assessment of Pilard's credibility.<sup>162</sup>

As it did with the element of materiality, the Federal Circuit rejected RPR's arguments challenging the finding of intent to deceive the Patent Office by failing to disclose the JACS Article.<sup>163</sup> First, RPR claimed that Pilard lacked the requisite intent because he approved publication of the JACS Article without requesting the omission or qualification of the statements regarding the limitations of the MOM and TMS protecting groups.<sup>164</sup> The Federal Circuit disagreed, stating that RPR's duty of disclosure was to the Patent Office, and publication of the JACS Article did not constitute a disclosure to the Patent Office.<sup>165</sup>

The Federal Circuit also rejected RPR's argument that Pilard lacked intent because he deemed the JACS Article irrelevant.<sup>166</sup> In doing so, the court noted that Pilard's statement came after the issuance of the '011 patent, and thus had no bearing on Pilard's intent with regard to the prosecution of the '011 patent.<sup>167</sup>

RPR's claim that its inventors had a good faith belief that the MOM and TMS groups would work was also rejected.<sup>168</sup> The Federal Circuit found no such belief articulated in the JACS Article.<sup>169</sup> Moreover, the court found RPR's intent not to

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knowledge that "the protecting group at C-7 has to be stable . . . to the subsequent esterifying conditions" with his position that the statement in the JACS article, TMS "proved unstable to the subsequent esterification conditions," was not adverse.

*Id.*

<sup>158</sup> *Id.* at 1238–39.

<sup>159</sup> *Id.* at 1239–41.

<sup>160</sup> *Id.* at 1239.

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

<sup>162</sup> *Id.* at 1240 n.10. In doing so, the Court noted that Pilard did not even appear at the hearing on intent. *Id.* Consequently, the district court used portions of his videotaped depositions and a transcript of his depositions to assess his credibility. *Id.* The district court noted that Pilard's responses at that deposition were less than candid. *Id.*

<sup>163</sup> *Id.* at 1240.

<sup>164</sup> *Id.* at 1241.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

disclose the JACS Article was at issue, and not whether there was a good faith belief that their invention was enabled.<sup>170</sup>

Lastly, RPR argued that Pilard lacked the requisite intent because it was permissible for him to seek broad patent rights.<sup>171</sup> The Federal Circuit found this argument missed the point.<sup>172</sup> The issue was not that RPR could not seek broad patent rights, but rather that the motivation of seeking broad patent rights evidenced an impetus for Pilard intentionally withholding the JACS Article from the Patent Office.<sup>173</sup>

Therefore, the Federal Circuit affirmed the district court in finding that Bristol had met its burden by proving, with clear and convincing evidence, a material nondisclosure and an intent to deceive.<sup>174</sup> Failure to disclose the JACS Article with intent to mislead the Patent Office resulted in a finding of inequitable conduct and unenforceability of the '277 patent.<sup>175</sup>

*C. Dayco Products, Inc., v. Total Containment, Inc.*<sup>176</sup>

Dayco Products, Inc., (“Dayco”) sued Total Containment, Inc., (“TCI”) for infringement of four patents (“patents-in-suit”) related to flexible hoses and couplings for use in underground gas containment systems.<sup>177</sup> TCI moved for summary judgment based on purported inequitable conduct committed by Dayco during the prosecution of the patents-in-suit.<sup>178</sup> The district court granted TCI’s motion finding the patents unenforceable.<sup>179</sup> The Federal Circuit reversed and remanded, finding that summary judgment was improper because there were genuine issues of material fact to be resolved at trial.<sup>180</sup>

The patents-in-suit originated as a series of continuation applications to United States Application Serial No. 408,161 filed on September 15, 1989 (“the '161 application”).<sup>181</sup> On August 6, 1991, the '161 application issued as United States Patent No. 5,037,143 (“the '143 patent”).<sup>182</sup>

Dayco was also the assignee of a separate family of patents that claim original priority to United States Application Serial No. 993,196 (“the '196 family”) filed on

<sup>170</sup> *Id.*

<sup>171</sup> *Id.* at 1242.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> 329 F.3d 1358 (Fed. Cir. 2003).

<sup>177</sup> *Id.* at 1360. The four patents-in-suit were: U.S. Patent Nos. 5,199,752 (“the '752 patent”), 5,297,822 (“the '822 patent”), 5,380,050 (“the '050 patent”), and 5,486,023 (“the '023 patent”) (collectively “the patents-in-suit”).

<sup>178</sup> *Id.* TCI also moved for summary judgment of invalidity on certain claims of these patents.

*Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at 1361.

<sup>182</sup> U.S. Patent No. 5,037,143 (issued Aug. 6, 1991).

