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***Bayer AG v. Schein Pharmaceuticals, Inc.*<sup>1</sup> A  
Pharmaceutical Company's Victory in Securing a Patent  
Monopoly over Ciprofloxacin<sup>2</sup>**

*Glenna L. Gilbert\*\**

In 1980, Dr. Klaus Grohe, a scientist for Bayer, attended a conference in Japan where the structure of an antibiotic known as norfloxacin was disclosed.<sup>3</sup> From the structure of norfloxacin, the broad-spectrum antibiotic ciprofloxacin (Cipro) can be manufactured by a simple substitution of a cyclopropyl group for an ethyl group.<sup>4</sup> With this knowledge in hand, Dr. Grohe "hastened home from the conference determined to make such a compound."<sup>5</sup> Despite Dr. Grohe's efforts, his standard methodology was unsuccessful in his attempted synthesis of Cipro.<sup>6</sup> He could not construct the starting material needed for the intermediate chemical reaction.<sup>7</sup> Therefore, he called upon a colleague, Dr. Klauke, who "successfully synthesized the precursor 2,4-dichloro-5-fluorobenzoyl chloride, the so-called 'Klauke compound,' necessary to make [Cipro] via cycloaracyclation."<sup>8</sup> By using the Klauke compound, Dr. Grohe was able to synthesize the second intermediate in the synthesis of Cipro, known as 6-FQA, which he then successfully made into Cipro.<sup>9</sup>

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\* This article is published online at <http://mipr.umn.edu>.

1. *Bayer AG v. Schein Pharm., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002).

2. "Ciprofloxacin is a relatively simple heterocyclic organic compound developed by Bayer . . ." *Id.* at 1309.

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3. *Id.*

4. *See id.* Cipro is used to treat a wide variety of bacterial infections in humans. *See CiproUSA* at [http://www.ciprousa.com/cipro\\_other/index.asp](http://www.ciprousa.com/cipro_other/index.asp) (last visited November 5, 2003).

5. *Bayer*, 301 F.3d at 1309.

6. Dr. Grohe succeeded in making numerous compounds similar in structure to ciprofloxacin, but failed at making Cipro with his standard methodology. *Id.* at 1310.

7. *See id.*

8. *Id.*

9. *Id.*

In *Bayer AG v. Schein Pharmaceuticals, Inc.*,<sup>10</sup> Bayer AG and Bayer Corporation, collectively known as “Bayer”, sued five companies collectively known as “Schein”<sup>11</sup> for infringement of U.S. Patent No. 4,670,444 and Reexamination Certificate B1 4,670,444, collectively known as the “444 patent.”<sup>12</sup> The ‘444 patent claims a class of compounds that includes Cipro.<sup>13</sup> However, the ‘444 patent was not the first filed patent that claimed Cipro.<sup>14</sup> Seven other applications preceded the ‘444 patent, four of which are foreign applications that are relevant to this case.<sup>15</sup>

The five defendants<sup>16</sup> in this case filed Abbreviated New Drug Applications (ANDAs) with the FDA, seeking “approval to market generic versions of [Cipro].”<sup>17</sup> These ANDAs led Bayer to sue Schein for infringement of the ‘444 patent.<sup>18</sup> On cross-motions for summary judgment, Schein conceded infringement of the ‘444 patent but claimed that the ‘444 patent “is invalid based on the filing and issuance of the Chilean, South African, Spanish and Argentinean patents,<sup>19</sup> because under 35 U.S.C. § 102(d) those foreign patents are prior art that would invalidate the ‘444 patent.”<sup>20</sup> Bayer argued that the ‘444 patent is

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10. *Id.*

11. The five companies are Schein Pharmaceutical, Inc., Danbury Pharmacal, Inc., Reddy-Cheminor, Inc., Mylan Pharmaceuticals, Inc., and Mylan Laboratories Inc. *Id.* at 1308.

12. *Id.*

13. *Id.* at 1310.

14. *Id.*

15. *Id.* at 1310-11. “Bayer filed the first relevant patent application in Chile on August 12, 1981.” *Id.* at 1311. The next day, Bayer filed the ‘560 application in the United States, followed by “applications in South Africa (September 2, 1981), Spain (September 2, 1981), and Argentina (September 3, 1981).” *Id.* The applications in Chile, South Africa, Spain and Argentina issued as patents between May and September of 1982. *Id.* On October 22, 1982, after the issuance of the foreign patents, Bayer filed for a second United States application, the ‘112 application, as a continuation of the ‘560 application. *Id.* Bayer subsequently abandoned the ‘560 application. *Id.* Bayer then filed a third United States application, the ‘923 application, on May 29, 1984, as a continuation-in-part of the ‘112 application. *Id.* The ‘923 application eventually “matured into the ‘444 patent, which [finally] issued on June 2, 1987.” *Id.*

16. *See supra* note 11 and accompanying text.

17. *Bayer*, 301 F.3d at 1311.

18. *See id.* “Bayer sued under 35 U.S.C. § 271(e)(2), alleging that filing the ANDAs infringed the ‘444 patent, and this suit stayed the ANDAs before the FDA.” *Id.*

19. *See supra* note 15 and accompanying text.

20. *Bayer*, 301 F.3d at 1311.

entitled to the same filing date as the '560 application: August 13, 1981.<sup>21</sup> Schein countered by arguing that Bayer could not rely on the '560 application date because that application did not disclose "Grohe's best mode of making ciprofloxacin as required by section 112."<sup>22</sup>

In *Bayer*, the district court granted Bayer's motion for summary judgment, holding that "the '560 application satisfies the best mode requirement."<sup>23</sup> Schein subsequently appealed.<sup>24</sup> The Federal Circuit affirmed the lower court's decision.<sup>25</sup> The court held that "[b]ecause the '560 application complies with the disclosure requirements of section 112, the '444 patent can claim the benefit of the '560 application's August 13, 1981, filing date."<sup>26</sup> Thus, because this date is within one year of the filing dates of the four foreign patents, the "issuance of those . . . patents does not invalidate the '444 patent under section 102(d)."<sup>27</sup>

This Comment argues that, contrary to the Federal Circuit's holding in *Bayer*, the '444 patent failed to comply with § 112 and violated the best mode requirement when it failed to disclose fully the synthesis pathways for the precursors to Cipro.<sup>28</sup> The first section of this Comment focuses on the legislative and case history behind the best mode requirement. The second section analyzes *Bayer* in detail, examining each of the Federal Circuit's holdings in the case. The final section then analyzes these holdings in light of the legislative purposes and case law precedent of the best mode requirement. This Comment concludes that the Federal Circuit's decision in *Bayer* both does not honor the purpose of the best mode requirement and does not follow its own precedent in prior cases concerning the best mode requirement.

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21. *Id.* Bayer alternatively argued "that under 35 U.S.C. § 119, it should be entitled to the filing date of the second German application, October 29, 1981." *Id.* See also *supra* note 15 and accompanying text.

22. *Bayer*, 301 F.3d. at 1311. See also *infra* notes 34-35 and accompanying text.

23. *Bayer*, 301 F.3d. at 1311.

24. *Id.* at 1312.

25. *Id.* at 1323.

26. *Id.*

27. *Id.*

28. See *supra* notes 6-9 and accompanying text.

## I. A HISTORICAL PERSPECTIVE OF THE BEST MODE REQUIREMENT

### A. THE BACKGROUND AND PURPOSES OF THE BEST MODE REQUIREMENT

The United States Constitution grants Congress the power “[t]o 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>29</sup> In response, Congress enacted the Patent Act,<sup>30</sup> which grants successful patentees a monopoly on their invention for a limited time.<sup>31</sup> This monopoly is granted in exchange for the disclosure of the invention to the public and its eventual entry into the public domain.<sup>32</sup>

However, a patent is only granted if the invention satisfies the substantive and procedural statutory requirements set out in Title 35 of the United States Code.<sup>33</sup> Disclosure is one of these statutory requirements.<sup>34</sup> This requirement is stated as follows:

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 . . . to make and use the same, and *shall set forth the best mode contemplated by the inventor of carrying out his invention*.<sup>35</sup>

The disclosure requirement ensures that the public receives information on every essential aspect of the patented invention.<sup>36</sup> Therefore, in essence, the public receives a “quid

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29. U.S. CONST. art. I, § 8, cl. 8.

