

12-1-2009

## **Vol. 1 No. 1, Fall 2009; Current Trends in Inequitable Conduct are Adverse to Patent Policy as Seen Through the Exemplary Case of Big Pharma**

Joshua M. Austin

Follow this and additional works at: [https://huskiecommons.lib.niu.edu/niulr\\_sup](https://huskiecommons.lib.niu.edu/niulr_sup)



Part of the [Law Commons](#)

---

### **Original Citation**

Joshua M. Austin, Comment, Current Trends in Inequitable Conduct are Adverse to Patent Policy as Seen Through the Exemplary Case of Big Pharma, 1 N. Ill. Univ. L. Rev. Online Supp. 33 (2009).

This Article is brought to you for free and open access by the College of Law at Huskie Commons. It has been accepted for inclusion in Northern Illinois Law Review Supplement by an authorized administrator of Huskie Commons. For more information, please contact [jschumacher@niu.edu](mailto:jschumacher@niu.edu).

# Current Trends in Inequitable Conduct are Adverse to Patent Policy as Seen Through the Exemplary Case of Big Pharma

I.	INTRODUCTION.....	33
II.	AN INTRODUCTION TO PATENT LAW .....	34
	A. A BRIEF LOOK AT PATENT LAW AND INEQUITABLE CONDUCT ...	34
III.	INEQUITABLE CONDUCT.....	38
	A. INTENT .....	38
	B. MATERIALITY .....	44
IV.	A BRIEF INTRODUCTION TO THE FEDERAL CIRCUIT .....	49
V.	CURRENT INTERPRETATIONS OF INEQUITABLE CONDUCT VIOLATE THE POLICIES BEHIND PATENT LAW .....	50
VI.	THE EXEMPLARY CASE OF BIG PHARMA .....	52
	A. WHY BIG PHARMA IS A PARTICULARLY CONCRETE EXAMPLE OF AN INDUSTRY HURT BY THE CURRENT TRENDS IN INEQUITABLE CONDUCT .....	52
	B. CASES WHERE BIG PHARMA HAS FELT THE STING OF RECENT CONFUSION IN INEQUITABLE CONDUCT.....	58
	C. THE KINDS OF PROBLEMS CURRENT TRENDS CREATE FOR BIG PHARMA .....	62
VII.	SOLUTIONS FOR THE PROBLEMS CREATED BY CURRENT TRENDS ....	63
VIII.	CONCLUSION .....	64

## I. INTRODUCTION

Patent law is a varied and rapidly changing sector of law. As a result, it is exceedingly difficult for patent attorneys to keep abreast of the changing laws and the varying interpretations that judges pass down. In the words of two practitioners, “Trying to keep current with changes in patent law is like trying to navigate the rooms of a carnival fun house.”<sup>1</sup>

One of the most confusing aspects of patent law is the doctrine of inequitable conduct. This confusion stems from the courts in the Federal Circuit changing how they view the elements of inequitable conduct, that is,

---

1. Janet A. Pioli & Meredith Martin Addy, *The Patent Law Fun House—What Next?*, 1 NO. 1 LANDSLIDE 46, 47 (2008) (discussing recent Supreme Court and Federal Circuit decisions in patent cases, as well as proposed reforms, and comparing them to a fun house in that these decisions “throw IP practitioners off balance and make them wonder, as they grab for a hand-hold, what surprises can possibly be next”).

the changes in the element of intent and its standard,<sup>2</sup> as well as the changes in the element of materiality and its standard.<sup>3</sup>

This Comment addresses the doctrine of inequitable conduct, its changes, how current interpretations of inequitable conduct by the Federal Circuit run contrary to the principles of patent law, and the special impact that these changes in inequitable conduct have upon a particularly affected group: the industry of big pharmaceutical companies (“Big Pharma”). First, this Comment briefly familiarizes the reader with the basics of patent law and the basics of the doctrine of inequitable conduct. Second, this Comment discusses the elements of inequitable conduct and its meaning, including its role as a defense in patent infringement cases and what results come from a finding of inequitable conduct. The discussion of inequitable conduct will involve an examination of the recent changes and trends that have led to the present confusion in the doctrine of inequitable conduct. Third, this Comment briefly discusses the role the Federal Circuit plays in patent law. This Comment then postulates that the current interpretations and confusion in inequitable conduct are contrary to the major policy reasons behind patent law. A discussion of the exemplary case of Big Pharma follows this postulation and exists as an example of an industry particularly damaged by the current trends. This includes a discussion of why Big Pharma is in a particular situation within patent law and why they are particularly harmed by the current trends, which make Big Pharma an example of the impacts the current trends can have. The Comment then addresses the problems that inequitable conduct creates for Big Pharma outside of patent law, and finally, offers potential solutions to the problem of unclear and inconsistent holdings in inequitable conduct, and, more specifically, how to clarify the rule so that one can ensure that one works within the law in order to enjoy all the potential benefits of patents and the policy reasons therein.

## II. AN INTRODUCTION TO PATENT LAW

### A. A BRIEF LOOK AT PATENT LAW AND INEQUITABLE CONDUCT

Patents play an important role in our system of economics,<sup>4</sup> as well as our legal system. The United States Constitution grants Congress power to

---

2. See, e.g., James E. Hanft & Stacey S. Kearns, *The Return of the Inequitable Conduct Plague: When “I Did Not Know” Unexpectedly Becomes “You Should Have Known,”* INTELL. PROP. & TECH. L.J., Feb. 2007, at 1.

3. See, e.g., Elizabeth Peters, *Are We Living in a Material World?: An Analysis of the Federal Circuit’s Materiality Standard Under the Patent Doctrine of Inequitable Conduct*, 93 IOWA L. REV. 1519, 1531-39 (2008).

4. ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2, at 11 (5th ed. 2001).

“promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>5</sup>

Further, patent law serves important policy concerns. First and foremost among the policy concerns behind patent law is encouraging inventiveness.<sup>6</sup> Due to the fact that many people can use innovative technology without depriving others of the same usage, it is “hard to identify and prevent those who will not pay for its use from using it.”<sup>7</sup> Thus patent law exists to protect inventors from encroachment of this nature in order to “preserve incentives to invent.”<sup>8</sup> In fact, “[t]he principal basis for intellectual property protection in the United States is the utilitarian or economic incentive framework. That is, intellectual property in the United States is fundamentally about incentives to invent and create.”<sup>9</sup> A further policy concern, as the Constitution notes, is to allow one to have secured rights in one’s invention for a limited time.<sup>10</sup> Finally, patent law policy protects and furthers consumer interests as well.<sup>11</sup> Patent law makes innovation a tradable commodity, allowing for freer communication and specialization, as well as demanding disclosure, which allows inventors to learn from the progresses made by one another.<sup>12</sup> All of this can arguably benefit consumers by the creation of better goods at lower costs. But what does it take to obtain a patent so that one can enjoy the above benefits?

In order to obtain a patent, there must first be an invention, which can take significant time and money.<sup>13</sup> An applicant must then file an application with the United States Patent and Trademark Office (USPTO).<sup>14</sup> And finally, one must prosecute the patent application before the USPTO.<sup>15</sup> An examiner will then look into each claim made in the application to deter-

5. U.S. CONST. art. I, § 8.

6. See 1 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST* § 1.1, at 1-2 to 1-3 (Supp. 2008).

7. FEDERAL TRADE COMMISSION, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* 6 (2003), <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (calling intellectual property “non-rivalrous”).

8. *Id.*

9. See HOVENKAMP ET AL., *supra* note 6, at 1-2.

10. U.S. CONST. art. I, § 8.

11. FEDERAL TRADE COMMISSION, *supra* note 7, at 6.

12. *Id.* at 5.

13. Keith A. Zullo & Raivo A. Karmas, *Intellectual Property: Obtaining a Patent*, 53.3 CEREAL FOODS WORLD 147, 147 (2008).

14. 35 U.S.C. § 111 (2000); see also Peters, *supra* note 3, at 1525.

15. Zullo & Karmas, *supra* note 13, at 147.

mine if a patent should be awarded.<sup>16</sup> In order to qualify for a patent, the invention or process must be “(1) patentable subject matter, (2) useful, (3) novel, and (4) nonobvious.”<sup>17</sup>

In order to meet the requirement of patentable subject matter, the invention must be “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>18</sup> As is apparent by this statutory language, usefulness is also an essential element of an invention in order to obtain a patent.<sup>19</sup> Further, an applicant must fully describe such usefulness of the invention in clear terms.<sup>20</sup>

One must also meet the element of novelty in addition to patentable subject matter and usefulness, and, in pertinent part, in regard to novelty:

A person shall be entitled to a patent unless—(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or sale in this country, more than one year prior to the date of the application for patent in the United States.<sup>21</sup>

Therefore, if anyone else has patented or described the invention in any country,<sup>22</sup> or if the inventor is beaten to the patent office,<sup>23</sup> then the invention fails to meet the threshold of novelty and is unpatentable.<sup>24</sup>

---

16. Russell E. Levine et al., *Ex Parte Patent Practice and the Rights of Third Parties*, 45 AM. U. L. REV. 1987, 1993 (1996) (detailing the process by which an examiner determines patentability by scrutinizing an application and looking for prior art).

17. See 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”).

18. *Id.*

19. *Id.*

20. 35 U.S.C. § 112 (2000) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”).

21. 35 U.S.C. § 102 (2000).

22. *Id.*

23. 35 U.S.C. § 102(g)(1) (“[B]efore such person’s invention thereof, the invention was made by such other inventor and not abandoned, suppressed, or concealed, or . . . before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.”).

24. 35 U.S.C. § 102.

Finally, an applicant must ensure that the invention is nonobvious.<sup>25</sup> Even if the invention is of patentable subject matter, useful, novel, and not identical to prior patented material, a patent will not be issued if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”<sup>26</sup>

The application process also involves certain disclosures, specifically “all information known to that individual to be material to patentability.”<sup>27</sup> Information is considered to be material to patentability when it is not just adding to existing information and it either establishes a prima facie case of unpatentability or contests “a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.”<sup>28</sup> If one fails to meet these materiality standards, the court has a doctrine by which to punish transgressors, the doctrine of inequitable conduct.