December 18, 1992.<sup>183</sup> The technology disclosed in the '196 family is substantially identical to that disclosed in the '161 family of applications.<sup>184</sup>

Both the applications for the patents-in-suit and the '196 family of applications were drafted by the same attorney, and both were pending at the Patent Office at the same time.<sup>185</sup> However, the applications had been assigned to two different examiners at the Patent Office.<sup>186</sup> The '196 family of applications included specific references to the applications for the patents-in-suit.<sup>187</sup> However, the applications for the patents-in-suit from the '161 family of applications, made no reference to the applications in the '196 family.<sup>188</sup> The patents-in-suit issued without an indication that the examiner was aware of applications and patents in the '196 family.<sup>189</sup>

During prosecution of the applications in the '196 family, the examiner, on three separate occasions, rejected the claims under 35 U.S.C. § 103 as being obvious over United States Patent No. 3,331,981 (“the Wilson reference”) and another reference.<sup>190</sup> The Wilson reference was never cited by Dayco to the examiner of the applications for the patents-in-suit.<sup>191</sup>

TCI moved for summary judgment based on inequitable conduct.<sup>192</sup> The district court granted TCI's motion, holding the patents to be unenforceable based on inequitable conduct.<sup>193</sup> The district court cited three facts as its basis for finding unenforceability:

- (1) pendency of the '196 application before a different examiner;
- (2) the Wilson patent; and
- (3) the obviousness rejection of claims in the '196 application based on Wilson.<sup>194</sup>

The Federal Circuit overturned the district court's inequitable conduct findings.<sup>195</sup>

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<sup>183</sup> *Dayco*, 329 F.3d at 1361. “The '196 application itself was abandoned during prosecution, and two continuation applications, U.S. Application Nos. 197,891 (“the '891 application”) and 263,275 (“the '275 application”), were filed claiming priority therefrom. The '891 and '275 applications respectively issued as U.S. Patent Nos. 5,356,182 (“the '182 patent”) and 5,430,929 (“the '929 patent”).” *Id.*

<sup>184</sup> *Id.* The technology disclosed in the '196 family is directed to flexible hoses and coupling assemblies. *Id.*

<sup>185</sup> *Id.* at 1365.

<sup>186</sup> *Id.* at 1361.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 1361. Claims submitted in the '196 family of applications were rejected as being unpatentable over United States Patent No. 3,331,981 (“Wilson”) in view of United States Patent No. 5,096,234 (“Oetiker”).

<sup>191</sup> *Id.* at 1362.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 1363–64. The Federal Circuit initially reviewed the standard for materiality applied by the PTO, which was altered in 1992 during the prosecution of the patents-in-suit. *Id.* at 1363. The Court stated: “for many years this court has 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.” *Id.* The information did not need to be prior art, but merely any information a reasonable examiner would be likely to

The Federal Circuit agreed with the district court that materiality was established.<sup>196</sup> The *Manual of Patent Examining Procedure* (“M.P.E.P.”) required the inventors to disclose the existence of the co-pending '196 application to the examiner of the applications for the patents-in-suit.<sup>197</sup> Citing *Akron Polymer Container Corp., v. Exxel Container, Inc.*, the Federal Circuit held that under the “reasonable examiner” standard of materiality, “[an] application was highly material to the prosecution of [an application, where] it could have conceivably served as the basis of a double patenting rejection.”<sup>198</sup> Thus, the Federal Circuit concluded that had Dayco disclosed the '196 application to the examiner, the examiner could have rejected the applications that issued as the patents-in-suit because of the prohibition against double patenting.<sup>199</sup>

Dayco claimed that there was no double patenting issue because the patents-in-suit were subject to a terminal disclaimer limiting their terms to the priority date of the '143 patent which would be shorter than any patent that could have conceivably issued from the '196 application.<sup>200</sup> Thus, information as to the pendency of the '196 application was irrelevant and could not be material. The Federal Circuit rejected Dayco's argument noting that the shortening of the term of the patent is not the only effect of filing a terminal disclaimer.<sup>201</sup> The terminal disclaimer also would have subjected the patents-in-suit to a common ownership limitation with the '196 family.<sup>202</sup> Thus, the failure to disclose the co-pending '196 patent did not subject them to this limitation, and was found to be material.

While affirming the district court's findings of materiality, the Federal Circuit found that TCI failed to establish Dayco's deceptive intent.<sup>203</sup> The Federal Circuit, citing *Akron Polymer*, indicated that “intent could not be inferred because the patentee did ‘disclose the existence of the application [that became the patents-in-

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consider important in determining patentability. *Id.* In 1992, the PTO amended its rules and more narrowly defined materiality. *Id.* Material art either establishes “a prima facie case of unpatentability” or “refutes, or is inconsistent with a position an applicant takes.” *Id.* at 1364. The Federal Circuit, without applying a specific standard, agreed with the district court finding of materiality. *Id.* The Court indicated that because of the restrictive effect of a possible double-patenting rejection, nondisclosure of the '196 applications was clearly material under either standard. *Id.* at 1366.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.* at 1365. The M.P.E.P. § 2001.06(b) states in relevant part: “[I]f a[n] . . . inventor has different applications pending in which similar subject matter but patentably indistinct claims are present, that fact must be disclosed to the examiner of each of the involved applications. Manual of Patent Examining Procedure, 8th ed. Rev. 1, (2003).