30. Patent Act of 1952, 35 U.S.C. §§ 1-376 (2000).

31. Richard M. Mescher, *Patent Law: Best Mode Disclosure—Genetic Engineers Get Their Trade Secret and Their Patent Too?—Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S.Ct. 169 (interim ed. 1991), 18 U. DAYTON L. REV. 177, 177 (1992); see also Christopher S. Marchese, *Confusion, Uncertainty, and the Best Mode Requirement*, 2 FED. CIR. B.J. 1, 4-6 (1992) (explaining that the exclusive rights conferred on an inventor by a patent includes licensing the invention and suing for infringement when others make, use, or sell the invention).

32. Mescher, *supra* note 31, at 177.

33. 35 U.S.C. § 101; Mescher, *supra* note 31, at 177.

34. Patent Act, 35 U.S.C. §112, ¶ 1 (2000).

35. *Id.* (emphasis added).

36. See *Bonita Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-52 (1989). The Supreme Court stated:

The federal patent system thus embodies a carefully crafted bargain

pro quo" for granting the monopoly to the inventor.<sup>37</sup>

In a patent infringement suit, an alleged infringer can claim inadequate disclosure as a defense if a patent is issued without proper disclosure.<sup>38</sup> The claim of inadequate disclosure includes the enablement<sup>39</sup> and best mode defenses.<sup>40</sup> This comment concerns the best mode requirement,<sup>41</sup> which focuses on an "inventor's particular embodiment or method of making the invention."<sup>42</sup>

The best mode requirement serves two main purposes. First, it "assures that the [patent] specification provides information to the public concerning what the invention is and how it can be practiced."<sup>43</sup> As Judge Rich explained in *In re Nelson*,<sup>44</sup> the best mode requirement prevents an inventor from "disclos[ing] only what he knows to be his second-best embodiment, retaining the best for himself."<sup>45</sup> The second

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for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.

. . . We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law.

*Id.* at 150-52.

37. See *supra* note 36 and accompanying text; see also Marchese, *supra* note 31, at 1 (expounding the purpose of the best mode requirement as "providing the public with full disclosure of inventors' innovations in exchange for the exclusive rights that accompany the grant of a patent, while simultaneously preventing inventors from selfishly concealing their preferred embodiments.") (footnotes omitted); Mescher, *supra* note 31, at 177 (stating that the inventor must fully disclose an invention to comply with statutory requirements).

38. Mescher, *supra* note 31, at 178 ("[I]f a patent is issued without proper disclosure it can be invalidated by the courts when an alleged infringer claims inadequate disclosure as a defense in an infringement suit."); see also William F. Herbert, *Failure to Disclose the "Best Mode": What the Public Doesn't Know Will Hurt Them*, 64 J. PAT. OFF. SOC'Y 12, 25 (1982) (citing failure to disclose best mode as defense to non-infringement).

39. The purpose of the enablement requirement is to enable those skilled in the art to make and use the invention. See *In re Nelson*, 280 F.2d 172, 184 (C.C.P.A. 1960).

40. Mescher, *supra* note 31, at 178.

41. See *infra* notes 42-46 and accompanying text.

42. Marchese, *supra* note 31, at 9.

43. Mescher, *supra* note 31, at 181 (footnote omitted); see also Herbert, *supra* note 38, at 32.

44. *In re Nelson*, 280 F.2d 172.

45. *Id.* at 184; see also Gordon T. Arnold, *Developing the Evidence on Patent Validity Issues*, in 1 PATENT LITIGATION 1993 509, 536 (Tom Arnold et al. eds., 1993) ("One of the main reasons for the Patent Code is to encourage

purpose of the best mode requirement is to ensure that the disclosure of the invention provides the public with information that encourages current and future research in the “art of the invention” by the public and competitors.<sup>46</sup>

#### B. LEGISLATIVE HISTORY OF 35 U.S.C. §112

Congress adopted the first Patent Act in 1790.<sup>47</sup> This act contained an enablement requirement<sup>48</sup> as well as a requirement for the “whole truth.”<sup>49</sup> The “whole truth” requirement, a forerunner of the best mode requirement,<sup>50</sup> formed the basis of the “whole truth” defense of patent infringement.<sup>51</sup> When charged with patent infringement, Defendants could argue that the specification “does not contain the whole truth concerning his invention,’ or ‘contains more than is necessary to produce that effect described’ if either ‘appear[ed] to have been intended to mislead, or shall actually mislead the public, so as the effect described cannot be

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inventors to make the necessary disclosures to permit others to advance the art; inventors may not keep secret information essential for that purpose.”) (quoting *Imperial Chem. Indus. v. Barr Lab.*, 22 USPQ2d 1906, 1907 (S.D.N.Y. 1992)); Marchese, *supra* note 31, at 9 (“The best mode disclosure requirement prevents inventors from selfishly concealing their preferred embodiments, which are developed before filing the application, thereby retaining the best for themselves.”) (footnote omitted).

46. Mescher, *supra* note 31, at 181; *see also* David Conlin, *The Patent Application*, in 2 PATENT PRACTICE 9, at 9-1 to 9-3 (Irving Kayton, ed., 1985) (listing important functions of the patent application, including “disclosure by which the public may learn what the invention is and how to practice it when the patent term expires”); Marchese, *supra* note 31, at 7 (“Through disclosure, the patent system introduces new designs and technologies into the public domain, and thereby increases the public store of knowledge and information.”).

47. Act of April 10, 1790, ch. 7, 1 Stat. 109-12; Thomas L. Irving et al., *The Significant Federal Circuit Cases Interpreting Section 112*, 41 AM. U. L. REV. 621, 624 (1992); Marchese, *supra* note 31, at 10.

48. The enablement requirement in the 1790 Patent Act required patent applicants to “file a specification describing the applicant’s invention to distinguish the invention from prior art and ‘to ensure a workman or other person skilled in [the] art’ could make, build, or use the invention.” Marchese, *supra* note 31, at 10 (quoting Act of April 10, 1790, ch. 7, § 2, 1 Stat. 109).

49. Act of April 10, 1790, ch. 7, § 6, 1 Stat. 109. *See* Marchese, *supra* note 31, at 10 (stating that the 1790 Act provided “the forerunner of the best mode requirement” in the form of the whole truth defense that could be asserted in a patent infringement suit).

50. Marchese, *supra* note 31, at 10.

51. Act of April 10, 1790, ch. 7, § 6, 1 Stat. 109. *See also* Irving, *supra* note 47, at 624 (for a discussion of the “whole truth” defense).

produced by the means specified.”<sup>52</sup>

In the Act of 1793,<sup>53</sup> Congress added the requirement that applicants of mechanical inventions must “fully explain the principle, and the *several modes* in which he has contemplated the application of that principle.”<sup>54</sup>

The “best mode” provision superseded the “several modes” provision in the Patent Act of 1870.<sup>55</sup> However, as in the Act of 1793,<sup>56</sup> this best mode requirement only applied to machines.<sup>57</sup> The relevant section of the 1870 Act “provided that an inventor ‘shall explain the principle [of the machine], and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions.’”<sup>58</sup>

Finally, in the Patent Act of 1952, the best mode requirement was expanded to include all inventions<sup>59</sup> and the best mode requirement replaced the whole truth defense.<sup>60</sup> Therefore, failure to disclose the invention is now a defense regardless of intent.<sup>61</sup>

### C. JUDICIAL INTERPRETATION OF THE BEST MODE REQUIREMENT

1. The Early Cases Before the Establishment of the Federal Circuit Courts first recognized the purpose of the best mode requirement in *In re Gay*.<sup>62</sup> The United States Court of Customs and Patent Appeals declared that the “sole purpose of [the best mode requirement] is to restrain inventors from

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52. Irving, *supra* note 47, at 624 (quoting Act of April 10, 1790, ch. 7, § 6, 1 Stat. 109) (alteration in original).

53. Act of February 21, 1793, ch. 11, 1 Stat. 318-23 (amended 1836).

54. *Id.* (emphasis added).

55. Irving, *supra* note 47, at 625 (discussing the 1870 amendments to the Act of July 8, 1870, ch. 230, §26, 16 Stat. 198, 201).

56. Act of February 21, 1793, ch. 11, 1 Stat. 318-23 (amended 1836).

57. See Marchese, *supra* note 31, at 12.

58. *Id.* (quoting Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201) (alteration in original).