Inequitable conduct is a failure, during the patent application process, to disclose any of the aforementioned material information, or submitting false information, “with an intent to deceive.”<sup>29</sup> This means that in order to have a finding of inequitable conduct, two separate elements must be proved: intent and materiality.<sup>30</sup> If inequitable conduct is found by a court, the result is that the patent at issue is rendered unenforceable,<sup>31</sup> and other closely related patents may be held unenforceable as well.<sup>32</sup>

---

25. 35 U.S.C. § 103 (2000).

26. 35 U.S.C. § 103(a).

27. 37 C.F.R. § 1.56 (1992).

28. *Id.*

29. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

30. *Id.*

31. *Id.* at 877; *J.P. Stevens & Co., v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984).

32. *Baxter Int'l, Inc. v McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998) (“[I]nequitable conduct with respect to one claim renders the entire patent unenforceable. However, where the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.” (citations omitted)).

### III. INEQUITABLE CONDUCT

#### A. INTENT

Traditionally, courts have swung back and forth between requiring clear and convincing proof of an intent to deceive<sup>33</sup> and allowing a showing of gross negligence where one knew or should have known of a failure to disclose material information<sup>34</sup> when looking for a standard to use for finding intent. Shortly before the Federal Circuit definitively clarified the intent standard, however, courts were still allowing a standard of gross negligence to apply.<sup>35</sup> This standard can also be thought of as a “should have known” standard.<sup>36</sup> Although there may have been no actual knowledge of an invention already patented or published<sup>37</sup> or of an invention whose differences in subject matter with the invention being patented would have been obvious<sup>38</sup> (“prior art”) that was material, there were circumstances which nevertheless gave rise to a neglected duty.<sup>39</sup> The court in *FMC Corp. v. Hennessy Industries, Inc.*, in considering the fact that there is, in general, no duty to conduct a prior art search, rejected any defense to inequitable conduct that involved an applicant acting in a manner to avoid gaining knowledge of pertinent information, which the court noted did not happen in the case, when it was unclear whether the examiner had looked at the prior art at issue.<sup>40</sup> In other words, “one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art.”<sup>41</sup>

The Federal Circuit finally provided what appeared to be a definitive clarification for how one must prove intent in the case of *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*<sup>42</sup> In *Kingsdown Medical*, an attorney for Kingsdown, while submitting a continuation application,<sup>43</sup> accidentally

33. See, e.g., *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987).

34. See, e.g., *In re Jerabek*, 789 F.2d 886, 891 (Fed. Cir. 1986); *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984).

35. *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 (Fed. Cir. 1987).

36. *Id.* at 526 n.6.

37. 35 U.S.C. § 102 (2000).

38. 35 U.S.C. § 103 (2000).

39. *FMC Corp.*, 836 F.2d at 526.

40. *Id.*

41. *Id.* at 526 n.6.

42. 863 F.2d 867, 876 (Fed. Cir. 1988).

43. United States Patent and Trademark Office, *201.07 Continuation Application [R-3]* - 200 Types, Cross-Noting, and Status of Application, [http://www.uspto.gov/web/offices/pac/mpep/documents/0200\\_201\\_07.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/0200_201_07.htm) (last visited Feb. 14, 2009) (“A continuation is a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented.”).

included a rejected version of a patent claim instead of the new, approved version.<sup>44</sup> The district court found intent for inequitable conduct because they held that the attorney was grossly negligent in failing to notice this error.<sup>45</sup> The Federal Circuit, on appeal, held that alone, gross negligence was insufficient to prove intent to deceive.<sup>46</sup> 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.”<sup>47</sup> The Federal Circuit, using this reasoning, held that the district court erred when it found inequitable conduct due to the inclusion of the rejected version of a patent claim because it drew an inference of intent to deceive from gross negligence.<sup>48</sup> In order to overturn the case law and precedent that had been established by prior decisions in the Federal Circuit, the portion of *Kingsdown Medical* declaring that gross negligence is insufficient to show intent was heard and decided by an en banc court<sup>49</sup> because precedent cannot be changed by a panel.<sup>50</sup> This effectively created a much more conservative and difficult to prove standard for finding inequitable conduct,<sup>51</sup> thus helping to alleviate what the Federal Circuit had coined “an absolute plague” in the field of patent law.<sup>52</sup> This meant that one is required to show “sufficient culpability to require a finding of intent to deceive,”<sup>53</sup> which could “be met by direct evidence of intent, circumstantial evidence of intent, or evidence of recklessness.”<sup>54</sup> This created a more difficult path for showing intent to deceive than the prior gross negligence standard had laid out.

Unfortunately, this clarity has become confused in the decisions of the Federal Circuit following *Kingsdown*.<sup>55</sup> The confusion first began in 2003 with the Federal Circuit’s decision in *Hoffman-La Roche, Inc. v. Promega*

44. *Kingsdown*, 863 F.2d at 870-71.

45. *Id.* at 871-72.

46. *Id.* at 876.

47. *Id.*

48. *Id.* at 875-76.

49. *Kingsdown*, 863 F.2d at 876-77.

50. *S. Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982).

51. This finding meant that inequitable conduct must be proven beyond gross negligence and must, at the very least, include evidence of additional circumstances that help to show a finding of intent. Christopher Darrow & Scott R. Hansen, *Defending on the Equities: Five Equitable Defenses for Patent Litigators*, 424 PLI / PAT 185, 194 (1995).

52. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

53. *Kingsdown*, 863 F.2d at 876.

54. Shashank Upadhye, *Liar Liar Pants on Fire: Towards a Narrow Construction for Inequitable Conduct as Applied to the Prosecution of Medical Device and Drug Patent Applications*, 72 UMKC L. REV. 669, 670 tbl.I (2004).

55. *Id.* One author, who tackled the inequitable conduct problem as a whole, has compiled a list, as of 2004, of all the Federal Circuit cases in the last twelve years involving inequitable conduct. *Id.*



*Corp.*,<sup>56</sup> which dealt with two different findings of inequitable conduct.<sup>57</sup> The two findings of inequitable conduct stemmed from failing to perform all steps in an example in the specific order set forth, while using past tense<sup>58</sup> and characterizing prior art as being less effective than the invention at hand—a comparison the court found to be inaccurate.<sup>59</sup> The inventor used the past tense to describe an experiment, giving the impression that it had been completed when it had not.<sup>60</sup> The court held that discussing an experiment in a specific way using the past tense on a patent application would make people understand that the experiment had been done exactly in that fashion, and, therefore, a finding of intent to deceive would be proper based on the confusion such actions would cause.<sup>61</sup> The court further stated that inequitable conduct was an appropriate finding in a case in which the inventor stated that everything in the application was true, despite having known how the past tense language would be taken and not giving a “reasonable explanation” for that use of past tense.<sup>62</sup> The court rejected the argument that regardless of how the experiment had progressed it would have worked, stating that the use of past tense, its inference of completion, and the fact that the experiment was not completed as stated, was still determinative of intent.<sup>63</sup>

The court in *Hoffman-La Roche* further confused the standard when it did not address specifically what the knowledge level of the inventor was and instead accepted the interpretation of an expert, used by the defendant infringer, as to what the knowledge level of the inventor was, claiming that this established an intent to deceive.<sup>64</sup> The court was not persuaded by the fact that the inventor did not testify as to his own knowledge, and instead

---

56. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003); see also Hanft & Kearns, *supra* note 2, at 2-3.

57. *Hoffman-La Roche*, 323 F.3d at 1357-72; see also Hanft & Kearns, *supra* note 2, at 2-3.

58. *Hoffman-La Roche*, 323 F.3d at 1363-66; see also Hanft & Kearns, *supra* note 2, at 2-3. In biotechnology patents, use of the past tense is understood to mean that action or experiment was done, while the present tense is used to show experiments that have yet to be done. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURES, § 608.01(p) (8th ed. 2001).

59. *Hoffman-La Roche*, 323 F.3d at 1366; see also Hanft & Kearns, *supra* note 2, at 2-3.

60. *Hoffman-La Roche*, 323 F.3d at 1363-66.

61. *Id.* at 1363-67; see also Hanft & Kearns, *supra* note 2, at 2-3.

62. *Hoffman-La Roche*, 323 F.3d at 1366-67; see also Hanft & Kearns, *supra* note 2, at 2-3.

63. See *Hoffman-La Roche*, 323 F.3d. at 1364; see also Hanft & Kearns, *supra* note 2, at 2-3.

64. *Hoffman-La Roche*, 323 F.3d at 1371-72; see also Hanft & Kearns, *supra* note 2, at 2-3.

allowed an inference from what an expert who worked with the inventor said the inventor knew or should have known.<sup>65</sup>

The Federal Circuit further confused this issue in the case of *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*<sup>66</sup> The patent in this case was for a ripe human growth hormone beneficial for cell growth and metabolism.<sup>67</sup> The language used on the patent included phrases such as “was purified,” “was evaluated,” and “was then treated,” despite the fact that actions had not been performed as described.<sup>68</sup> That means that this case, like *Hoffman-La Roche*, also involved drafting and the use of the past tense, with one difference: the inventor in this case was foreign.<sup>69</sup> Despite that fact, the court rejected the argument that he could not be charged with knowledge because he was not aware of what the past tense would mean.<sup>70</sup> The Federal Circuit held that an inventor was charged with knowledge of the law despite the lack thereof, and then, from there, inferred that the inventor should have known of the materiality of certain information.<sup>71</sup>

The court once again clouded intent for practicing attorneys shortly after *Novo Nordisk* in the case of *Ferring B.V. v. Barr Laboratories, Inc.*<sup>72</sup> In this case, a patent was filed for an orally administered antidiuretic.<sup>73</sup> Originally, the examiners were not entirely convinced of the claims that language used in an old patent held by Ferring did not discuss oral administration but rather discussed absorption through the walls of the mouth.<sup>74</sup> As such, the examiners suggested that they “obtain evidence from a non-inventor.”<sup>75</sup> The inventor failed to use “disinterested persons” as affiants as to the effectiveness of the invention despite being present to hear the examiners state that they were concerned about the identity of affiants and the self-serving nature of the affiants used by the inventor.<sup>76</sup> The Federal Circuit held that the inventor should have known he was to use “disinterested persons,” a material fact, and thus inferred an intent to deceive.<sup>77</sup> This is evidence that the court once again swung back to easier standards for inequitable conduct by using the “should have known” standard despite the court’s holding in

---

65. See *Hoffman-La Roche*, 323 F.3d at 1371-72; see also Hanft & Kearns, *supra* note 2, at 2-3.

66. 424 F.3d 1347 (Fed. Cir. 2005).