<sup>198</sup> *Dayco*, 329 F.3d at 1365 (citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998)). Under the double patenting doctrine an inventor is prohibited from obtaining “a second patent for claims that are not patentably distinct from the claims of a first patent.” *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997).

<sup>199</sup> *Dayco*, 329 F.3d at 1366.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.* Had Dayco disclosed the '196 applications, it could have received a double patenting rejection from the examiner. *Id.* To overcome this rejection Dayco must file a terminal disclaimer, which includes a provision stating: “that any patent granted on that application . . . shall be enforceable only for and during such period *that said patent is commonly owned with the application or patent which formed the basis for the rejection.*” 37 C.F.R. § 1.321(c)(3) (2002) (emphasis added).

<sup>203</sup> *Dayco*, 329 F.3d at 1366.

suit] to the [196] application's examiner, and thus put the Patent Office on notice of the co-pendency of the two applications.”<sup>204</sup> Because the examiner of the '196 patent application was notified of the '161 application's existence, no intent to deceive could be inferred.<sup>205</sup>

The Federal Circuit also reversed the district court's finding of materiality and intent to deceive based upon the nondisclosure of the Wilson reference.<sup>206</sup> Dayco submitted a declaration from its expert explaining why the Wilson reference was not submitted.<sup>207</sup> The expert explained that Wilson was from the field of electrical conduits, which he felt did not address the point of novelty of the patents-in-suit.<sup>208</sup> Thus, the Federal Circuit held that this evidence created a question of material fact that precluded summary judgment.<sup>209</sup>

The Federal Circuit also ruled that “[i]ntent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.”<sup>210</sup> Dayco submitted an affidavit from the attorney who prosecuted the applications, who explained that in good faith he considered the Wilson reference to be far afield from the accused patents at the time it was cited.<sup>211</sup> The Federal Circuit found this explanation plausible.<sup>212</sup>

Moreover, the Federal Circuit held the fact that the examiner found the Wilson reference to be material, while informative, was not dispositive.<sup>213</sup> For these reasons, the Federal Circuit reversed the district court and found that TCI failed to make a threshold showing of materiality or intent in connection with the Wilson reference.<sup>214</sup>

In remanding the issue to the trial court, the Federal Circuit noted that on the present record, there was no basis for a claim of unenforceability concerning the failure to disclose the co-pending '196 application or the Wilson patent.<sup>215</sup> Absent the discovery of material new evidence, the Federal Circuit directed the district court to entertain summary judgment of no inequitable conduct.<sup>216</sup>

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<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 1367.

<sup>207</sup> *Id.* at 1366.

<sup>208</sup> *Id.* Dayco's expert also opined that two references cited to the examiner were also cumulative of the Wilson reference. *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.* The Federal Circuit also addressed the district court's finding that Dayco's failure to disclose the rejection of the substantially similar co-pending '196 application was a material omission. In doing so, it stated that it had not addressed this issue previously. *Id.* In affirming the district court's finding, the Federal Circuit announced that under the *Akron Polymer* “reasonable examiner” standard and under new Rule 56, a contrary decision of another examiner reviewing substantially similar claims meets the threshold of materiality. *Id.* at 1368. However, the district court made no finding on the issue of intent. *Id.* Thus, a trial on the issue was necessary. *Id.*

<sup>215</sup> *Id.* at 1371.

<sup>216</sup> *Id.* at 1371.

*D. Ulead Systems, Inc., v. Lex Computer & Management Corp.*<sup>217</sup>

In the most recent of the Federal Circuit decisions addressing the issue of inequitable conduct, Ulead Systems, Inc. (“Ulead”) brought a declaratory judgment action of invalidity and unenforceability of Lexmark Computer & Management Corporation’s (“Lex”) United States Patent No. 4,538,188 (“the ‘188 patent”).<sup>218</sup> In its complaint, Ulead charged that the ‘188 patent was unenforceable and invalid because Lex misrepresented to the Patent Office that it qualified as a small entity to avoid paying the higher periodic maintenance fee for its ‘188 patent.<sup>219</sup> Ulead moved for summary judgment based on unenforceability.<sup>220</sup>