59. Irving, *supra* note 47, at 626.

60. Marchese, *supra* note 31, at 13.

61. See Pasquale J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A §§ 1-376 (1954), reprinted in 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 216 (1993) (“Since intention to deceive the public was an element of [the whole truth] defense it was seldom raised; [therefore] failure to give a description of the invention as required by Section 112 is a defense without regard to intention”).

62. *In re Gay*, 309 F.2d 769 (C.C.P.A. 1962).



applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived.”<sup>63</sup>

Another early case which was central to current judicial interpretations of the best mode requirement is *Flick-Reedy Corp. v. Hydro-Line Manufacturing Co.*<sup>64</sup> This case concerned a seal for preventing leakage between the end of a cylinder and its head,<sup>65</sup> and the court determined that “[t]he findings of fact and the patent specifications and claims ma[d]e clear that an essential element of the patent [was] the ‘sealing relation’ between the outer machined surface of the reduced thickness at the end of the tube and the outer surface of the recessed groove in the head.”<sup>66</sup> The court also found that the specification stated that the outer surface of the reduced thickness section was made with a special tool.<sup>67</sup> Furthermore, this special tool was not disclosed in the specifications or claims.<sup>68</sup> Because of this nondisclosure, the Seventh Circuit Court of Appeals upheld the District Court’s holding that the patent was invalid under 35 U.S.C. § 112.<sup>69</sup>

The First Circuit Court of Appeals then distinguished *Flick-Reedy* in *International Telephone & Telegraph Co. v. Raychem Corp.*<sup>70</sup> In this case, the patent involved a wire insulation composed of a primary layer of a cross linked polyolefin and a secondary, outer layer of cross linked polyvinylidene fluoride.<sup>71</sup> International Telephone & Telegraph claimed that the patent did not disclose the “precise chemical formulations” that Raychem used to produce its commercial wire.<sup>72</sup> More specifically, Raychem did not disclose the “use of two copolymers in the polyethylene layer of the wire insulation” and “the formula of a secret, proprietary compound” added to

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63. *Id.* at 772.

64. *Flick-Reedy Corp. v. Hydro-Line Mfg. Co.*, 351 F.2d 546 (7th Cir. 1965).

65. *Id.* at 550.

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.* at 551; *see also supra* notes 34-35 and accompanying text.

70. *Int’l Telephone & Telegraph Corp. v. Raychem Corp.*, 538 F.2d 453, 460 (1st Cir. 1976).

71. *Id.* at 454.

72. *Id.* at 459.

the outer layer.<sup>73</sup> Raychem claimed that these omissions did not violate the best mode requirement since the copolymers and the secret proprietary compound did not change the qualities of the finished product.<sup>74</sup> Instead, they were used to aid in the “extrusion of the plastics during the manufacturing process.”<sup>75</sup> In response, the First Circuit reiterated its previous interpretation of the best mode requirement as requiring the disclosure of “specific material[s] which will make possible the successful reproduction of the effects claimed by the patent.”<sup>76</sup> The court concluded, however, that the undisclosed elements were not essential to the production of the patented wires; and therefore the patent was valid against a best mode defense.<sup>77</sup> In *Flick-Reedy* the special tool was essential,<sup>78</sup> in *International Telephone* the copolymers were not essential to the invention claimed.<sup>79</sup> Thus, the court appeared to make a distinction between essential materials and nonessential materials, holding that essential materials must be disclosed in order to satisfy the best mode requirement.<sup>80</sup>

## 2. Cases From the Inception of the Federal Circuit to 1991

The first major best mode case decided by the Federal Circuit was *Christianson v. Colt Industries Operating Corp.*<sup>81</sup> The court held that the best mode requirement relates to what is required to practice the *claimed* invention,<sup>82</sup> not what is required for mass production and sales of the invention to customers.<sup>83</sup> Therefore, after *Christianson*, a patentee could

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73. *Id.*

74. *Id.* at 459-60.

75. *Id.* at 460.

76. *Id.* (quoting *Dale Elec., Inc. v. R.C.L. Elec., Inc.*, 488 F.2d 382, 389 (1st Cir. 1973)).

77. *Id.*

78. *See supra* notes 64-69 and accompanying text.

79. *Int'l Telephone & Telegraph*, 538 F.2d at 460.

80. *See supra* notes 64-79 and accompanying text.

81. *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544 (Fed. Cir. 1987).

82. *Id.* at 1563.

83. *See id.* “Christianson accused Colt of violating the best mode requirement because Colt failed to disclose the tolerances and mass production data necessary to make the claimed invention (a part for a rifle) interchangeable in a particular use (the M16).” Arnold, *supra* note 45 at 565. The *Christianson* court stated that “[t]he patent system has conferred on Colt no exclusivity or economic advantage respecting Colt’s dimensions, tolerances, and drawings necessary for interchangeability.” *Christianson*, 822 F.2d at

not base a best mode violation on unclaimed subject matter that was necessary for optimal production and sales of the claimed invention.<sup>84</sup>

The next major case, *Spectra-Physics, Inc. v. Coherent, Inc.*,<sup>85</sup> involved two of Coherent's patents, the Hobart patent, which is directed to an ion laser structure and the Mefferd patent, which is directed to a method of fabricating the ion laser.<sup>86</sup> Both patents stress the fact that the bond between the copper cups and the ceramic tube must be able to withstand "repeated heat cycling" in order for the laser to be reliable.<sup>87</sup> To make the critical copper-ceramic bond, Wayne Mefferd developed a six-stage braze cycle involving the use of Titanium-Copper-Silicon (TiCuSil) brazing.<sup>88</sup> The patent specification did identify several techniques for attaching the copper cups to the ceramic tube including the TiCuSil brazing.<sup>89</sup> However, details of the brazing cycle, were not adequately disclosed in either patent, nor was it known in the prior art.<sup>90</sup> As a result, the Federal Circuit held that both patents were invalid because they did not disclose the best mode of carrying out the invention.<sup>91</sup> According to the Federal Circuit, if the patent applicant "develops specific instrumentalities or techniques which are recognized at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public

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1563.

84. See *Christianson*, 822 F.2d at 1563; Irving, *supra* note 47, at 711 (explaining the holding in *Christianson*).

85. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987).

86. *Id.* at 1526.

87. *Id.* at 1529.

88. *Id.* at 1531 ("Mefferd's six-stage cycle produced a reliable braze joint between the copper cups and the ceramic tube. Because this approach worked, Coherent continued to use TiCuSil and . . . [did not] further experiment[] with soldering.").

89. Arnold, *supra* note 45, at 545.

90. The court stated "[t]he appropriate question then is not whether the inventors disclosed TiCuSil brazing *at all*—they did—but whether TiCuSil brazing was *adequately* disclosed." *Spectra-Physics*, 827 F.2d at 1536 (emphasis in original). Furthermore, "[e]ven though there may be a general reference to the best mode, the quality of the disclosure may be so poor as to effectively result in concealment." *Id.* The court then concluded "[t]he facts found by the district court . . . plainly demonstrate that the TiCuSil brazing technique used by Coherent was not adequately disclosed." *Id.* The court also noted that "Coherent admits that its braze cycle is not disclosed in either patent nor is it contained in the prior art." *Id.*

91. *Spectra-Physics*, 827 F.2d at 1538.

as well.”<sup>92</sup>

Crucial to the Federal Circuit's opinion in *Spectra-Physics* was the fact that the prior art did not show how to use the TiCuSil technique that Coherent employed.<sup>93</sup> This case “shows that at least some judges on the Federal Circuit want to see the disclosure of something more than the preferred structure.”<sup>94</sup>

Following *Spectra-Physics*, the Federal Circuit stated in *Randomex, Inc. v. Scopus Corp.*:<sup>95</sup>

Because not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing, in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed.<sup>96</sup>

Therefore, in order to find a best mode violation, it must be shown that the inventor possessed an undisclosed preferred embodiment at the time of filing of the patent application.<sup>97</sup> In this case, the court also explained the best mode requirement in dicta: “if one should invent a new and improved internal combustion engine, the best mode requirement would require a patentee to divulge the fuel on which it would run best. This patentee, however, would not be required to disclose the formula for refining gasoline or any other petroleum product.”<sup>98</sup> *Randomex* involved a patent for a portable apparatus for cleaning computer disk packs.<sup>99</sup> The court viewed the cleaning solution “as a fluid for use with the claimed invention,” but “not as a limiting feature of the claims.”<sup>100</sup> The cleaning solution was not “a part of the ‘essence’ of the invention.”<sup>101</sup> In other words, the cleaning solution was the “fuel” that would run the disk, or “engine” of the invention.<sup>102</sup>

In *Dana Corp. v. IPC Ltd. Partnership*,<sup>103</sup> the patent

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92. *Id.* at 1532.