67. *Id.* at 1349.

68. *Id.* at 1363.

69. See *id.* at 1361.

70. *Id.* at 1361-62.

71. *Novo Nordisk*, 424 F.3d at 1361-62.

72. 437 F.3d 1181 (Fed. Cir. 2006).

73. *Id.* at 1183.

74. *Id.*

75. *Id.* at 1183-84.

76. *Id.* at 1191-92.

77. *Ferring B.V.*, 437 F.3d at 1191-94.

*Kingsdown Medical*.<sup>78</sup> Judge Newman, in her dissent, berated the majority for, as she put it, “not only ignor[ing] *Kingsdown* . . . [but] also impos[ing] a positive inference of wrongdoing, replacing the need for evidence with a ‘should have known’ standard.”<sup>79</sup>

The court appeared to swing back toward the *Kingsdown* standard in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, an infringement case based on Purdue Pharma’s patent on Oxycontin.<sup>80</sup> The trial court inferred intent from materiality<sup>81</sup> when “Purdue failed to disclose material information because it did not inform the PTO that the ‘discovery’ was based on ‘insight’ without ‘scientific proof.’”<sup>82</sup> This was based upon a finding that “the lack of scientific proof of a four-fold dosage range for oxycodone was a material fact inconsistent with statements made by Purdue to obtain allowance of the patent claims over the examiner’s rejections.”<sup>83</sup> But the Federal Circuit held, correctly, that the trial court should not have inferred intent from materiality.<sup>84</sup> Unfortunately, right after this statement, the court used language reopening the door by stating that “when materiality . . . is relatively low, there are fewer bases for inferring intent from materiality alone.”<sup>85</sup> This sounds as though the court is saying if something were highly material, then intent could be inferred, despite the court’s reiteration of the error in the trial court’s analysis.<sup>86</sup>

Even more recently, the Federal Circuit seemed to use a less strict standard of intent in the case of *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*<sup>87</sup> This case dealt with a claim that new compositions, marketed as Lovenox, showed a large increase in half-life which would result in lower dosages being needed in order to treat the same problems as prior art.<sup>88</sup> Aventis argued that this comparison was allowable to show a difference in *property*, not *composition*.<sup>89</sup> The court, however, found that in failing to disclose that the dosage of the prior art used in the experiment was

---

78. *Id.* at 1196 (Newman, J., dissenting); *see also* Hanft & Kearns, *supra* note 2, at 3-4.

79. *Ferring B.V.*, 437 F.3d at 1196 (Newman, J., dissenting).

80. *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006).

81. *Id.* at 1134-35; *see also* Hanft & Kearns, *supra* note 2, at 4.

82. *Purdue Pharma*, 438 F.3d at 1128.

83. *Id.* at 1130.

84. *Id.* at 1134-35.

85. *Id.* at 1135; *see also* Hanft & Kearns, *supra* note 2, at 4.

86. *See Purdue Pharma*, 438 F.3d at 1135; *see also* Hanft & Kearns, *supra* note 2, at 4.

87. 525 F.3d 1334 (Fed. Cir. 2008).

88. *Id.* at 1339.

89. *Id.* at 1342-43.

was different; there was intent to deceive.<sup>90</sup> The court deferred to the district court as to this finding of deceptive intent *over direct testimony* as to what a non-inventor chemist meant in his very own representations made to the examiners regarding dosages.<sup>91</sup> This appears to be less than specific intent, especially in light of the dissenting opinion of Judge Rader.<sup>92</sup> Judge Rader noted that *Kingsdown* was a clear response by the court to the abuse of inequitable conduct in too many patent infringement cases.<sup>93</sup> He articulated that “*Kingsdown* properly made inequitable conduct a rare occurrence” and was further discomfited by the more recent process of emphasizing materiality to the near exclusion of intent altogether.<sup>94</sup> Judge Rader noted that the non-inventor voluntarily revealed the error, showing a candor that stands against a finding of deceptive intent and, when looked at in the context of *Kingsdown*, the trial court’s finding of inequitable conduct should have been overturned because such candor and actions in good faith are inconsistent with findings of intent to deceive.<sup>95</sup>

Recently, the Federal Circuit took what might very well be a huge leap forward.<sup>96</sup> Following through on her dissent in *Ferring B.V. v. Barr Laboratories*,<sup>97</sup> Judge Newman recently passed down a decision sending the Federal Circuit back on the right course, which is back toward *Kingsdown*.<sup>98</sup> In light of this decision, there is hope that the doctrine of inequitable conduct will become clear once more, and further that it will return to the doctrine the Federal Circuit initially deemed to be correct.<sup>99</sup>

In this new case, *Abbott Laboratories v. Sandoz, Inc.*, the court reiterated the holding in *Kingsdown* that “[t]o be guilty of inequitable conduct, one must have intended to act inequitably” . . . and . . . “[i]nequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements . . . must be proven by clear and convincing evidence.”<sup>100</sup> The court also reiterated that gross negligence is insufficient for a holding of inequitable conduct, thus reiterating the need for clearly articulated intent to deceive.<sup>101</sup>

---

90. *Id.*

91. *Id.* at 1348.

92. *Aventis*, 525 F.3d at 1349-53 (Rader, J., dissenting).

93. *Id.* at 1350.

94. *Id.*

95. *Id.* at 1352-53.

96. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

97. *Ferring B.V. v. Barr Labs., Inc.*, F.3d 1181, 1196 (Fed. Cir. 2006) (Newman, J., dissenting).

98. 863 F.2d 867 (Fed. Cir. 1988).

99. *Id.* at 876.

100. *Abbott Labs.*, 544 F.3d at 1353.

101. *Id.*

The court then proceeded to hold, on two different patents marketed as Biaxin®XL,<sup>102</sup> that inequitable conduct had not been established.<sup>103</sup> The charges were that “Abbott submitted a false declaration to the PTO, and also that Abbott withheld from the examiner the results of certain tests after the patent applications were filed and that were inconsistent with information in the patent applications.”<sup>104</sup> The trial court rejected the argument that intent could be inferred from materiality and the Federal Circuit agreed.<sup>105</sup> As to the ‘718 patent, the court stated that clear error had not been shown to overrule the district court’s judgment that a study was not material under any standard.<sup>106</sup> As for the ‘616 patent, the court’s continuation of *Kingsdown* was even more clear, in that the court found that “[t]here was no evidence of intent to deceive . . . [and further] [m]ateriality, even if found, does not establish intent.”<sup>107</sup> This may begin to swing the pendulum away from the Federal Circuit having been comfortable with the idea of inferring intent when some information was found to have been material.<sup>108</sup> However, the Federal Circuit is subject to change,<sup>109</sup> and while this decision might be comforting, it is unclear as to whether this is just a blip on the radar, or whether the Federal Circuit is actually coming back to *Kingsdown*.

This trend and confusion of loosening the standard for finding intent becomes even more problematic when matched with recent trends in findings of materiality because both elements must be met. Confusion with one element alone would make this a difficult topic, but confusion in both elements makes it nearly impossible to plan for this kind of litigation.

#### B. MATERIALITY

Before the current standard for materiality was set forth in the Code of Federal Regulations, materiality was determined by addressing whether or not there was a “substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”<sup>110</sup> In 1992, a new version of this rule came into effect and upon

---

102. *Id.* at 1343-44; *see also* U.S. Patent No. 6,010,718 (filed Apr. 11, 1997); U.S. Patent No. 6,551,616 (filed Dec. 19, 1995).

103. *Abbott Labs.*, 544 F.3d at 1353-58.

104. *Id.* at 1353.

105. *Id.* at 1354-55.

106. *Id.* at 1356.

107. *Id.* at 1357.

108. *See, e.g.*, *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196 (Fed. Cir. 2006) (Newman, J., dissenting); *see also* Hanft & Kearns, *supra* note 2, at 3-4.

109. *See infra* notes 156-64 and accompanying text.

110. 37 C.F.R. § 1.56 (1989); Douglas R. Nemeck, *Current Trends in Equitable Defenses to Patent Infringement: Prosecution Laches and Inequitable Conduct*, 766 PRAC. L. INST. 1035, 1072 (2003).

its adoption, it created a narrower definition of materiality.<sup>111</sup> Unfortunately, the Federal Circuit has not allowed itself to be bound by this new, clear definition, instead stating that the new definition was not a clear break from the old,<sup>112</sup> leaving themselves open to use different standards to judge materiality.

This newer rule, breaking from the old “reasonable examiner” test, although under the same code section, designated information as material if it “establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or . . . [i]t refutes, or is inconsistent with, a position the applicant takes in: . . . [o]pposing an argument of unpatentability relied on by the [o]ffice, or . . . [a]sserting an argument of patentability.”<sup>113</sup> The USPTO acknowledged that this section was amended to provide a “clearer and more objective definition” of what is considered by the USPTO to be material.<sup>114</sup> Unfortunately, much like the element of intent, this clarity would not remain.