The district court agreed with Ulead, and on summary judgment, declared Lex’s ‘188 patent unenforceable because Lex had intentionally misrepresented itself to the Patent Office as qualifying for small entity status.<sup>221</sup> The district court found Lex’s misrepresentation material.<sup>222</sup> The Federal Circuit remanded, finding that while Lex had made a material misrepresentation to the Patent Office concerning its status as a small entity, genuine issues of fact remained as to intent.<sup>223</sup>

*1. The District Court’s Finding of Inequitable Conduct*

When Lex acquired the ‘188 patent in 1986, it had fewer than twenty employees.<sup>224</sup> When Lex paid its first maintenance fee in 1988, Lex properly paid the fee at the reduced rate.<sup>225</sup> Later, Lex granted several non-exclusive licenses to companies with more than 500 employees.<sup>226</sup> These entities did not qualify for small entity status under 37 C.F.R. § 1.9.<sup>227</sup> After granting these licenses, Lex submitted its second maintenance fee for the ‘188 patent to the Patent Office, along with a

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<sup>217</sup> 351 F.3d 1139 (Fed. Cir. 2003).

<sup>218</sup> *Id.* at 1141.

<sup>219</sup> *Id.* at 1143.

<sup>220</sup> *Id.*

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> *Id.* at 1150.

<sup>224</sup> *Id.* at 1142.

<sup>225</sup> *Id.* As stated by the Federal Circuit:

The PTO rules define a “small entity” as a small business concern, independent inventor, or non-profit organization. 37 C.F.R. § 1.9(f) “Small business concern” is defined in accordance with the definition established by the Small Business Administration (“SBA”). 37 C.F.R. § 1.9(d). The applicable SBA regulation states as follows: a small business concern for purposes of paying reduced fees . . . to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.

*Id.*

<sup>226</sup> *Id.* at 1142.

<sup>227</sup> *Id.*

petition that included a Verified Statement Claiming Small Entity Status.<sup>228</sup> The verified statement stated in relevant part: “no rights . . . are held by any person . . . who could not qualify as a small business concern under 37 C.F.R. § 1.9(d).”<sup>229</sup> The Patent Office accepted the reduced fee.<sup>230</sup> When Lex submitted its third maintenance fee, it again represented its entitlement to small entity status.<sup>231</sup>

After Ulead moved for summary judgment of inequitable conduct, Lex immediately acted to correct the error in fee payment by submitting the balance of the deficiency to the Patent Office, in accordance with the procedures for correcting the erroneous underpayment.<sup>232</sup> The Patent Office accepted the payment and changed Lex's status.<sup>233</sup>

In response to Ulead's motion for summary judgment, Lex admitted it was not entitled to claim small entity status and was not entitled to the reduced rates at the time it paid its second and third maintenance fees.<sup>234</sup> While Lex claimed that it had innocently claimed small entity status and failed to pay the proper fee,<sup>235</sup> the district court granted Ulead's motion, holding the patent unenforceable because of Lex's misrepresentation to the Patent Office.<sup>236</sup>

## 2. *The Federal Circuit Vacates and Remands*

The Federal Circuit vacated and remanded the district court's finding of inequitable conduct.<sup>237</sup> In doing so, it stated that there was no serious question as to the materiality of the misrepresentation to the Patent Office.<sup>238</sup> The misrepresentation that Lex qualified as a small entity was material to the Patent Office's acceptance of the reduced maintenance fees, and thus, survival of the patent.<sup>239</sup>

However, the Federal Circuit found that there was a genuine issue of material fact in dispute as to intent unresolvable on summary judgment.<sup>240</sup> As pointed out by

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<sup>228</sup> *Id.* Lex had also apparently let his patent lapse and submitted a petition to reinstate or revive, which was accepted by the Patent Office. *Id.*

<sup>229</sup> *Id.* at 1142–43.

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* at 1143.

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.* at 1146. In a strong dissent issued by Justice Newman, she challenged that the underpayment of fees is not a matter of inequitable conduct. *Id.* at 1151. Rather, Justice Newman would require proof of fraudulent conduct associated with fee payment. *Id.* Justice Newman noted the differences between the inequitable conduct standard and the Walker Process fraud standard, as explained in *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998). Specifically, the action of fraud cannot be maintained without showing affirmative knowledge of its falsity. *Id.* The history of 37 U.S.C. § 1.28(c) governing the maintenance fees to be paid by small entity refers to fraud, rather than to inequitable conduct, and Justice Newman felt it inappropriate to apply an inequitable test to this provision of the Federal Code. *Id.* at 1150–56.

<sup>239</sup> *Id.* at 1146.