93. Arnold, *supra* note 45, at 545-46.

94. *Id.* at 547.

95. *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585 (Fed. Cir. 1988).

96. *Id.* at 587 (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986)).

97. *See id.* at 587.

98. *Id.* at 590.

99. *Id.* at 586.

100. Arnold, *supra* note 45, at 554.

101. *Id.*

102. *See supra* note 98 and accompanying text.

103. *Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d 415 (Fed. Cir. 1988).

claimed a valve stem seal for internal combustion engines.<sup>104</sup> The alleged infringer claimed that fluoride treatment of the rubber for the seal was essential for the valves to seal properly.<sup>105</sup> Since Dana's patent did not state the fluoride requirement,<sup>106</sup> the infringer asserted the defense that the best mode requirement was not satisfied.<sup>107</sup>

Dana countered by submitting an article to the court that explained that fluoride treatment is known to those skilled in the art.<sup>108</sup> The Federal Circuit disagreed with Dana's argument, holding that the "best mode requirement is not satisfied by reference to the level of skill in the art."<sup>109</sup> Rather, the best mode requirement "entails a comparison of the facts known to the inventor regarding the invention at the time the application was filed and the disclosure in the specification."<sup>110</sup> Therefore, since the established facts showed that fluoride treatment was the best mode, the patent did not satisfy this requirement when it failed to make the fluoride disclosure.<sup>111</sup>

Next, in *Chemcast Corp. v. Arco Industries Corp.*,<sup>112</sup> the patent claimed a sealing member in the "form of a grommet or plug button" that was designed to seal an opening in a panel.<sup>113</sup> Unlike its previous holding in *Dana*,<sup>114</sup> the Federal Circuit in *Chemcast* held that "the disclosure required by section 112 is directed to those skilled in the art."<sup>115</sup> Therefore, "one must consider the level of skill in the relevant art in determining whether a specification discloses the best mode."<sup>116</sup> The court held there to be a second "objective limitation on the extent of the disclosure required to comply with the best mode

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104. *See id.* at 416.

105. *Id.* at 417.

106. *See Arnold, supra* note 45, at 548 (citing the actual specification).

107. *Id.*

108. *See Dana*, 860 F.2d at 418-19 (Fed. Cir. 1988) (stating that Dana argued the best mode requirement was satisfied because the "fluoride treatment of Buna-N rubber for seal applications was known to the public [for] years . . . . A technical article from *Rubber Age* magazine and certain expert testimony was cited by Dana as supporting the view that such a treatment was common to the skilled artisan"). *See also Arnold, supra* note 45, at 549.

109. *See Dana*, 860 F.2d at 419.

110. *Id.*

111. *See id.* at 420.

112. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923 (Fed. Cir. 1990).

113. *Id.* at 924.

114. *See supra* notes 103-111 and accompanying text.

115. *Chemcast*, 913 F.2d at 926 (emphasis added).

116. *Id.* at 927.

requirement.”<sup>117</sup> The limitation is that the best mode requirement is restricted to what is claimed in the invention.<sup>118</sup> Unlike the holding in *Christianson v. Colt*<sup>119</sup>, this time the Federal Circuit put no parameters on the best mode requirement.<sup>120</sup>

Therefore, the court summarized a proper best mode analysis as having two parts.<sup>121</sup> The first component is “whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other.”<sup>122</sup> This part of the analysis is entirely subjective.<sup>123</sup> The second part of the analysis “compares what [the inventor] knew with what he disclosed—is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor ‘concealed’ his preferred mode from the ‘public?’”<sup>124</sup> This component is objective, and “depends upon the scope of the claimed invention and the level of skill in the art.”<sup>125</sup>

Thus, by employing a two-prong analysis, the court found the patent in *Chemcast* invalid.<sup>126</sup> The inventor in this case knew that the preferred material for the locking portion of the grommet was a “rigid polyvinyl chloride plastisol composition, having a ‘75 +/-5 Shore D’ hardness.”<sup>127</sup> The only compound fitting this description was a compound known as R-4467.<sup>128</sup> However, this compound was not disclosed in the specification.<sup>129</sup> Furthermore, this concealed information was a preferred ingredient for making an element of the invention, and therefore involved unclaimed subject matter.<sup>130</sup> Therefore,

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117. *Id.*

118. *Id.*

119. *See supra* notes 81-84 and accompanying text.

120. *See Chemcast*, 913 F.2d at 927-28 (Fed. Cir. 1990).

121. *Id.* at 927.

122. *Id.* at 928.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.* at 930. *See also* Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931 (Fed. Cir. 1990) (a case involving an inventor who failed to disclose his preferred embodiment for a specific type of audio tape with different features than standard audio tapes. The court held the patent to be in violation of the best mode requirement).

127. Arnold, *supra* note 45, at 559.

128. *Id.*

129. *See* Arnold, *supra* note 45, at 560 (discussing the actual specification).

130. *See id.* at 561.

the Federal Circuit seemed to “adopt a rule that any information necessary to practice the best mode of carrying out the claimed invention must be disclosed.”<sup>131</sup>

As a result of the Federal Circuit’s holdings in the previous line of cases,<sup>132</sup> it could not be assumed that the best mode requirement is a “synonym for disclosure of the ‘preferred embodiment’ of the claimed invention.”<sup>133</sup> In other words, the best mode requirement is not limited to the preferred structure, but may include both the preferred method of making the invention *and* the preferred method of using the invention.<sup>134</sup>

### 3. Federal Circuit Opinions Since 1991

In *Wahl Instruments Inc. v. Acvious Inc.*,<sup>135</sup> the court held that the words in 35 U.S.C. § 112 are “not without ambiguity.”<sup>136</sup> Furthermore, the court found that “the term ‘mode’ and the phrase ‘carrying out the invention’ are not definable with precision.”<sup>137</sup>

However, the Federal Circuit in *Engel Industries, Inc. v. Lockformer Co.*<sup>138</sup> held that “[t]he best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.”<sup>139</sup> Furthermore, the court held that unclaimed subject matter is *not* subject to the best mode requirement.<sup>140</sup> Therefore, it seems the Federal Circuit has been inconsistent in determining whether the best mode requirement is ambiguous.<sup>141</sup>

Since 1996, the Federal Circuit has found best mode requirement violations in three cases.<sup>142</sup> The first case was *United States Gypsum Co. v. National Gypsum Co.*,<sup>143</sup> decided

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131. *See id.*

132. *See supra* notes 81-131 and accompanying text.

133. Arnold, *supra* note 45, at 538.

134. *Id.*

135. *Wahl Instruments Inc. v. Acvious Inc.*, 950 F.2d 1575 (Fed. Cir. 1991).

136. *Id.* at 1579.

137. *Id.*

138. *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528 (Fed. Cir. 1991).

139. *Id.* at 1531.

140. *Id.*

141. *See supra* notes 135-40 and accompanying text.

142. *Bayer AG v. Schein Pharms. Inc.*, 301 F.3d 1306, 1316-19 (Fed. Cir. 2002).

143. *United States Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209 (Fed. Cir. 1996).

by the Federal Circuit in 1996.<sup>144</sup> This case involved a lightweight joint compound.<sup>145</sup> The joint compound contained a silicone-treated perlite known as Sil-42 perlite.<sup>146</sup> However, the patent's specification did not refer to Sil-42 perlite.<sup>147</sup> The court determined the inventor selected Sil-42 perlite "because it did not require screening and because it significantly improved the physical properties of the joint compound."<sup>148</sup> In other words, the court found that the inventor "believed that Sil-42 perlite was essential to improving the *invention*; the material was not selected as a matter of commercial expediency."<sup>149</sup> Further, the court held that disclosure concerning the best mode of *practicing* an invention is required under 35 U.S.C. § 112.<sup>150</sup> Therefore, the patent was found invalid by the Federal Circuit for failure to satisfy the best mode requirement.<sup>151</sup>

In *Great Northern Corp. v. Henry Molded Products, Inc.*,<sup>152</sup> the Federal Circuit held a patent invalid for failure to disclose the best mode of carrying out the invention when the specification did not refer to diamonds that were used in the invention.<sup>153</sup> The factual record of the case indicated that, at a minimum, the supports for large-diameter rolls could not be produced without the diamonds.<sup>154</sup> This fact demonstrated that the diamonds were critical to practicing the claimed invention,<sup>155</sup> and were therefore required to be disclosed under section 112.<sup>156</sup>

In *Nobelpharma AB v. Implant Innovations, Inc.*,<sup>157</sup> the patent was on a dental implant that was preferably made of

144. *Id.* at 1209.