While it took some time after the amending of 37 C.F.R. § 1.56 for the issue of the definition to come before the Federal Circuit,<sup>115</sup> the definition has still been handled, since its adoption, in a way so as to convolute it and confuse those applying for patents.<sup>116</sup> For instance, much like the element of intent, the Federal Circuit has confused the issue of materiality by failing to abide by the Code of Federal Regulations.<sup>117</sup> The Federal Circuit has justified these breaks from the new definition by stating that “the new standard was not intended to constitute a significant break with the previous standard.”<sup>118</sup>

The confusion began when the court looked to the pre-1992 definition of materiality, in light of the new standard, when it looked at the case of *Hoffman-La Roche*,<sup>119</sup> a case discussed factually earlier in this Comment,<sup>120</sup> which involved experimental results that were claimed to have been accomplished when they actually were not.<sup>121</sup> The court held that, “[u]nder

111. 37 C.F.R. § 1.56(b) (1992); *see also* Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1363-64 (Fed. Cir. 2003); Nemec, *supra* note 110, at 1073.

112. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 (Fed. Cir. 2003) (citing Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992)).

113. 37 C.F.R. § 1.56(b) (1992); Nemec, *supra* note 110, at 1073.

114. Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992).

115. *Id.* (stating that the new standard laid out in 37 C.F.R. § 1.56 only applies to “applications pending or filed after March 16, 1992”); *see also* Peters, *supra* note 3, at 1532.

116. *See infra* notes 119-54 and accompanying text.

117. *See, e.g., Hoffman-La Roche*, 323 F.3d at 1368.

118. *Id.* (citing Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992)).

119. 323 F.3d at 1353 (Fed. Cir. 2003).

120. *See supra* notes 56-65 and accompanying text.

121. *Hoffman-La Roche*, 323 F.3d at 1363-68; *see also* Nemec, *supra* note 110, at 1074.

the circumstances, a reasonable examiner would have wanted to know that the patentability argument . . . was unsupported by the experimental results cited.”<sup>122</sup> The court did not use the current standards due to the prosecution of this patent beginning before the new standard took effect, but still acknowledged in a footnote that if the current standards had been used to determine materiality in this case, “there would be no questions that the . . . representations would be material.”<sup>123</sup> The court then said that the new standard was not intended to be a substantive break from the old “reasonable examiner” standard and was instead intended to simply clarify the old rule.<sup>124</sup> Why, if the Federal Circuit was dealing with the old standard, did they give an opinion as to what the new standard meant in light of the old standard?<sup>125</sup> One author answered this question by stating that this action by the court was a “clear implication . . . that the Federal Circuit does not intend to unduly restrict its analysis when judging materiality under one standard or the other.”<sup>126</sup>

The confusion continued when the Federal Circuit decided the case of *Dayco Products, Inc. v. Total Containment, Inc.*<sup>127</sup> The inequitable conduct in this case was based upon a failure to disclose prior applications that had very similar technology.<sup>128</sup> The court stated that despite typically following USPTO standards, it had not made the decision to follow the new standards as amended in 1992.<sup>129</sup> Much like in *Hoffman-La Roche*, the court acknowledged that their holding would be the same under either the old or new materiality standards.<sup>130</sup> The court then proceeded to use both standards in analyzing the issue of inequitable conduct.<sup>131</sup> This meant that they used both the “reasonable examiner” standard and the “prima facie/inconsistent” standard set out in the newly amended 37 C.F.R. § 1.46.<sup>132</sup> The only matter the court really clarified was what they were already obligated to do by law, namely that they would continue to use the pre-1992 “reasonable examiner” standard for patents prosecuted fully before the

---

122. *Hoffman-La Roche*, 323 F.3d at 1368.

123. *Id.*

124. *Hoffman-La Roche*, 323 F.3d at 1368 (citing Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992)).

125. *Hoffman-La Roche*, 323 F.3d at 1368.

126. Nemeč, *supra* note 110, at 1075.

127. 329 F.3d 1358 (Fed. Cir. 2001).

128. *Id.* at 1361-62.

129. *Id.* at 1364; *see also* Peters, *supra* note 3, at 1534.

130. *Dayco*, 329 F.3d at 1364.

131. *Id.* at 1364-68.

132. Peters, *supra* note 3, at 1534.

1992 amendment to 37 C.F.R. § 1.56.<sup>133</sup> Unfortunately, no clarity was given as to which standard would apply if a patent was issued after 1992.<sup>134</sup>

The Federal Circuit actually appeared to clarify the issue of when to use which standard of materiality shortly after *Dayco* in its decision in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*<sup>135</sup> This case dealt with a device that assisted in the ascending and descending of staircases by those who were mobility-impaired.<sup>136</sup> In *Bruno* the alleged inequitable conduct was an assertion by the defendant infringer that there had been an intentional withholding of prior art that could have quashed the patent during application due to a lack of novelty.<sup>137</sup> Specifically the argument was that Bruno had failed to disclose the existence of several “invalidating stairlifts that Bruno had submitted to the Food and Drug Administration in seeking approval to sell a stairlift covered” by a patent.<sup>138</sup> After stating that they had “consistently referred to the definition provided in 37 C.F.R. § 1.56,”<sup>139</sup> the court further stated that it would defer to the “[US]PTO’s formulation at the time an application [was] being prosecuted” in order to follow the expected standard.<sup>140</sup> Following this reasoning, the court used the new, amended standard that was set forth in the 1992 version of 37 C.F.R. § 1.56.<sup>141</sup> Under this standard, the court found that the matter in question was material, and since the court had already found intent, it found Bruno had committed inequitable conduct.<sup>142</sup>

The reasoning and holding in *Bruno*<sup>143</sup> appeared to bring the clarification that had been missing in *Dayco*,<sup>144</sup> that is, what the court would do if a patent were prosecuted after March 16, 1992.<sup>145</sup> *Dayco* had already clarified that the old rule for materiality would be used if the patent was prosecuted before March 16, 1992,<sup>146</sup> but now it appeared as if the court conclusively would be using post-1992 standards if the patent was prosecuted after that inception of 37 C.F.R. § 1.56.<sup>147</sup>

- 
- 133. *Dayco*, 329 F.3d at 1364.
  - 134. Peters, *supra* note 3, at 1534.
  - 135. 394 F.3d 1348 (Fed. Cir. 2005).
  - 136. *Id.* at 1350.
  - 137. *Id.*; *see also* Peters, *supra* note 3, at 1535.
  - 138. *Bruno*, 394 F.3d at 1350.
  - 139. *Id.* at 1352.
  - 140. *Id.*; *see also* Peters, *supra* note 3, at 1535.
  - 141. *Bruno*, 394 F.3d at 1352-53.
  - 142. *Id.*
  - 143. *Id.*
  - 144. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2001).
  - 145. *See* Peters, *supra* note 3, at 1535.
  - 146. *Dayco*, 329 F.3d at 1364.
  - 147. *Bruno*, 394 F.3d at 1352-53.



But, once again, the clarity did not remain. This became evident when the court heard the case of *Digital Control, Inc. v. Charles Machine Works*.<sup>148</sup> This case dealt with a patent prosecuted after the 1992 amendment to 37 C.F.R. § 1.56 and an accusation of inequitable conduct based upon multiple actions.<sup>149</sup> Before appeal, the district court found the matters to be material under the “reasonable examiner” standard.<sup>150</sup> At the Federal Circuit, the court decided that a court could use any of three standards to find materiality: (1) variations on a but-for test that had been used before the Code of Federal Regulations defined materiality,<sup>151</sup> (2) the “reasonable examiner” standard, or (3) the post-1992 amended standard.<sup>152</sup> The court considered that the new rules have provided an alternative way to find materiality, not set a definitive rule that must be followed to the exclusion of all others.<sup>153</sup> The court answered the question of what the court would do if the different standards required a higher or lower showing of materiality by stating that they would lower the “requisite finding[s] of intent” necessary to find inequitable conduct.<sup>154</sup>

Thus, it is difficult for any practicing attorney to anticipate which standard of materiality the court will use, and as such, it is difficult to determine what information must, or need not be, disclosed. This leaves the applicant submitting the patent open to challenges on inequitable conduct, despite thinking that he or she addressed all pertinent issues to ensure good faith and candor. This is contrary to the purpose of precedent in the legal system as it is to ensure that later attorneys will act in the proper fashion and later judges will have a framework for their decisions.<sup>155</sup>

---

148. 437 F.3d 1309 (Fed. Cir. 2006).

149. *Id.* at 1312-17. The first action that led to questions of inequitable conduct was a submission of a declaration “establishing that he had reduced his invention to practice prior to the effective date of the prior art reference” despite having never utilized the device below ground. *Id.* at 1312, 1317. The second action was when the inventor had a colleague submit a declaration confirming the truthfulness of the inventor’s declaration. *Id.* at 1312-13. The third and final action was a failure to disclose, as prior art, a patent that the inventor had previously submitted during a prior application. *Id.* at 1313.

150. *Digital Control*, 437 F.3d at 1316.

151. For an in-depth discussion of the even older standard of materiality, the three variations of a but-for test, see Peters, *supra* note 3, at 1530-31.

152. *Digital Control*, 437 F.3d at 1314-16.

153. *Id.* at 1315-16.

154. *Id.* at 1316.

155. As one social anthropologist has put it,

Regularity is what law in the legal sense has in common with law in a scientific sense. Regularity, it must be warned, does not mean absolute certainty. There can be no true certainty where human beings enter . . . In law, the doctrine of precedent is not the unique possession of the Anglo-American common law jurist . . . [P]rimitive law also builds on precedents, for there too, new decisions rest on old rules of law or norms

#### IV. A BRIEF INTRODUCTION TO THE FEDERAL CIRCUIT

Before discussing what current trends in inequitable conduct mean for patent law, especially when looked to under the exemplary case of Big Pharma, it is first important to have a basic understanding of the court that hears such cases, the Federal Circuit.

The United States Court of Appeals for the Federal Circuit was formed on October 1, 1982, when the Court of Customs and Patent Appeals and the Court of Claims merged.<sup>156</sup> The Federal Circuit has nationwide jurisdiction over matters such as government contracts, international trade, and, more importantly for present purposes, patent law.<sup>157</sup> Although specialized with what subject matter jurisdiction it has, the Federal Circuit also hears cases on appeal from all federal districts.<sup>158</sup>

The Federal Circuit consists of twelve judges.<sup>159</sup> These judges are appointed by the President and subject to the consent of the Senate.<sup>160</sup> When a case is heard, a panel of three judges is randomly assigned to the case.<sup>161</sup> In other words, it is unclear which judges a practitioner will face on appeal in front of the Federal Circuit. Thus, with different judges appearing at random<sup>162</sup> and new judges being appointed when necessary,<sup>163</sup> the Federal Circuit is likely to show varied opinions and changing standards. It is even clearer that decisions by the Federal Circuit are subject to change when precedent can be overturned when the court sits en banc.<sup>164</sup>

---

of custom, and new decisions which are sound tend to supply the foundations of future action.