<sup>240</sup> *Id.*



the court, Lex's president, Mr. Haberman, testified that he was not aware that a non-exclusive license to a large entity would result in the loss of small entity status.<sup>241</sup> The court noted, despite the fact that Lex's president is a lawyer, his primary expertise was real estate law.<sup>242</sup> The court also found that the Patent Office form to be submitted with the small entity fee was ambiguous.<sup>243</sup> Unlike the codified regulation, the small entity form used does not specifically refer to licensing.<sup>244</sup>

Lex also provided the declaration from its patent counsel, Mr. Weiner ("Weiner"), who testified that he did not intend to deceive the Patent Office.<sup>245</sup> While Weiner testified that he understood the law governing the qualifications for small entity status, he was unaware until after Ulead raised the issue in this case that Lex had entered into any licenses with companies having more than 500 employees.<sup>246</sup> Lex's patent counsel further indicated that "he did not directly represent Lex in acquiring any of its licenses" and "was unaware that Lex had finalized license agreements" with entities having more than 500 employees.<sup>247</sup> The Federal Circuit found Lex's patent counsel's statements were plausible and the misrepresentation appeared to be negligent, rather than made with actual intent to deceive.<sup>248</sup> Consequently, the court concluded that a trial on the issue of intent was required to assess the credibility of the witnesses would be assessed.<sup>249</sup>

#### IV. NECESSITY AND EFFECT OF A PLAUSIBLE EXPLANATION AS TO LACK OF INTENT TO DECEIVE IN LIGHT OF *HOFFMANN*, *BRISTOL-MYERS*, *DAYCO* AND *ULEAD*

Nothing in these recent Federal Circuit decisions changes the law that even high materiality alone is not enough to support a finding of inequitable conduct.<sup>250</sup> However, the Federal Circuit's decisions in *Hoffmann-La Roche*, *Bristol-Myers*, *Dayco*, and *Ulead* suggest that conduct surrounding a misrepresentation or withholding of highly material information may be so suspect, or at least can be cast so negatively, that proceeding without a plausible explanation of the conduct raises an unacceptable risk of an inequitable conduct finding.

Interestingly, the more highly technical the subject matter of the dispute, the greater the uncertainty of whether the challenged err or omission will be considered material. This may dictate a need to provide a plausible explanation of the conduct. While strengthening the defense to an inequitable conduct charge, providing such an explanation may open the door to intrusive and costly discovery.

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<sup>241</sup> *Id.*

<sup>242</sup> *Id.* at 1147.

<sup>243</sup> *Id.*

<sup>244</sup> *Id.* Specifically, the 1993 declaration stated: "[i]f the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person . . . who could not qualify as a small business concern under 37 C.F.R. 1.9(d)." *Id.*

<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

<sup>247</sup> *Id.*

<sup>248</sup> *Id.* at 1148.

<sup>249</sup> *Id.*

<sup>250</sup> *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1366 (Fed. Cir. 2003)

*A. Factual Underpinnings Bearing on Materiality Can Raise an Inference of Intent Sufficient to Support a Finding of Inequitable Conduct*

In *Bristol-Myers*, the facts surrounding withholding the clearly material JACS Article gave rise to a strong inference of intent to mislead and ultimately a finding of inequitable conduct.<sup>251</sup> In *Hoffmann-La Roche*, the court found that because there was an affirmative misrepresentation that tests had been performed rather than merely an omission of information, the misrepresentation was judged more material.<sup>252</sup> Thus, the facts surrounding this material misrepresentation also provided the basis for an inference of intent to deceive the Patent Office, sufficient to support a finding of inequitable conduct.<sup>253</sup> In both *Bristol-Myers* and *Hoffmann-La Roche* the inference of intent to deceive the Patent Office was not adequately rebutted.

*B. Providing “A Plausible Explanation” Is Essential When a Credible Inference of Deceptive Intent Can Be Made*

In *Dayco* and *Ulead*, unlike *Hoffmann-La Roche* and *Bristol-Myers*, there was no finding of inequitable conduct because “a plausible explanation” was provided for the questioned conduct.<sup>254</sup> In *Dayco*, the Federal Circuit agreed that the failure to disclose the '196 family of applications as part of the prosecution of applications in the '161 patent family was material.<sup>255</sup> Nonetheless, the Federal Circuit found the district court erred regarding the required intent element of inequitable conduct.<sup>256</sup> In doing so, the court reaffirmed that the applicable standard for the intent element is an intent to deceive, not merely an intent to withhold.<sup>257</sup> Evaluated on that basis, the evidence offered by the patentee regarding a lack of intent to deceive the Patent Office was found to be “plausible,” and thus sufficient, to avoid finding inequitable conduct on summary judgment.

Specifically, in *Dayco*, the declaration of the attorney, who prosecuted the patent, explained that in good faith he had concluded the withheld Wilson reference was not material.<sup>258</sup> He explained he did not consider it prior art because “he

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<sup>251</sup> *Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239–40 (Fed. Cir. 2003).

<sup>252</sup> *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003).

<sup>253</sup> *Id.* at 1366–67.