145. *Id.* at 1210. Joint compounds are adhesives used in the construction of building walls and ceilings to fill and coat the joints between adjacent gypsum wallboards. *Id.*

146. *Id.* at 1211.

147. *Id.*

148. *Id.* at 1213.

149. *Id.* (emphasis added).

150. *See id.*

151. *See id.* at 1216.

152. *Great N. Corp. v. Henry Molded Prods. Inc.*, 94 F.3d 1569 (Fed. Cir. 1996).

153. *Id.* at 1574.

154. *Id.* at 1572.

155. *Id.*

156. *See id.* (holding that the diamonds related to the best mode for practicing the claimed invention).

157. *Nobelpharma AB v. Implant Innovations Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).



titanium and a network of particularly-sized and particularly-spaced micropits.<sup>158</sup> These micropits allow a secure connection to form between the implant and the growing bone<sup>159</sup> in a process known as osseointegration.<sup>160</sup> The patent neglected to mention a variety of machining parameters that were critical to the production of a functional dental implant.<sup>161</sup> Therefore, the Federal Circuit held that the patent did not satisfy the best mode requirement.<sup>162</sup>

Finally, *Eli Lilly & Co. v. Barr Laboratories, Inc.*<sup>163</sup> involved a pharmaceutical manufacturer of an antidepressant drug (commercially known as Prozac).<sup>164</sup> The patent in this case disclosed the compound fluoxetine hydrochloride, the active form of the drug, but did not disclose the inventor's preferred method for synthesizing the starting material, p-trifluoromethylphenol,<sup>165</sup> necessary to synthesize the drug.<sup>166</sup> The Federal Circuit held that an inventor need not disclose a mode for obtaining unclaimed subject matter unless the "subject matter is novel and essential for carrying out the best mode of the invention."<sup>167</sup>

The court found that Lilly did disclose the preference for using p-trifluoromethylphenol when making fluoxetine hydrochloride.<sup>168</sup> However, they also found that Lilly did not disclose the unclaimed method for synthesizing the starting material.<sup>169</sup> The court went on to hold that "[t]o be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter *even if it is unclaimed.*"<sup>170</sup> This poses a potential problem however because matter disclosed in the specification but not claimed is given to the public and therefore cannot be claimed later.<sup>171</sup> Nevertheless, in this case,

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158. *Id.* at 1062.

159. *Id.*

160. *Id.*

161. *Id.* at 1065.

162. *See id.* at 1066.

163. *Eli Lilly & Co. v. Barr Labs. Inc.*, 222 F.3d 973 (Fed. Cir. 2000).

164. *Id.* at 973.

165. *Id.* at 978-79.

166. *See id.* at 977.

167. *Id.* at 981.

168. *Id.* at 982.

169. *Id.*

170. *Id.* (emphasis added).

171. *See Johnston & Johnston Assoc., Inc. v. R.E. Service Co., Inc.*, 285

the court held that the record demonstrated that the starting material was not novel.<sup>172</sup> This was based on the fact that the starting material actually was commercially available.<sup>173</sup> Furthermore, the record included prior art references that showed how to prepare the starting material in fluoxetine hydrochloride.<sup>174</sup>

#### D. UNITED STATES PATENT AND TRADEMARK OFFICE'S INTERPRETATION OF THE BEST MODE REQUIREMENT

The first step that a patent examiner from the United States Patent and Trademark Office (USPTO) must follow is to determine how the invention is defined in the claims.<sup>175</sup> Under the Rules of Examination, the specification “need not set forth details not relating to the essence of the invention.”<sup>176</sup> In other words, unclaimed subject matter that is not related to the operation of the invention is not required under the best mode requirement.<sup>177</sup> However, if the patent applicant “develops specific instrumentalities or techniques which are recognized by the applicant at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well.”<sup>178</sup>

The examiner should then assume that the best mode is disclosed in the application, unless evidence is presented that proves otherwise.<sup>179</sup> Furthermore, the patent examiner should follow the two-prong best mode analysis set out in *Chemcast*.<sup>180</sup> Only evidence of concealment is to be considered in determining the adequacy of a best mode disclosure.<sup>181</sup> This concealment can either be intentional or accidental.<sup>182</sup> This evidence of concealment must “tend to show that the quality of an applicant’s best mode disclosure is so poor as to effectively

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F.3d 1046, 1051 (Fed. Cir. 2002).

172. See *Eli Lilly*, 222 F.3d at 982.

173. *Id.*

174. *Id.*

175. MANUAL OF PATENT EXAMINING PROCEDURE § 2165.01 (2003) [hereinafter MANUAL].

176. *Id.*

177. *Id.*

178. *Id.* at § 2165.02.

179. *Id.* at § 2165.03.

180. See *id.*; see also *supra* notes 120-26 and accompanying text.

181. See MANUAL, *supra* note 175, at § 2165.04.

182. See *id.*

result in concealment.”<sup>183</sup>

In conclusion, Congress has extensively dealt with the best mode requirement through several acts leading up to the Patent Act of 1952.<sup>184</sup> Furthermore, the courts have interpreted the best mode requirement at length since Congress established the Patent Act in 1952.<sup>185</sup> In light of this legislative history and judicial precedent, the Federal Circuit decided *Bayer v. Schein*.<sup>186</sup>

## II. THE FEDERAL CIRCUIT'S RESOLUTIONS IN *BAYER V. SCHEIN*

### A. THE BACKGROUND HOLDINGS OF THE FEDERAL CIRCUIT

The Federal Circuit decided *Bayer v. Schein* on August 9, 2002.<sup>187</sup> The court first described the basis for Schein's assertion of Bayer's patent invalidity under 35 U.S.C. §102(d).<sup>188</sup> Section 102(d) provides in relevant part:

A person shall be entitled to a patent unless . . . the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant . . . in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States .<sup>189</sup>

Schein made two allegations in support of invalidity under section 102(d). First, Schein argued that Bayer filed foreign patent applications on Cipro more than one year prior to October 22, 1982.<sup>190</sup> October 22, 1982 was the earliest priority date of the '923 application that issued as the '444 patent.<sup>191</sup> Second, the foreign patent applications issued before October 22, 1982.<sup>192</sup> Therefore, the '444 patent was filed more than one year after the filing of the foreign patents and is invalid under section 102(d), unless Bayer can rely upon an earlier filing

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183. *Id.*

184. *See supra* notes 47-61 and accompanying text.

185. *See supra* notes 62-174 and accompanying text.

186. *Bayer AG v. Schein Pharm, Inc.*, 301 F.3d 1306 (Fed. Cir. 2002).

187. *Id.* at 1306.

188. *See id.* at 1312.

189. *Id.* at 1312 (quoting 35 U.S.C. § 102(d) (2000)).

190. *See id.* at 1312-13.

191. *Id.*

192. *Id.*

date.<sup>193</sup>

However, Bayer countered that the '444 patent is not invalid under section 102(d) because the '444 patent can claim priority to the filing date of the '560 application under 35 U.S.C. § 120.<sup>194</sup> Section 120 provides in relevant part:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment or termination of proceedings on the first application.<sup>195</sup>

Bayer argued that under section 120, the '444 patent can claim priority to August 13, 1982, the filing date of the '560, application,<sup>196</sup> Since this date is within a year of the filing date of the foreign patents, Bayer argued that 102(d) should not apply.<sup>197</sup> However, the court stated that section 120 only applies if the earlier application fulfills the disclosure requirements of 35 U.S.C. § 112.<sup>198</sup> Therefore, "Bayer may defeat the 102(d) bar . . . only if the '560 application fulfills the disclosure requirements of section 112."<sup>199</sup>

Schein argued that the '560 application did not satisfy 35 U.S.C. § 112 because it failed to disclose the best mode contemplated by Dr. Grohe for making Cipro.<sup>200</sup> According to Schein, the application failed to do so because it did not "disclose the synthesis of the Klauke compound or the use of the cycloaracyclation reaction to make 6-FQA."<sup>201</sup> However, both of these compounds are intermediates which are not claimed in the '444 patent.<sup>202</sup> Nevertheless, Schein asserted that 6-FQA and its synthesis via cycloaracyclation of the Klauke compound is novel and therefore the preferred method of making them is required to be disclosed under section 112 in order to adequately describe the best mode of synthesizing

193. *Id.* at 1313.