E. ADAMSON HOEBEL, *THE LAW OF PRIMITIVE MAN: A STUDY IN COMPARATIVE LEGAL DYNAMICS* 28 (1954).

156. United States Court of Appeals for the Federal Circuit: About the Court, <http://www.cafc.uscourts.gov/about.html> (last visited Jan. 31, 2009).

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. United States Court of Appeals for the Federal Circuit: About the Court, <http://www.cafc.uscourts.gov/about.html> (last visited Jan. 31, 2009).

162. *Id.*

163. *Id.*

164. Note, *The Politics of En Banc Review*, 102 HARV. L. REV. 864, 864 (1989) (“En banc review gives all the judges on a circuit court of appeals an opportunity to reconsider a decision rendered by a three-judge panel.”).

## V. CURRENT INTERPRETATIONS OF INEQUITABLE CONDUCT VIOLATE THE POLICIES BEHIND PATENT LAW

The current trends and interpretations noted above<sup>165</sup> are adverse to the policy reasons for the existence of patent law. As discussed previously, the three major policy reasons for patent law are: (1) to encourage inventiveness, (2) to allow one to have secured rights in their invention for a limited time, and (3) to protect and further consumer interests.<sup>166</sup>

The current trends have arguably created more lenient standards for inequitable conduct, which may arguably lead to more frivolous allegations of inequitable conduct in patent cases—the same activity that was originally equated to a “plague.”<sup>167</sup> A rise of frivolous allegations can be seen first in a 1998 study which estimated that inequitable conduct was charged in 80% of patent cases, while only a small percentage were sustained.<sup>168</sup> Another study found that, in 2004, inequitable conduct was raised in 35% of all reported patent opinions.<sup>169</sup> Finally, another study showed that, from 1995 to 2004, the Federal Circuit granted (found no inequitable conduct) 42% of summary judgment motions on inequitable conduct.<sup>170</sup> As one author noted, this appears to show “that inequitable conduct is frequently raised when courts find no evidence of any wrongdoing.”<sup>171</sup> Further, one blogger performed a search of inequitable conduct on the LexisNexis electronic database of case law and found that between the years of 1993 and the time of his posting in 2008, inequitable conduct was charged in over 2100 patent cases—379 of which made it to the Federal Circuit.<sup>172</sup>

This rise in charges of inequitable conduct, especially in frivolous instances, could force patent holders to worry too much about litigation. It is likely that worrying about rising litigation will deter inventors from spending their time figuring out new inventions and improving on existing ones. This is adverse to the patent policy of protecting consumers because they

165. See *supra* notes 33-154 and accompanying text.

166. See *supra* notes 4-12 and accompanying text.

167. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

168. Committee Position Paper, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 76 (1988).

169. Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 156 (2006).

170. Katherine Nolan-Stevaux, Note, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 161 (2005).

171. Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 14 (2007).

172. Posting of Kevin E. Noonan to Patent Docs, [http://patentdocs.typepad.com/patent\\_docs/2008/04/new-york-times.html](http://patentdocs.typepad.com/patent_docs/2008/04/new-york-times.html) (Apr. 30, 2008, 23:57 EST).

may lose out on new and improved products. This is also adverse to encouraging inventiveness because people may choose to not pursue a patent due to uncertainty about such charges.<sup>173</sup> Further, this could drive litigation costs, hurting consumers who will probably feel this impact the most when it is passed to them in the form of higher costs for consumer goods at market.

The impact of looser standards and more charges of inequitable conduct is more far reaching than just encouraging more frivolous charges. As noted previously, less strict standards have led the Federal Circuit to find inequitable conduct, although the *Kingsdown* and Code of Federal Regulations standards may not have justified such a conclusion.<sup>174</sup> This might actually encourage patent infringement because it may be easier to find inequitable conduct. Having a “broad availability will encourage those charged with patent infringements to search for any evidence of misrepresentation or omissions years earlier.”<sup>175</sup> If so, this may encourage poaching on inventions, which would clearly violate the policies of encouraging inventiveness and securing rights for a limited time.

Further, with more findings of inequitable conduct, due to lessening standards, which arguably means that even more patents would be held unenforceable,<sup>176</sup> these findings would effectively end the life of the patent. A finding of inequitable conduct shortens the amount of time that one would have to profit from his or her invention through a finding of inequitable conduct, which may not have occurred had *Kingsdown* and the Code of Federal Regulations been more closely followed. As such, this too is adverse to the patent law policy of ensuring rights for a limited time. More importantly, as stated previously, this specific policy is found in the Constitution of the United States.<sup>177</sup>

---

173. ROBERT J. SHAPIRO & APARNA MATHUR, BIOTECHNOLOGY INDUSTRY ORGANIZATION, THE ECONOMIC IMPLICATIONS OF PATENT REFORM: THE DEFICIENCIES AND COSTS OF PROPOSALS REGARDING THE APPORTIONMENT OF DAMAGES, POST-GRANT OPPOSITION, AND INEQUITABLE CONDUCT 2 (2008), [http://www.bio.org/reg/media/patent\\_reform\\_study.pdf](http://www.bio.org/reg/media/patent_reform_study.pdf) (“[B]road use of the doctrine [of inequitable conduct] will increase investor uncertainties about the value of patents which they might finance, buy or license, discouraging the development and spread of economic innovations.”).

174. See *supra* notes 33-154 and accompanying text.

175. SHAPIRO & MATHUR, *supra* note 173.

176. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988); *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984).

177. The United States Constitution grants Congress power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8.

These current trends and their impact on patent policy can be confusing and damaging for all who wish to enforce a patent;<sup>178</sup> however, the harm that these current trends cause is clear when one looks at an example of an industry particularly damaged by the current trends in inequitable conduct: Big Pharma.

## VI. THE EXEMPLARY CASE OF BIG PHARMA

This Comment notes the changes and confusion in recent inequitable conduct decisions passed down by the Federal Circuit, but it seems easiest to discuss the ramifications of these decisions and their contrariness to patent law by looking at an example of an industry particularly harmed by recent trends. As such, the following discussion entails a look at the exemplary case of Big Pharma and how it is impacted by recent trends.

### A. WHY BIG PHARMA IS A PARTICULARLY CONCRETE EXAMPLE OF AN INDUSTRY HURT BY THE CURRENT TRENDS IN INEQUITABLE CONDUCT

There are three major reasons why Big Pharma is an example of an industry particularly impacted by recent changes in inequitable conduct and why it is particularly harmed: (1) the already limited amount of time that Big Pharma is able to maintain its patents, (2) the amount of money involved in pharmaceutical patents, and (3) the fierce competition and challenges that Big Pharma faces at the hands of generic pharmaceutical companies.

Patents filed on or after June 8, 1995 “begin on the date on which the patent issues and [end twenty] years from the date on which the application for the patent was filed in the United States.”<sup>179</sup> Patents filed before June 8, 1995 have terms which are the greater of the twenty year term as provided above, or seventeen years from grant.<sup>180</sup> Patents are granted to those who have invented a new drug that must be approved by the Food and Drug Administration (FDA) in order to send the drug to market.<sup>181</sup> Discovering

178. Hanft & Kearns, *supra* note 2, at 5 (“[T]he inventor and prosecuting attorney must be *mind-readers* regarding materiality during prosecution and must stay on guard for anything that can be the basis for inequitable conduct charges.” (emphasis added)). Further, the current “trend fails to recognize that prosecuting attorneys generally do not monitor the day-to-day activities of their clients” and surely more of this would be needed in order to be aware of any and all potentially material information in order to prepare for litigation. *Id.*

179. 35 U.S.C. § 154(a)(2) (2000).

180. 35 U.S.C. § 154(c)(1) (2000).

181. New Drug Application (NDA), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited Jan. 5, 2010). A New Drug Application must be filed with the FDA in order to be approved for sale and

and fully developing a new drug, which one obtains a patent and works towards FDA approval, takes, on average, twelve to fifteen years.<sup>182</sup> The natural effect of such time constraints is that “despite the standard [twenty] year patent life, the average effective patent life for a new drug—the amount of time where the product is sold under patent protection—is roughly [ten] to [twelve] years.”<sup>183</sup> Dealing with this FDA process, as well as the time constraints therein, shows how Big Pharma is a special case within patent law. Further, due to the fact that inequitable conduct renders a patent unenforceable,<sup>184</sup> thus effectively ending the time period for the product to be sold under patent protection, and the fact that current trends make it easier to find inequitable conduct,<sup>185</sup> Big Pharma’s time to sell under patent protection is cut even shorter. Big Pharma already deals with a shortened-time period due to FDA procedures and thus a finding of inequitable conduct effectively shortens an already curtailed time period. Given the fact that Big Pharma’s period of time to sell an invention protected by patent is cut even shorter than the typical time that an inventor enjoys patent protection, and because having exclusive rights to a patent is one of the major policies behind patent law,<sup>186</sup> Big Pharma is an example of an industry particularly harmed by the recent trends in the inequitable conduct doctrine as developed by the Federal Circuit.

Another pertinent reason why Big Pharma is a helpful example of an industry particularly harmed by current inequitable conduct trends is the sheer amount of money that is involved in the patent process of the pharmaceutical business. Even simple inventions can be fairly expensive to ob-

---

marketing commercially. *Id.* The New Drug Application should provide enough information to the reviewer from the FDA so that he or she has enough information to decide

[w]hether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks . . . [w]hether the drug’s proposed labeling (package insert) is appropriate, and what it should contain . . . [and] [w]hether the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity.