<sup>254</sup> *Dayco*, 329 F.3d at 1367; *Ulead*, 351 F.3d at 1147–48; *see also* *CFMT, Inc., v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342–43.

This court recognizes that a district court may infer intent to deceive the PTO. However, even gross negligence does not alone suffice to establish intent. Instead, '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'.

*CFMT*, 349 F.3d at 1342–43 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)).

<sup>255</sup> *Dayco*, 329 F.3d at 1366.

<sup>256</sup> *Id.*

<sup>257</sup> *Id.* at 1367.

<sup>258</sup> *Id.*

considered it far afield from the accused patents at the time it was cited.”<sup>259</sup> The Federal Circuit found that explanation plausible and suggested Dayco's good faith sufficient for remand.<sup>260</sup>

As in *Dayco*, the Federal Circuit agreed in *Ulead* with the district court's finding that the misrepresentation of entitlement to small entity status was material; however, it vacated the district court's finding of intent to deceive in view of the patentee's evidence that an innocent error occurred.<sup>261</sup> Specifically, in *Ulead*, the declarations of the patentee's general counsel and patent counsel were found at summary judgment to be sufficient to overcome any presumption of intent that attached as a consequence of the material misrepresentation to the Patent Office that Lex qualified as small entity.<sup>262</sup>

In contrast to *Dayco* and *Ulead*, the patentee in *Hoffmann-La Roche* offered no evidence that use of the past tense in Example VI (describing an experiment that was never performed) was merely an oversight by the inventor.<sup>263</sup> Nor did the inventor provide a reasonable explanation as to why he used past tense in the patent when, in the context of a scientific publication, to do so would clearly imply that the experiment was actually performed.<sup>264</sup> As stated by the court:

There was no suggestion by Roche that the use of the past tense in Example VI was an oversight—Dr. Gelfand admitted he understood that, at least in a scientific publication, the use of the past tense means that an experiment was actually performed. He provided no reasonable explanation as to why a different principle would apply in a patent application. Nor did Roche introduce any other evidence to explain why the past tense was used to describe an experiment that was not performed. Accordingly, the district court did not clearly err in determining that the inventors' use of the past tense in Example VI was knowingly false.<sup>265</sup>

The misrepresentation concerning Example VI was clearly material.<sup>266</sup> The facts surrounding Example VI and what it described gave rise to the inference of intent—an inference found not to have been rebutted in a meaningful fashion.<sup>267</sup>

Similarly, in regards to Hoffmann La Roche's misrepresentations with respect to the fidelity issue, Promega offered testimony of an expert in the field who had allegedly worked with the inventors.<sup>268</sup> The Promega expert testified that he was aware of the inventors' knowledge of template dependency and fidelity and that the inventors could not possibly believe the representations they were making were

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<sup>259</sup> *Id.*

<sup>260</sup> *Id.*

<sup>261</sup> *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1148 (Fed. Cir. 2003).

<sup>262</sup> *Id.* at 1146–48. The materiality of an erroneous representation of small entity status was an issue of disagreement between the majority and Judge Newman as expressed in her dissent. *Id.* at 1151.

<sup>263</sup> *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003).

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> *Id.* at 1368.

<sup>267</sup> *Id.* at 1367–68.

<sup>268</sup> *Id.* at 1371–72.

accurate.<sup>269</sup> Again, Hoffman-La Roche failed to put forward any evidence to suggest that its inventors' interpretation of the prior art testing, while inaccurate, was reasonable.<sup>270</sup> Thus, the only evidence before the court was the expert testimony of the accused infringer, who felt very strongly that the inventors knew better.<sup>271</sup>

In *Bristol-Myers*, the failure to disclose the JACS Article in the prosecution of the '011 patent was clearly a material omission and the facts surrounding the failure to disclose the article raised a strong inference of intent.<sup>272</sup> Strong rebuttal evidence was needed. Instead, as found by the court, the patentee offered implausible testimony to rebut intent.

The district court viewed the patent agent's testimony that the prior art article that was withheld was "irrelevant"<sup>273</sup> as being neither persuasive, nor credible, given the clear materiality of the article.<sup>274</sup> The Federal Circuit commented on the district court's finding, indicating that given the extensive chemical engineering background of the patent agent, he knew or should have known that a person of ordinary skill in the art would read the statements in the withheld article as applying to the subject matter of the patent.<sup>275</sup> The decision of the Federal Circuit was clear: to counter the inference of deceptive intent, based on the circumstances surrounding withholding the highly material JACS Article, something more than the conclusionary testimony of the patent agent was required.<sup>276</sup>

Because the facts underlying a finding of materiality can also give rise to an inference of intent to deceive, the need for evidence countering any such inference of intent to deceive increases as the level of materiality rises. In *Hoffmann-La Roche* and *Bristol-Myers*, the failure to provide any credible evidence ("plausible explanation") supported a finding of inequitable conduct in each case. Contrastingly, in *Dayco* and *Ulead*, the patentee offered a credible explanation for the challenged conduct, at least for the purposes of avoiding summary judgment.