194. *Id.*

195. *Id.* (quoting 35 U.S.C. § 120 (2000)).

196. *Id.* at 1313.

197. *See supra* note 15.

198. *Bayer*, 301 F.3d at 1313.

199. *Id.*

200. *Id.*

201. *Id.*; *see also supra* notes 5-10 and accompanying text.

202. *Bayer*, 301 F.3d at 1313.

Cipro.<sup>203</sup>

In its analysis, the Federal Circuit stated, “compliance with the best mode requirement requires disclosing the inventor’s preferred embodiment of the *claimed invention*.”<sup>204</sup> In addition, the court stated, “cases examining the scope of the best mode requirement demonstrate that the best mode disclosure requirement only refers to the invention defined by the claims.”<sup>205</sup> Finally, the Federal Circuit held that the “existence of a best mode is a purely subjective matter depending upon what the inventor actually believed at the time the application was filed . . . [Therefore], the best mode requirement . . . cannot be met by mute reference to the knowledge of one of skill in the art.”<sup>206</sup>

Furthermore, the court found that the best mode requirement does not “demand disclosure of every preference an inventor possesses as of the filing date . . .”<sup>207</sup> The Federal Circuit explained that “[a]s is always the case, the text of the statute provides the proper boundaries of the disclosure requirement.”<sup>208</sup> The court went on to hold that “[s]ection 112 only demands disclosure of ‘the best mode contemplated by the inventor of *carrying out his invention*.’”<sup>209</sup>

Nevertheless, the court admitted that it has “found violations of the best mode requirement for failure to disclose subject matter not strictly within the bounds of the claims.”<sup>210</sup> The court found that there had been seven occasions in the history of the Federal Circuit and its predecessor courts when patents had been invalidated for failure to meet the best mode requirement.<sup>211</sup> The court found that these cases “involved either failure to disclose a preferred embodiment, or else failure to disclose a preference that materially affected making or using the invention.”<sup>212</sup>

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203. *Id.* (drawing on the holding in *Eli Lilly*, 251 F.3d at 964 (Fed. Cir. 2001)). See also *supra* note 170 and accompanying text.

204. *Bayer*, 301 F.3d at 1316 (emphasis added).

205. *Id.* at 1315.

206. *Id.* at 1314.

207. *Id.* at 1314-15.

208. *Id.* at 1315.

209. *Bayer*, 301 F.3d at 1315 (quoting 35 U.S.C. § 112 (1994)) (alteration in original).

210. *Id.* at 1316 (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1331 (Fed. Cir. 2002)).

211. *Id.*

212. *Id.*

B. THE CASE ANALYSES OF THE FEDERAL CIRCUIT IN *BAYER V. SCHEIN*

The first case discussed by the Federal Circuit was *Spectra-Physics*.<sup>213</sup> The Federal Circuit stated that although the patent specification at issue in *Spectra-Physics* disclosed the preference for using TiCuSil as a brazing material, it did not disclose the parameters for performing the TiCuSil brazing cycle developed by the inventor.<sup>214</sup> Since the patent specification stressed the importance of brazing in obtaining efficiency and reliability of the claimed laser, the “failure to disclose the actual method of brazing preferred by the inventor rendered the patent claims invalid for ‘failure to disclose the best mode contemplated by the inventors for practicing their . . . inventions.’”<sup>215</sup>

The Federal Circuit then discussed *Dana Corp.*<sup>216</sup> In this case, the invention was a valve stem seal for an internal combustion engine.<sup>217</sup> The inventor found that a 60-second fluoride surface treatment was necessary for the seal to function without leaking.<sup>218</sup> According to the Federal Circuit, “the undisclosed fluoride surface treatment had a material effect on the properties of the claimed invention.”<sup>219</sup> Since “the inventor ‘believed that the best way of carrying out his invention included fluoride treating the surface of the valve seals,’” and the “specification never ‘disclosed that a fluoride treatment must or even should be applied’ . . . as preferred by the inventor,” the patent was held to be invalid for failure to disclose the best mode.<sup>220</sup>

Next, the court discussed *Northern Telecom*.<sup>221</sup> In this case, the defendant raised a best mode challenge to claims directed to capturing data on magnetic tape cassettes.<sup>222</sup> The inventor preferred certain audio tapes with specific yield strength and magnetic characteristics which were different from standard

213. *Id.*

214. *Id.* at 1316. *See supra* notes 85-94 and accompanying text.

215. *Bayer*, 301 F.3d at 1316-17 (quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1537 (Fed. Cir. 1987)).

216. *Id.* at 1317. *See supra* notes 103-11 and accompanying text.

217. *Bayer*, 301 F.3d at 1317.

218. *Id.* at 1317.

219. *Id.*

220. *Id.* (quoting *Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d at 419-20).

221. *Id.* *See supra* text accompanying note 126.

222. *Bayer*, 301 F.3d at 1317.

audio tapes.<sup>223</sup> The specification however disclosed neither the inventor's specifications for the preferred tape nor the identity of the brand on the market that met the inventor's specifications.<sup>224</sup> The court held the patent in violation of the best mode requirement because the "inventor had developed a preferred embodiment of his invention that used a very specific type of audiotape, and failure to disclose that preferred embodiment . . . ."<sup>225</sup>

The fourth case discussed by the Federal Circuit is *Chemcast*.<sup>226</sup> In this case, the claim was directed to a grommet and the inventor had a preference for a particular material for making the locking portion of the grommet.<sup>227</sup> The patent's disclosure was found to be deficient for failure to disclose this fact in the specification.<sup>228</sup> In concealing the preferred embodiment, the best mode requirement was not satisfied, and the claims were invalid.<sup>229</sup>

The fifth case discussed by the Federal Circuit in *Bayer* is *Gypsum*.<sup>230</sup> *Gypsum* dealt with the validity of a claim directed to a compound that contained an "expanding perlite."<sup>231</sup> The court stated that the inventor "believed that Sil-42 perlite was essential to improving the *invention*; the material was not selected as a matter of commercial expediency."<sup>232</sup> Therefore, by not disclosing the Sil-42 perlite, the patent did not disclose the best mode of carrying out the inventor's preferred embodiment, and was thus held invalid.<sup>233</sup>

The Federal Circuit also discussed *Great Northern Corp.*<sup>234</sup> In this case, the patent specification failed to disclose diamond indentations that were "crucial to producing a usable version of the invention." because without them, the support, "simply collapsed under the weight of the rolls it was supposed to

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223. *Id.*

224. *Id.*

225. *Id.*

226. *Id.* See *supra* notes 112-31 and accompanying text.

227. *Bayer*, 301 F.3d at 1317.

228. *Id.*

229. *Id.*

230. *Id.* See *supra* notes 142-51 and accompanying text.

231. *Bayer*, 301 F.3d at 1318.

232. *Id.* (emphasis added) (quoting *United States Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209, 1213 (Fed. Cir. 1996)).

233. See *id.* at 1318.

234. *Id.* See *supra* notes 152-56 and accompanying text.

hold.”<sup>235</sup> The claims were held to be invalid because the diamonds that materially affected the properties of the claimed invention were not disclosed and resulted in a failure to satisfy the best mode requirement.<sup>236</sup>

Lastly, the Federal Circuit discussed *Nobelpharma*.<sup>237</sup> In this case, the patent claimed “an element intended for implantation in to bone tissue” that contained micropits.<sup>238</sup> The production of the implant depended decisively on a number of undisclosed machine parameters.<sup>239</sup> The undisclosed parameters were said to be “related to manufacture of the claimed implant, and were critical to production of a functional implant.”<sup>240</sup> Since the undisclosed preference materially affected the properties of the invention, failure to disclose it resulted in a violation of the best mode requirement.<sup>241</sup>

### C. ACCORDING TO THE FEDERAL CIRCUIT, BAYER DID NOT VIOLATE THE BEST MODE REQUIREMENT IN ITS '560 PATENT

According to the Federal Circuit, the first step in any best mode analysis is to identify the invention recited in the claims.<sup>242</sup> The Federal Circuit noted that the claims of the '444 patent involve “compositions of matter that either comprise or consist solely of the target antibiotic compound—in this case ciprofloxacin.”<sup>243</sup> Furthermore, the court noted that the claims do not recite 6-FQA or any other starting material.<sup>244</sup> Thus,

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235. *Bayer*, 301 F.3d at 1318.