*Id.*

182. Neal Masia, *The Cost of Developing a New Drug*, in FOCUS ON INTELLECTUAL PROPERTY RIGHTS 82, Apr. 23, 2008, <http://www.america.gov/st/econ-english/2008/April/20080429230904myleen0.5233981.html>.

183. *Id.*

184. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988); *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984).

185. *See supra* notes 33-154 and accompanying text.

186. *See* U.S. CONST. art. I, § 8. The United States Constitution grants Congress power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” *Id.*

tain patents for.<sup>187</sup> But the process for Big Pharma to develop a new drug, obtain a patent, and get it to market, currently averages approximately \$1.7 billion.<sup>188</sup> Even more amazing than this large number is the fact that “the average expected annual return on investment from a new drug has fallen to only 5%, and only one in six drugs will generate a return as high as 12%.”<sup>189</sup> This means that a finding of inequitable conduct, which renders a patent unenforceable, would end the already-shortened amount of time<sup>190</sup> that Big Pharma has to earn this rate of return. In an industry just as impacted by the economy as everyone else,<sup>191</sup> the limited time to make a profit on the drug is all the more important to maintain jobs, be able to continue to develop new drugs, and to ultimately get those drugs into the market to the people who need them. In fact, the general director of the European Pharmaceutical Federation noted that a report put together by the European Union, which included evidence of raids at the heads of some major United States Big Pharma companies, “acknowledges that patents are key to pharmaceutical innovation and should be protected.”<sup>192</sup> Further, the report “acknowledges that the [pharmaceutical] industry spends more of its turnover on R&D than any other industry sector in Europe.”<sup>193</sup> Thus, in order to be able to encourage innovation through research and development, profit margins must be maintained by Big Pharma, and a shortening of the time period for profit, by findings of inequitable conduct, would likely cut these profit margins and dampen innovation.

Just as important as the money that Big Pharma spends, is the fact that the United States government is under increasing pressure to lower the

---

187. For instance, one patent attorney in Wisconsin informs potential clients that [t]he cost of the entire process of obtaining a patent for a simple invention including fees payable to the Patent office and to the attorney will be at least \$6,500, assuming that your patent is allowed on a first examination. If the claims are not accepted on the first examination, the cost will increase. The complexity of the invention will [also] increase the cost of writing the patent.

Donald J. Ersler, Patent Process, <http://www.itspatentable.com/patentprocess.html#how> (last visited Feb. 13, 2009).

188. MICHAEL STEINER ET AL., THE CONTINUING EVOLUTION OF THE PHARMACEUTICAL INDUSTRY: CAREER CHALLENGES AND OPPORTUNITIES 23 (Fiduciary Network, LLC 2007) (on file with author).

189. *Id.*

190. *See supra* notes 179-86 and accompanying text.

191. Linda Johnson, *Drug Industry Sees Big Job Cuts*, BOSTON GLOBE, Aug. 3, 2007, [http://www.boston.com/business/articles/2007/08/03/drug\\_industry\\_sees\\_big\\_job\\_cuts/](http://www.boston.com/business/articles/2007/08/03/drug_industry_sees_big_job_cuts/). Johnson & Johnson planned to cut up to 4,800 jobs, AstraZeneca cut 7,600 jobs, and Pfizer eliminated a very large, 10,000 jobs, a full 10% of their work force. *Id.*

192. Leo Cendrowicz, *Big Pharma Faces a Crackdown in Europe*, TIME, Nov. 28, 2008, available at <http://www.time.com/time/world/article/0,8599,1862791,00.html>.

193. *Id.*

costs of health care,<sup>194</sup> which inevitably includes pharmaceuticals. This is evidenced by the fact that “more than 39 million senior Americans receive their prescription drug benefits from the government, 24 million of whom participate in the [Medicare] Part D program.”<sup>195</sup> More startling is the cost to the government of providing this health care to individuals, and the potential for even higher costs in the future.<sup>196</sup> These increased costs are due in large part to the increasing numbers of American citizens over the age of sixty-five and the projected continuing rise of this portion of the population.<sup>197</sup> In fact, 16% of the United States’ Gross Domestic Product is attributable to health care costs, and this number is expected to rise.<sup>198</sup> With such expenses facing the government and the pressure they are under to lower their costs,<sup>199</sup> there is fear that the government could use its considerable power to the detriment of the pharmaceutical industry.<sup>200</sup>

Given the fact that one of the policies behind patent law is to protect and ensure consumer interests,<sup>201</sup> these easier standards for findings of inequitable conduct—coupled with the large amount of money already involved in the pharmaceutical industry—show an example of an industry particularly harmed by the current trends. As costs continue to increase<sup>202</sup> and findings of inequitable conduct, which may never have been if *Kingsdown* and the Code of Federal Regulations had been more closely followed, cut the time short for profiting on a drug, Big Pharma will likely have to raise prices as they must constantly find pricing structures to recoup their costs.<sup>203</sup> For instance, “[a]s an example, for every 5000 medicines initially evaluated, on average, only five are tested in clinical trials, and

194. STEINER ET AL., *supra* note 188, at 21.

195. *Id.* at 20.

196. *Id.* (“The total costs in 2006 were projected to be \$28 billion. By 2017, the annual costs of the program are projected to reach almost \$120 billion.”).

197. *Id.* at 20-21 (“[B]y 2020 the number of people over 65 is expected to reach almost 55 million, and by 2030 will exceed 70 million.”).

198. *Id.* at 21-22.

199. STEINER ET AL., *supra* note 188, at 21.

200. *Id.* Steiner and others are concerned about the broad power of the government and how they may decide to use it.

Given that the U.S. government has very broad power – through regulation and legislation – that extends even beyond its role as the largest consumer of prescription medications, there is a risk that the pharmaceutical industry’s economics could be changed literally overnight. For example, just as it did with gasoline and beef prices in the 1970s, the government could mandate prices for certain drugs, regardless of the cost of developing and bringing them to market.

*Id.*

201. See FEDERAL TRADE COMMISSION, *supra* note 7, at 6.

202. Milton Zall, *The Pricing Puzzle*, MOD. DRUG DISCOVERY, Mar. 2001, at 36, available at <http://pubs.acs.org/subscribe/archive/mdd/v04/i03/html/03zall.html>.

203. *Id.*



only one of those is approved for patient use. Accordingly, the industry strongly believes that revenues from successful medicines must cover the costs of the vast majority of ‘losers.’”<sup>204</sup> Thus, the consumer is the one ultimately harmed by the combination of increasing costs, pressure to lower prices, and the current trends in inequitable conduct.

Perhaps even more indicative of an industry particularly harmed by current inequitable conduct trends are the interactions between Big Pharma and generic prescription companies, and the way these interactions tie in to inequitable conduct. To understand the impact generics, as well as their potential for infringement cases, have on the patent process for Big Pharma, it is first necessary to understand how the patent process is different for Big Pharma than it is for generics.

When Big Pharma is looking for new drugs to develop and market, “[i]ndustry scientists searching for a new drug typically must sort through 5,000 to 10,000 new chemical inventions that look promising, in order to identify a pool of 250 compounds that then enter into preclinical laboratory and animal testing.”<sup>205</sup> After this narrowing down is completed, the drugs must still undergo three phases of human testing before being considered for patentability.<sup>206</sup> Only one of every five compounds (out of the original five-to-ten thousand compounds) make it through human testing, and only one on average will be approved by the government to make it to market.<sup>207</sup> Generic drug companies have a much easier time with profitability because federal law allows generic drug applicants to file patent applications for the same drug previously approved on a New Drug Application “without full safety and efficacy testing.”<sup>208</sup> The only “elements” that generic applicants must meet when submitting an application for a drug, whose patent will be expiring, are that the product must be a “bioequivalent”<sup>209</sup> of the approved

204. *Id.*

205. Neal Masia, *The Cost of Developing a New Drug*, in FOCUS ON INTELLECTUAL PROPERTY RIGHTS 82, 82, Apr. 23, 2008, <http://www.america.gov/st/econ-english/2008/April/20080429230904myleen0.5233981.html>.

206. *Id.*

207. *Id.*

208. 21 U.S.C. § 355(j) (2006). This provision provided for this by allowing what they called an “Abbreviated New Drug Application.” *Id.*

209. A drug is considered to be bioequivalent of a drug if

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is in-

drug and the Abbreviated New Drug Application (ANDA) must be for the “same drug,”<sup>210</sup> as was approved on the original New Drug Application.<sup>211</sup> Generic companies are allowed to begin this process, specifically testing and data collection for submission to the FDA, via use of the protected drug without having to worry about infringement thanks to “safe harbor” provisions provided by law.<sup>212</sup>

While generics have an easier time preparing to sell a drug whose patent is about to run out, there are still infringement cases, and inequitable conduct continues to be charged.<sup>213</sup> These ANDAs that may be submitted by generics for drugs whose patents are approaching expiration allow generics an easier path to market.<sup>214</sup> As such, Big Pharma and generics are no exception to the continuous charges of inequitable conduct.<sup>215</sup> With the continuing ability of generics to bring up the defense of inequitable conduct due to the easier methods of finding it, Big Pharma is yet another example of the current trends violating patent policy. This ease of finding inequitable conduct makes it a more enticing charge for generics to levy, thus adding to the complication of Big Pharma’s preparations for litigation.<sup>216</sup> This means litigation will not only be more time consuming, but much more expensive due to the attorney’s need to prepare for anything.<sup>217</sup> Consequently, it will become even more expensive and difficult for Big Pharma and their attorneys to prepare for the process of obtaining a patent and filing at the USPTO due to the large amount of information and past experiments or

---

tentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B) (2006).

210. The drug need not be identical. 21 U.S.C. § 355(j)(2)(A)(ii)(I-II) (2006); 54 Fed. Reg. 28872, 28881 (July 10, 1989).

211. 21 U.S.C. § 355(j) (2006).

212. 35 U.S.C. § 271(e)(1) (2006). This extends to “all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.” *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

213. After all, it was the Federal Circuit itself who termed the influx of inequitable conduct charges being raised in patent infringement cases as being “an absolute plague.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit noted that inequitable conduct was being charged in nearly every major patent infringement case. *Id.*

214. *See supra* notes 208-12 and accompanying text.