#### V. A PLAUSIBLE EXPLANATION MAY WAIVE PRIVILEGE

While a plausible explanation can counter an inference of deceptive intent, conduct asserted to be improper in connection with withholding or misrepresenting material information does not come without a cost. When confronted with withheld prior art or an erroneous statement to the Patent Office, the need to provide an explanation for the error or omission may require that the patentee introduce otherwise privileged communications.

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<sup>269</sup> *Id.*

<sup>270</sup> *Id.* at 1372.

<sup>271</sup> *Id.* at 1371–72.

<sup>272</sup> *Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239–40 (Fed. Cir. 2003).

<sup>273</sup> *Id.* at 1237–38.

<sup>274</sup> *Id.* at 1238.

<sup>275</sup> *Id.*

<sup>276</sup> For example, there was no indication of credible testimony as to *why* the patent agent felt the article was "irrelevant."

For example, the Federal Circuit has held that an invention record is a privileged attorney-client communication.<sup>277</sup> However, providing the “plausible explanation” to refute any inference of deceptive intent may require the disclosure of client communications that are part of the invention record. If such a disclosure is made, attorney-client privilege will likely be waived.<sup>278</sup>

Waiver of attorney client privilege of communications to support an inequitable conduct charge is exemplified in *Winbond Electronics Corp. v. International Trade Commission*.<sup>279</sup> There, the plaintiff, Amtel, filed a complaint with the International Trade Commission (“ITC”) alleging that Macronix International, Co., Ltd, and Windbond Electronics Corp., (among others) were importing, selling for importation, or selling in the United States semiconductor chips that infringed Amtel’s United States Patent No. 4,451,903 (“the ‘903 patent”).<sup>280</sup> The alleged infringers responded, claiming that the ‘903 patent was invalid for failing to name Anil Gupta (“Gupta”) as a co-inventor on the ‘903 patent.<sup>281</sup>

During the first ITC hearing, Gupta testified that he was not an inventor of the ‘903 patent’s claimed device.<sup>282</sup> Gupta testified that he merely implemented the element of the invention using well-known techniques.<sup>283</sup> However, Gupta also testified that he *designed* circuits that were part of the structure corresponding to the means-plus-function claims of the invention.<sup>284</sup> The administrative law judge (“ALJ”) concluded that Gupta was in fact an inventor of the ‘903 patent, and the failure to list Gupta as an inventor rendered the patent unenforceable.<sup>285</sup> The ITC, looking at the ALJ’s decision, stated that it had no power to correct the inventorship of the ‘903 patent, and therefore affirmed the finding of the ALJ that the patent was unenforceable until either the Patent Office or a court corrected the record.<sup>286</sup>

In response, Amtel filed a Certification of Correction with the Patent Office identifying Mr. Gupta as a named inventor.<sup>287</sup> In his declaration to the Patent Office, Gupta stated:

The standard for inventorship as it relates to the 903 patent has been explained to me. Based on my understanding of that standard, I hereby state that I have made an inventive contribution to the subject matter

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<sup>277</sup> *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 806 (Fed. Cir. 2000) (technical information is privileged as long as it is provided to an attorney “for the purpose of securing primarily legal opinion, or legal services, or assistance in a legal proceeding.”) *Spalding* contrasted directly with a line of cases, including *Jack Winter, Inc., v. Koratron Co.*, 50 F.R.D. 225, 228 (N.D. Cal. 1970), which held that such technical information communicated to an attorney, and documents relating to the prosecution of patent applications are non-privileged.

<sup>278</sup> *See, e.g.*, *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1273 (Fed. Cir. 2001) (Where patent attorney testified at an earlier trial about prior art and communications with client, the privilege was waived to all communications and documents related to that same subject).

<sup>279</sup> No. 01-1031, 2001 U.S. App. LEXIS 25113 (Fed. Cir. 2001).

<sup>280</sup> *Id.* at \*6. The Complaint was filed in January of 1997. *Id.* at \*31.

<sup>281</sup> *Id.* at \*6.

<sup>282</sup> *Id.* at \*6–7.

<sup>283</sup> *Id.* at \*7.

<sup>284</sup> *Id.* at \*23.

<sup>285</sup> *Id.* at \*7.