236. *Id.*

237. *Id.* See *supra* notes 157-62 and accompanying text.

238. *Bayer*, 301 F.3d at 1318.

239. *Id.*

240. *Id.* at 1318-19.

241. *Id.* at 1319.

242. See *id.* at 1320 (discussing *N. Telecom Ltd. v. Samsung Elec. Co.*, 215 F.3d 1281, 1286-87 (Fed Cir. 2000)). *Bayer* described the holding in *N. Telecom* as follows:

[T]he first step in a best mode inquiry, before application of the familiar two-part best mode test, *must* be to define the invention by construing the claims. Definition of the invention ‘is a legal exercise, wherein the ordinary principles of claim construction apply.’ Defining the invention by analyzing the claim language is a crucial predicate to the factual portions of the best mode inquiry because it ensures that the finder of fact looks only for preferences pertaining to carrying out the claimed invention.

*Id.* (emphasis in original) (quoting *N. Telecom*, 215 F.3d at 1286-87).

243. *Id.*

244. *Id.* at 1321.



“the invention . . . consists of the final antibiotic product and not the starting materials.”<sup>245</sup> In addition, the court noted that the inventor had a preferred method of making ciprofloxacin by “manipulating 6-FQA by reacting it with piperazine.”<sup>246</sup> Furthermore, the ‘560 application did not disclose either the Klauke compound or its use in making 6-FQA, which are both intermediate steps in the synthesis of Cipro.<sup>247</sup>

However, the Federal Circuit held that Bayer’s failure to disclose Dr. Grohe’s preferred method of making 6-FQA was not a violation of the best mode requirement.<sup>248</sup> The court stated that only “[p]references that are reflected in a preferred embodiment or that relate to making or using the invention and have a material effect on the properties of the claimed invention” are required to be disclosed.<sup>249</sup> The court found that failure to disclose the method of making 6-FQA was not fatal because it had no material effect on the properties of Cipro.<sup>250</sup> As a result, the court found this case “clearly distinguishable from the four cases in which this court has found a best mode violation where an undisclosed preference clearly had a material affect on the properties of the claimed invention.”<sup>251</sup>

Schein raised the argument that disclosure of Dr. Grohe’s preferred method of producing 6-FQA is mandatory because it is novel.<sup>252</sup> Schein based this contention on the Federal Circuit’s holding in *Eli Lilly*.<sup>253</sup> However, the court held that Schein misunderstood the Federal Circuit’s holding in *Eli Lilly*.<sup>254</sup> The court in *Bayer* explained that the Federal Circuit in *Eli Lilly* “merely acknowledged that when a novel compound is necessary to practice the best mode, one of skill in the art must be able to obtain that compound.”<sup>255</sup> Therefore, the

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245. *Id.*

246. *Id.*

247. *Id.*

248. *See id.* at 1323.

249. *Id.* at 1321.

250. *See id.* at 1321-22.

251. *Id.* These four cases are *Spectra-Physics*, *Nobelpharma*, *Dana*, and *Great Northern*. *See supra* section II.B.

252. *Bayer*, 301 F.3d at 1322.

253. *Id.*; *see supra* notes 163-74 and accompanying text.

254. *Bayer*, 301 F.3d at 1322 (“Schein understands *Eli Lilly* to stand for the proposition that the best mode of obtaining novel subject matter necessary to practice the invention must be disclosed. *Schein* has misunderstood the impact of our statements in *Eli Lilly*”).

255. *Id.* at 1322.

following statements in *Eli Lilly*, such as “a method for obtaining that subject matter” and “a mode for obtaining unclaimed subject matter” refer only to a requirement that the best mode be enabled by the specification.<sup>256</sup> Since the ‘560 patent contains an enabling disclosure of 6-FQA, it complies with the holding in *Eli Lilly* as interpreted by the Federal Circuit.<sup>257</sup>

In conclusion, the Federal Circuit held in *Bayer* that Dr. Grohe’s preferred method of making 6-FQA does not materially affect the production of Cipro.<sup>258</sup> Therefore, its disclosure is not required to comply with the best mode requirement.<sup>259</sup> Since the ‘560 application is in compliance with 35 U.S.C. §112, paragraph 1, the ‘444 patent can claim the filing date of the ‘560 application under 35 U.S.C. §120.<sup>260</sup> Moreover, because this filing date is well within the filing date of the first foreign patent, the issuance of those foreign patents does not invalidate the ‘444 patent under 35 U.S.C. §102(d).<sup>261</sup>

### III. WHY THE COURT ERRED IN *BAYER V. SCHEIN*

In *Bayer*, the Federal Circuit stated that 35 U.S.C. § 112 demands disclosure of the best mode the inventor contemplated for carrying out the invention.<sup>262</sup> The court noted it had held that nondisclosure of unclaimed subject matter violated the best mode requirement when the specification failed to disclose a preferred embodiment or else failed to disclose a preference that materially affected making or using the invention.<sup>263</sup> The court subsequently held in the instant case that the ‘560 patent from which the ‘444 patent claimed benefit did not violate the best mode requirement, because the unclaimed subject matter did not materially affect making or using the claimed invention nor was it a preferred embodiment of the claimed invention.<sup>264</sup>

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256. *Id.*

257. *See id.* at 1323.

258. *See id.*

259. *See id.*

260. *See id.*

261. *Id.*

262. *Id.* at 1315.

263. *See id.* at 1316.

264. *See id.* at 1323.

#### A. THE KLAUKE COMPOUND AND 6-FQA MATERIALLY AFFECT THE PRODUCTION OF CIPRO

Analysis of the facts shows that the Klauke compound materially affected and was vital to the final synthesis of Cipro. Grohe's initial method of synthesizing 6-FQA was unsuccessful.<sup>265</sup> The Klauke compound was the only structure known by Grohe that could be used to synthesize 6-FQA.<sup>266</sup> As such, without the Klauke compound, 6-FQA was an obscurity to Dr. Grohe and without 6-FQA, the synthesis of Cipro would have been impossible for him.<sup>267</sup> Therefore, the Klauke compound and the preferred synthetic route to 6-FQA by Grohe were essential to the production of Cipro. Since essential steps in a process materially affect the final production of a product, these two properties of the final invention should have been disclosed in the specification in order to satisfy the best mode requirement as interpreted by the Federal Circuit in *Bayer*.<sup>268</sup>

The Federal Circuit looked to several cases to support its holding that the '560 patent did not violate the first prong of the best mode requirement.<sup>269</sup> These cases are outlined in sections I and II of this Comment. Like *Bayer*, these cases all involved unclaimed subject matter in the specification.<sup>270</sup> However, unlike *Bayer*, the Federal Circuit found best mode violations in every one by holding that the unclaimed subject matter materially affected the claimed invention.<sup>271</sup> In *Bayer*, the court erred by not finding a direct correlation between the facts of those cases and the facts in *Bayer*.

The facts of *Spectra-Physics* are essentially the same as the facts of *Bayer*.<sup>272</sup> Both cases involved a certain method that was optimal for ultimately producing the claimed invention.<sup>273</sup> In *Spectra-Physics*, the inventor had a preferred method for utilizing the TiCuSil brazing material.<sup>274</sup> In *Bayer*, it was the use of the Klauke compound and the synthetic pathway of 6-

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265. *Id.* at 1310.

266. *See id.*

267. *See id.*

268. *See supra* notes 135-74 and accompanying text.

269. *See supra* notes 213-61 and accompanying text.

270. *See supra* notes 213-41 and accompanying text.

271. *See supra* notes 213-41 and accompanying text.

272. *See supra* notes 85-94, 187-212 and accompanying text.

273. *See supra* notes 85-94, 187-212 and accompanying text.

274. *See supra* note 88 and accompanying text.