215. *See infra* notes 220-64 and accompanying text.

216. The current “trend fails to recognize that prosecuting attorneys generally do not monitor the day-to-day activities of their clients” and surely more of this would be needed in order to be aware of any and all potentially material information. Hanft & Kearns, *supra* note 2, at 5.

217. *See id.*

compounds they must account for.<sup>218</sup> It is therefore likely that some of those costs will be passed on to consumers as Big Pharma must maintain profit structures.<sup>219</sup> Thus, the impact of the relationship and ramifications between Big Pharma and generics, both economically and legally, is another shining example of the policy of protecting consumer interests being violated by current trends in inequitable conduct due to increases in costs that could likely be passed down to consumers.

Not only is Big Pharma theoretically impacted by these current trends, but also there are several practical examples of Big Pharma being stung by the recent trends in inequitable conduct, as seen by the cases that follow.

B. CASES WHERE BIG PHARMA HAS FELT THE STING OF RECENT CONFUSION IN INEQUITABLE CONDUCT

In the past fifteen years there have been forty positive findings of inequitable conduct by the Federal Circuit, fourteen of which have involved health care or pharmaceutical companies,<sup>220</sup> which show that Big Pharma is a group subject to findings of inequitable conduct. The following are examples of some of the cases in which inequitable conduct has been found against Big Pharma by the Federal Circuit.<sup>221</sup> In these cases, one can see a continuation of the muddled trends created by the Federal Circuit, the impacts that these decisions have, and their adversary nature to the policy reasons behind patent law.

This can first be seen in the cases discussed in previous portions of this Comment. Specifically, the cases of *Hoffman-La Roche*,<sup>222</sup> *Novo Nordisk*,<sup>223</sup> *Purdue Pharm.*,<sup>224</sup> and *Aventis Pharm.*<sup>225</sup> are examples of the confusing standards affecting Big Pharma.

A similar example can be seen in the case of *Pharmacia Corp. v. Par Pharmaceutical, Inc.*, in which the court once again veered from the *Kingsdown* standard.<sup>226</sup> This case involved an ANDA filed by Par Pharma-

218. Neal Masia, *The Cost of Developing a New Drug*, in FOCUS ON INTELLECTUAL PROPERTY RIGHTS 82, 82, Apr. 23, 2008, <http://www.america.gov/st/econ-english/2008/April/20080429230904myleen0.5233981.html> (“Industry scientists searching for a new drug typically must sort through 5,000 to 10,000 new chemical inventions that look promising . . .” (emphasis added)).

219. See *supra* notes 187-204 and accompanying text.

220. Robert Pear, *Patent Law Battle a Boon to Lobbyists*, N.Y. TIMES, Apr. 30, 2008, at C1, available at <http://www.nytimes.com/2008/04/30/business/30patent.html>.

221. See *infra* notes 222-64 and accompanying text.

222. See *supra* notes 56-65, 119-26 and accompanying text.

223. See *supra* notes 66-71 and accompanying text.

224. See *supra* notes 80-86 and accompanying text.

225. See *supra* notes 87-95 and accompanying text.

226. 417 F.3d 1369, 1373-75 (Fed. Cir. 2005).

ceutical for a generic of the drug Xalatan, a glaucoma medication.<sup>227</sup> Xalatan was set to expire on March 24, 2011.<sup>228</sup> The drug was also a fairly high seller for Pharmacia Corp.,<sup>229</sup> though these numbers are not as impressive when coupled with what Pharmacia Corp. spends on research and development in a given year.<sup>230</sup> The allegation of inequitable conduct in this case stemmed from a failure by the patent applicant to disclose articles, written in the past, which would have potentially undercut the level of novelty of this drug.<sup>231</sup> The court overemphasized the materiality element to the near exclusion of intent.<sup>232</sup> In fact, the court admitted, as has been done in prior cases,<sup>233</sup> that “[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct.”<sup>234</sup> This meant that due to the high materiality of a mistake in a declaration made by Pharmacia Corp.,<sup>235</sup> intent could be inferred without really being discussed by the Federal Circuit Court.<sup>236</sup> This intent was inferred despite proof from Pharmacia Corp. that the error was due to the author being a “foreign national”<sup>237</sup> and confusing “does not” with “did not.”<sup>238</sup> The argument was, if the author had used “did not” the statement would have been limited to only include the tests that had been conducted.<sup>239</sup> While the district court rejected this argument,<sup>240</sup> the Federal Circuit Court did not even address it, but simply agreed with the district court that the mistake was highly material.<sup>241</sup> Despite a purportedly good faith translation mistake,<sup>242</sup> the court seemingly ignored the candor of the author and found intent anyway due to the highly

---

227. *Id.* at 1370.

228. U.S. Patent No. 5,422,368 (filed Dec. 8, 1992), <http://patft.uspto.gov> (follow “Patent Number Search” hyperlink; then run search for “5,422,368”) (last visited Sept. 20, 2009).

229. For instance, in 2001, Pharmacia reported Xalatan as its third best-selling product at \$818 million that year. L.J. Sellers, *The Year 2001 Will Stand Out in any Historical Accounting*, PHARMACEUTICAL EXECUTIVE, May 2002, at 61, 63.

230. Specifically, in the same year, 2001, Pharmacia spent \$2.07 billion on research and development. L.J. Sellers, *The Year 2001 Will Stand Out in any Historical Accounting*, PHARMACEUTICAL EXECUTIVE, May 2002, at 61, 63.

231. *Pharmacia Corp.*, 417 F.3d at 1373.

232. *Id.* at 1370.

233. *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1135 (Fed. Cir. 2006).

234. *Pharmacia Corp.*, 417 F.3d at 1373 (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

235. *Pharmacia Corp.*, 417 F.3d at 1373.

236. *Id.*

237. *Id.* at 1372.

238. *Id.*

239. *Id.*

240. *Pharmacia Corp.*, 417 F.3d at 1372.

241. *Id.* at 1373.

242. *Id.* at 1372.

material nature of the mistake.<sup>243</sup> Here, the finding of inequitable conduct, and thus unenforceability, not only cut short the life of the patent by approximately six years, but also took away a significant profit generator, which had been covering significant research and development costs. This is yet another example of Big Pharma being affected by trends in inequitable conduct that are adverse to patent policy due to shortening their time to enjoy patent protection as well losing profit margins, which will likely result in higher costs for consumers. Had *Kingsdown* and the Code of Federal Regulations been more closely followed, it is likely that inequitable conduct would not have been found.

Additionally, in the case of *Ferring B.V. v. Barr Laboratories*, discussed factually earlier,<sup>244</sup> the court made a finding of inequitable conduct despite not following the codified<sup>245</sup> definition of materiality<sup>246</sup> and going against *Kingsdown* by using the should-have-known standard.<sup>247</sup> This case dealt with a patent for an “antidiureticly effective amount of 1-deamino-8-D-arginine vasopressin (DDAVP) and a pharmaceutically acceptable carrier,” a drug used in the treatment of diabetes insipidus.<sup>248</sup> This patent was set to expire on September 10, 2008, seventeen years after the date of issuance.<sup>249</sup> This was yet another case of the Federal Circuit using looser standards to make it easier to find inequitable conduct.<sup>250</sup> The majority in this case did not make a factual finding of materiality; instead they found materiality on a *per se* basis.<sup>251</sup> The majority relies on two cases<sup>252</sup> in order to hold that “a declarant’s past relationships with the applicant *are* material if (1) the declarant’s views on the underlying issue are material and (2) the past relationship to the applicant was a significant one.”<sup>253</sup> This holding is improper, as Judge Newman notes in her dissent when she states that the

243. *Id.*

244. *See supra* notes 72-79 and accompanying text.

245. 37 C.F.R. § 1.56 (1992).

246. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187-90 (Fed. Cir. 2006).

247. *Id.* at 1190-94.

248. USPTO Patent Full-Text and Image Database, Unites States Patent 5,047,398, <http://patft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.htm&r=2&p=1&f=G&l=50&d=PTXT&S1=19851217.AD.&OS=apd/12/17/1985&RS=APD/19851217> (last visited Jan. 5, 2010).

249. *Id.*

250. *See supra* notes 33-154 and accompanying text.

251. *See Ferring B.V.*, 437 F.3d at 1187-90.

252. The majority noted that the court had previously held that a declarant’s prior relationships could be material and such a failure to disclose could be inequitable conduct. *Ferring B.V.*, 437 F.3d at 1187-88 (citing *Refac Int’l, Ltd., v. Lotus Dev. Corp.*, 81 F.3d 1576, 1581-82 (Fed. Cir. 1996); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191-92 (Fed. Cir. 1993)).

253. *Ferring B.V.*, 437 F.3d at 1188 (emphasis added).

cases relied upon by the majority were both analyzed factually under the *Kingsdown* standard.<sup>254</sup> As Judge Newman further states, in this case, “[t]he panel majority’s new *per se* rule is contrary to precedent, contrary to the rules of evidence, and contrary to reason, as is its assertion that the omitted relationships in this case are ‘highly material.’”<sup>255</sup> Judge Newman also correctly notes that materiality and intent are both factual in nature and, as such, *per se* findings like the one made by the majority here are improper.<sup>256</sup> The majority further deviated from *Kingsdown* when they used the gross negligence, or should-have-known, standard in finding intent to deceive.<sup>257</sup> The majority used the should-have-known standard despite noting that when there is no clear evidence, “intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.”<sup>258</sup> Once again, Judge Newman correctly condemned the use of the gross negligence, or should-have-known, standard<sup>259</sup> and reiterated that the majority has ignored *Kingsdown*.<sup>260</sup> In fact, Judge Newman notes that not only has *Kingsdown* been ignored as to its holding that negligence alone is insufficient, but the majority here has not only “restore[d] a casually subjective standard, [but] they also impose[d] a positive inference of wrongdoing . . . from which deceptive intent is inferred, even in the total absence of evidence.”<sup>261</sup>

This case shows yet another example of a patent effectively cut short by inequitable conduct. This is especially true in light of the fact that while this patent was issued in 1991,<sup>262</sup> this drug did not receive FDA approval until September 6, 1995.<sup>263</sup> Therefore a drug with a patent life of seventeen years originally, was first only protected by patent for sale for twelve years,

254. *Id.* at 1199 (Newman, J., dissenting).