<sup>286</sup> *Id.*

<sup>287</sup> *Id.* at \*8–9.

claimed in the 903 patent, whereby I am a co-inventor of the claimed subject matter of the 903 patent.<sup>288</sup>

Amtel then petitioned the ITC for a rehearing.<sup>289</sup> At the rehearing, the ITC remanded the matter to the ALJ who again found the '903 patent unenforceable for listing the wrong inventors.<sup>290</sup> During the course of the second hearing, the ALJ ordered Amtel to disclose privileged documents concerning the inventors of the '903 patent.<sup>291</sup> Amtel again appealed the ALJ's decision to the ITC.<sup>292</sup>

At the rehearing of the ALJ's second decision, the ITC found that Amtel had not committed inequitable conduct before the Patent Office based upon Gupta's explanation.<sup>293</sup> The ITC did agree with the ALJ's finding that Amtel had waived attorney-client privilege and was required to produce all documents otherwise protectable by the work product doctrine.<sup>294</sup> The ITC stated: "Amtel explicitly placed the legal advice to [Mr.] Gupta—and the fact that [Mr.] Gupta had obtained legal advice—at issue' in these proceedings."<sup>295</sup>

The Federal Circuit affirmed the ALJ's finding (and ITC's affirmance) that Amtel had waived the attorney-client privilege.<sup>296</sup> The scope of the waiver included all communications and on all documents from the time period when Amtel was preparing for the ITC's initial review (January 1997), up to the time before Amtel petitioned the ITC for the second reconsideration hearing.<sup>297</sup>

Attorney-client communications may provide strong evidence that there was no attempt to withhold information or to otherwise deceive the patent examiner (rebutting an inference of intent). However, use of such communications will put them at issue, resulting in a waiver of the attorney-client privilege.<sup>298</sup> That being the case, the scope of the waiver becomes a significant issue.

In *Winbond*, Amtel could not dispute that a waiver occurred.<sup>299</sup> Rather, Amtel attempted to narrow the scope of the waiver to the time period after the ITC issued its initial decision addressing inventorship law, but before Amtel filed its correction with the Patent Office.<sup>300</sup> Because Amtel had placed Gupta's understanding of the law in issue in its petition for reconsideration, the Federal Circuit commented

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<sup>288</sup> *Id.* at \*23–24.

<sup>289</sup> *Id.* at \*9.

<sup>290</sup> *Id.* This time the ALJ found Gupta should not have been listed as a co-inventor because the inventors had withheld material information from the PTO in issuing the certificate of correction. *Id.*

<sup>291</sup> *Id.* at \*9–10.

<sup>292</sup> *Id.* at \*10.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> *Id.* at \*31.

<sup>296</sup> *Id.* at \*33. Under the ALJ's Order, Amtel was not required to produce any documents generated before January 1997, when Amtel filed its complaint with the ITC. *Id.* at \*31. The administrative law judge also limited the scope of the disclosure so that Amtel was not required to produce attorney-client communications or attorney work product made in preparation for the 1998 reconsideration hearing. *Id.* "The Commission affirmed the administrative law judge's temporal limitations on the scope of Amtel's waiver." *Id.*

<sup>297</sup> *Id.* at \*33.

<sup>298</sup> *Id.*

<sup>299</sup> *Id.* at \*31.

<sup>300</sup> *Id.* at \*31–\*32.

approvingly on the ALJ's determination that the period of waiver should include the time when Amtel filed its complaint with the ITC up to the time just before Amtel petitioned the ITC for a rehearing.<sup>301</sup>

In considering the use of otherwise privileged information to explain or counter an assertion of intentional deception of the Patent Office, one must appreciate that the potential scope of the waiver may be broad. To shed light on the motivations of the patentee or its representatives, the waiver could extend to all discussions and documents regarding the patentee's views of the patents or prior art that are considered.

Faced with possible unenforceability of the patent, the existence of credible "materiality" issues can force the patentee to waive privileged communications in order to withstand a charge of inequitable conduct. Such waiver can lead to far more intrusive and costly discovery activities. An accused infringer is more apt to tolerate, if not embrace, extensive discovery to avoid the specter of patent infringement, enhanced damages, and damages and payment of attorney's fees. As evidenced by *Hoffmann-La Roche* and *Bristol-Myers*, sometimes the defense succeeds. Including the decisions in *Dayco* and *Ulead*, one can see that employing the inequitable conduct defense adds complexity and cost to the underlying patent dispute. Given the high stakes of winning or losing patent infringement cases, inequitable conduct battles can be expected to continue.

## VI. CONCLUSION

*Hoffmann-La Roche*, *Bristol-Myers*, *Dayco*, and *Ulead* do not appear to have changed the basic inequitable conduct assessments of materiality and intent to deceive the Patent Office. However, when the level of materiality of the withheld or inaccurate information presented to the Patent Office increases, these decisions reiterate the need for measured, adequate, and credible explanations to establish good faith during the prosecution of the patent to rebut an inference of deceptive intent.

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<sup>301</sup> *Id.* at \*32–33.