255. *Id.* at 1199-1200.

256. *Id.* at 1200.

257. *Id.* at 1192 (majority opinion).

258. *Ferring B.V.*, 437 F.3d at 1191 (quoting *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005)) (second emphasis added). It seems a bit disconcerting that the majority would quote the knowledge standard when discussing how intent can be inferred and yet hold that should-have-known is sufficient for a finding of intent shortly thereafter. *Id.*

259. *Ferring B.V.*, 437 F.3d at 1196 (Newman, J., dissenting).

260. *Id.*

261. *Id.*

262. USPTO Patent Full-Text and Image Database, Unites States Patent 5,047,398, <http://patft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetatml%2FPTO%2Fsearch-adv.htm&r=2&p=1&f=G&l=50&d=PTXT&S1=19851217.AD.&OS=apd/12/17/1985&RS=APD/19851217> (last visited Jan. 5, 2010).

263. FDA Drug Details for DDAVP, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails> (last visited Feb. 13, 2009).

which was then effectively cut short an additional two years by this decision.<sup>264</sup> This is yet another example of Big Pharma being particularly harmed by the current trends in inequitable conduct and their adversarial nature to patent policy, specifically time protections because this finding would arguably not have happened under a stricter adherence to *Kingsdown* and the current Code of Federal Regulations.

These two cases are examples of how Big Pharma has been forced to deal with confusion in the standards used for materiality and intent in inequitable conduct cases. These are further examples of how that confusion can lead to findings of inequitable conduct that may not have come to be had *Kingsdown* and the Code of Federal Regulations been more closely followed. These cases have also showed the nature of current trends as they exist in connection with patent policy, and how Big Pharma is an example of an industry particularly harmed by such trends. But the trends resulting in finding inequitable conduct easier and more often can have more of an impact than just at the USPTO; to see this, Big Pharma is once again a helpful example of an industry particularly harmed.

#### C. THE KINDS OF PROBLEMS CURRENT TRENDS CREATE FOR BIG PHARMA

Including the practical problems listed above, such as the impact of current trends on Big Pharma in light of time,<sup>265</sup> money,<sup>266</sup> and their interactions with generics,<sup>267</sup> there are other problems that loosening standards have arguably created for Big Pharma.

These problems are specific to the image of Big Pharma in society and the business world. Findings of inequitable conduct carry the connotation of “cheating,” and there are plenty of people who think that Big Pharma is doing just that.<sup>268</sup> As a result, more findings of inequitable conduct, which may very well happen if the trends continue, will arguably lead to more people viewing Big Pharma as “cheaters.”

Further evidence of societal and political impressions of Big Pharma is found in “[m]ovies such as Michael Moore’s controversial ‘Sicko’ together with many aspiring politicians hav[ing] demonized the industry, portraying

---

264. *Ferring B.V.*, 437 F.3d at 1181.

265. See *supra* notes 179-86 and accompanying text.

266. See *supra* notes 187-204 and accompanying text.

267. See *supra* notes 205-19 and accompanying text.

268. Debra Barrett, a vice president of generic manufacturer Teva Pharmaceuticals said making inequitable conduct harder to find against Big Pharma “would make it easier for them to cheat and get away with it, easier for [Big Pharma] to defend their patents and more difficult for us to get generic products onto the market in a timely way.” Robert Pear, *Patent Law Battle a Boon to Lobbyists*, N.Y. TIMES, Apr. 30, 2008, at C1, available at <http://www.nytimes.com/2008/04/30/business/30patent.html>.

pharmaceutical companies as greedy and uncaring, ignoring the immense benefits its products provide to millions of people.”<sup>269</sup>

This is even more noticeable in light of the current lobbying battle taking place over potential statutory changes in patent law.<sup>270</sup> Further, “[c]ompanies from almost every major industry have joined the battle.”<sup>271</sup> This battle includes the American Association of Retired Persons (AARP), who, among other consumer groups, wants to be able to have access to generic drugs faster, which cost as much as thirty to eighty percent less than brand-name drugs.<sup>272</sup> That is just one example of a group other than generic pharmaceutical companies that are battling against Big Pharma. And can one really blame AARP for its distrust of Big Pharma when loosened standards make it appear that Big Pharma is “cheating” more often and still drug prices are so high? Therefore it is exemplified by the case of Big Pharma that current trends in inequitable conduct, while adverse to patent policy as currently interpreted, may also have an impact outside of the Federal Circuit and patent law as a whole.

But what can be done to curb the current problems, which are especially obvious in the case of Big Pharma, that recent trends in inequitable conduct are causing?

## VII. SOLUTIONS FOR THE PROBLEMS CREATED BY CURRENT TRENDS

While there has recently been a push for new legislation and patent law reform by both the House and the Senate,<sup>273</sup> neither bill addresses inequitable conduct (unlike last year’s attempts at reform).<sup>274</sup> While in the past, the hope was to clarify many issues—which would be beneficial for anyone worrying about patent infringement, including inequitable conduct—<sup>275</sup> that hope is beginning to look exceedingly desperate as those bills were ta-

269. STEINER ET AL., *supra* note 188, at 22.

270. Between *both* Big Pharma companies and the generic drug manufacturing companies, \$4.3 million had been spent, as of April 30, 2008 going backwards fifteen months, on lobbying on legislation impacting patent law. Robert Pear, *Patent Law Battle a Boon to Lobbyists*, N.Y. TIMES, Apr. 30, 2008, at C1, available at <http://www.nytimes.com/2008/04/30/business/30patent.html>.

271. *Id.*

272. *Id.*

273. Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2009, S. 610, 111th Cong. (2009); Patent Reform Act of 2009, S. 515, 111th Cong. (2009).

274. The bill introduced in 2008 sought to have inequitable conduct more fully codified by making it mandatory to show clear and convincing evidence of intent to mislead or deceive by misrepresenting, or failing to disclose some material information. See Patent Reform Act of 2008, S. 3600, 110th Cong. (2008).

275. See William D. Belanger, *Patent Reform Act and Case Law Updates: Impact on Patent Litigation*, 948 PLI / PAT 65, 76 (2008).



bled.<sup>276</sup> The goal had been to take the definition and standards of inequitable conduct out of the hands of the court, and instead provide for a doctrine that would be governed by the USPTO via regulation.<sup>277</sup> This would have been highly beneficial in providing for a more black letter law approach to inequitable conduct, an area that appears in need of just such an approach. After all, confusion in legal precedent, including inequitable conduct, does nothing to help our legal system.<sup>278</sup>

Since legislation regarding inequitable conduct appears to be off the table for now, a return to the *Kingsdown* standard<sup>279</sup> is ideal and ultimately the greatest hope for the inequitable conduct doctrine. As long as the make-up of the Federal Circuit can change, so too can the opinions and decisions of its justices.<sup>280</sup> Nonetheless, following the standard as put forth in *Kingsdown*<sup>281</sup> and following the definition of materiality laid out in the Code of Federal Regulations is the ultimate solution to this problem as this appears to be an area that more black letter law would be beneficial so everyone knows how to better prepare for litigation. Perhaps the opinion laid out in *Abbott Laboratories v. Sandoz*<sup>282</sup> and its adherence to *Kingsdown*,<sup>283</sup> will encourage the Federal Circuit to follow this standard more specifically. Since it does follow the clear standard laid out in *Kingsdown*, following *Abbott Laboratories* would be beneficial for clarity's sake; however, only time will tell whether such clarity will find support in the Federal Circuit.

## VIII. CONCLUSION

In conclusion, current trends in inequitable conduct, as interpreted by the Federal Circuit, arguably make it easier to find inequitable conduct, and potentially encourage the claim to be raised more often against patent policy. Specifically, incorrect and excessive findings of inequitable conduct lead to a shortening of time to enjoy patent protection, discourage inventiveness, and fail to protect consumer interests. This is particularly evident in light of the exemplary case of Big Pharma. Not only has Big Pharma

276. John Timmer, *Patent Reform Act Suffers Serious Setback, Stalled in Senate*, May 5, 2008, <http://arstechnica.com/news.ars/post/20080505-patent-reform-act-suffers-serious-setback-stalled-in-senate.html> ("The Senate version of the Patent Reform Act (S1145) has been taken off the schedule, meaning it will not be considered by the full Senate any time in the near future.").

277. Hanft & Kearns, *supra* note 2, at 5.

278. See, e.g., *supra* note 155 and accompanying text.

279. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

280. See *supra* notes 156-64 and accompanying text.

281. *Kingsdown*, 863 F.2d at 876.

282. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

283. *Id.* at 1353.

been on the convoluted end of inequitable conduct findings, feeling the sting of such in the shortening of patents and profit margins, but they have also suffered societal impacts at the hands of excessive charges of inequitable conduct. While Big Pharma is certainly not the only industry impacted by current trends—and perhaps not even the only industry that could be looked to as a particularly helpful example—they do exist as a strong example of the impact of current trends. And in order to correct all of these issues, clarity, more than anything else, is what is needed: clarity in the standards used to find the elements for inequitable conduct, and clarity in the decisions and precedent as set forth by the Federal Circuit, be it through an attempt at further legislation or by more strictly adhering to the standards set forth in *Kingsdown* and the Code of Federal Regulations.

JOSHUA M. AUSTIN\*

---

\* Joshua M. Austin, J.D. Candidate, May 2010, Northern Illinois University College of Law. Josh is currently a 3L at Northern Illinois University's College of Law and is a Lead Articles Editor on the Northern Illinois University Law Review. He owes a great deal of thanks to his wife, Cassandra, and his son, Holden, for always standing by his side during both the best and toughest times in law school. Special thanks is due to Janet Pioli, Counsel for Brinks, Hofer, Gilson & Lione, for helping Josh to not only formulate the topic of this article, but also for assisting with some of the more exotic subject matter discussed herein.