FQA.<sup>275</sup> In *Spectra-Physics*, the Federal Circuit made a clear holding that would directly support a best mode violation by Bayer – if the patent applicant develops specific instrumentalities or techniques which are recognized as the best way of carrying out the invention, the best mode requirement demands disclosure of the preference.<sup>276</sup> Therefore, the Federal Circuit did not make an adequate comparison between *Spectra-Physics* and *Bayer*, applying *Spectra-Physics* incorrectly to the facts of *Bayer*. Clearly, the Klauke compound is a specific compound (instrumentality) developed by *Bayer* to synthesize Cipro. Furthermore, the Klauke compound is the best way, if not the only way, of ultimately carrying out the claimed invention.<sup>277</sup> Therefore, according to the Federal Circuit's logic in *Spectra-Physics*, Bayer violated the best mode requirement of 35 U.S.C. § 112.

The Federal Circuit also erred in its analysis of *Bayer* in relation to *Dana Corp.*<sup>278</sup> In *Dana*, a fluoride treatment was necessary in order for the valve to work properly.<sup>279</sup> Thus, the treatment materially affected the claimed invention. In *Bayer*, the Klauke compound was necessary for the synthesis of 6-FQA, which was in turn essential to the production of the claimed invention, Cipro.<sup>280</sup> This was exactly like the undisclosed fluoride treatment in *Dana*. Therefore, when the court compared the facts in *Bayer* to the facts and holding in *Dana*, it should have found that Bayer violated the best mode requirement.

The Federal Circuit also erred in its analysis of *Bayer* in relation to *Great Northern Corp.*<sup>281</sup> In *Great Northern*, diamond indentations used to stabilize the molded pulp roll support were crucial to producing a workable version of the invention.<sup>282</sup> Without their disclosure, the Federal Circuit held that Great Northern's patent failed the best mode requirement, because the diamond indentations materially affected the claimed invention.<sup>283</sup> The Klauke compound and the synthetic

275. See *supra* notes 268-70 and accompanying text.

276. See *supra* note 92 and accompanying text.

277. See *supra* notes 265-68 and accompanying text.

278. See *supra* notes 216-20 and accompanying text.

279. See *supra* notes 218-19 and accompanying text.

280. See *supra* notes 265-68 and accompanying text.

281. See *supra* notes 234-36 and accompanying text.

282. See *supra* notes 234-36 and accompanying text.

283. See *supra* notes 234-36 and accompanying text.

route are the “diamond indentations” of *Bayer*. Without these parts of the claimed invention, there would be no usable version of Cipro. Thus, the court should have also found a best mode violation in *Bayer* when comparing the facts of this case to *Great Northern*.

Finally, in *Nobelpharma*, the court found a best mode violation when the inventor failed to disclose a subjective preference in the production of the claimed invention, a dental implant.<sup>284</sup> The patentee failed to disclose a variety of specific machining parameters required in order to produce a functional implant.<sup>285</sup> By analogy, the Klauke compound and synthesis of 6-FQA are the undisclosed “machining parameters” required to produce Cipro. Therefore, just as the parameters in *Nobelpharma* materially affected the claimed invention, the Klauke compound and 6-FQA synthesis materially affect Cipro.

#### B. THE KLAUKE COMPOUND IS A PREFERRED EMBODIMENT OF CIPRO

In *Northern Telecom*, the Federal Circuit found a best mode violation because a preferred embodiment of the claimed invention used a specific type of audiotape, which was not disclosed in the specification.<sup>286</sup> The court in *Bayer* did not appreciate the relationship between these two cases. The Klauke compound was a specific precursor to the synthesis of 6-FQA.<sup>287</sup> Dr. Grohe’s standard method of synthesizing bicyclics involved beginning with a starting material.<sup>288</sup> He was unsuccessful in producing the material needed for 6-FQA and enlisted the help of a colleague.<sup>289</sup> This method involved the specific use of the Klauke compound to synthesize 6-FQA.<sup>290</sup> It is undisputed that Dr. Grohe had a preference prior to August 13, 1981, for a class of starting materials including the Klauke compound.<sup>291</sup> Therefore, the court once again should have found a best mode violation, because the Klauke compound was a specific, preferred embodiment of the claimed invention.

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284. See *supra* notes 237-241 and accompanying text.

285. See *supra* notes 237-241 and accompanying text.

286. See *supra* notes 221-25 and accompanying text.

287. See *Bayer*, 301 F.3d at 1310.

288. See *id.*

289. See *id.*

290. See *id.*

291. *Id.* at 1321.

### C. BAYER IN LIGHT OF THE POLICY OF THE BEST MODE REQUIREMENT

The disclosure requirement set out in 35 U.S.C. § 112 ensures that every essential aspect of the invention is made public with the granting of the patent.<sup>292</sup> The entry of the information into the public domain is essential to promoting the sharing and expansion of knowledge and the benefits that flow there from. In the scientific community, for example, scientists share knowledge through journals and correspondence with one another. This dissemination of information advances the progress of science—one scientist builds on the research and discoveries of another scientist and so forth. In a similar way, progression of knowledge flows from patented inventions—one inventor builds on a preceding inventor's discoveries, thus advancing science, technology, and ultimately society.

In *Bayer*, disclosure of the intermediates in the synthesis of Cipro was not required according to the Federal Circuit.<sup>293</sup> Without their disclosure, however, the public is unaware of how to make Cipro according to Dr. Grohe's preferred embodiment. This lack of disclosure may seem harmless if one assumes most individuals in society are unlikely to synthesize Cipro. However, pharmaceutical companies and scientists are also deprived of the pathway for the synthesis of 6-FQA from the Klauke compound. If these two entities were granted this knowledge by its disclosure in the '560 patent's specification, they might have been able to build on the knowledge of Bayer and synthesize new and improved antibiotics or other drugs. Thus, what may seem harmless at first could have heavy societal consequences.

### D. BAYER IN LIGHT OF PRECEDENT

The courts early on recognized the social policy of the best mode requirement and recognized a quid pro quo status between patentee and the public.<sup>294</sup> In *In re Gay*, the United States Court of Customs and Patent Appeals held that a patentee might not be allowed to conceal an embodiment of his invention from the public in order to retain possible future

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292. See *supra* notes 34-38 and accompanying text.

293. *Bayer*, 301 F.3d at 1323.

294. See *supra* notes 62-63 and accompanying text.

benefits from such withholding.<sup>295</sup> Therefore, as early as 1962, the courts recognized the quid pro quo between patentee and the public. The court determined that the patent system, in addition to spreading knowledge that advances science and technology, sets up a social hierarchy between the patentee and the public. The patentee will be granted a limited patent upon one fundamental consideration—furnishing the public with the means to reproduce the invention at a later time. The best mode requirement is a vital aspect of this exchange between the patentee and public, because it ensures that the public will be equipped with the inventor's preferred method of producing the invention. The hope is that the public will eventually be able to reproduce the invention with the same amount of effort as the inventor.

As applied to *Bayer*, this judicial interpretation of policy behind the best mode requirement should have resulted in a holding that invalidated Bayer Corp's patent for failure to disclose the Klauke compound and the pathway to synthesis of 6-FQA. Without this disclosure, the public is not granted quid pro quo. Bayer reaps the benefits of its patent monopoly, but the public is not furnished with complete knowledge to produce Cipro after Bayer's patent monopoly expires. Thus, the social hierarchy set up by 35 U.S.C. § 112 fails in practice.

The courts have also been deliberate in differentiating between essential and non-essential elements in their requirements for patent disclosure. For example, in *Randomex*, a pivotal case in best mode jurisprudence, the Federal Circuit made a concrete distinction between those essential aspects of an invention that require disclosure and non-essential ones that do not, explaining that a patentee of an internal combustion engine would, for example, be required to disclose the fuel on which the engine runs because it is essential to the invention.<sup>296</sup> However, under the best mode requirement, the patentee would not be required to disclose the process for refining fuel because it is not essential to the engine.<sup>297</sup> To the extent that the engine has fuel to run as envisioned, it is irrelevant how the fuel was produced.<sup>298</sup>

Cases prior to *Randomex* also expressed this distinction

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295. See *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962).

296. See *supra* notes 95-97 and accompanying text.

297. See *supra* note 98 and accompanying text.

298. See *supra* notes 98-102 and accompanying text.

between essential embodiments of an invention and expendable ones. In *Flick-Reedy*, the court found a special tool used to create the unique seal that was an essential element of the patent also to be indispensable element of the claimed invention.<sup>299</sup> Therefore, its disclosure was required in order to satisfy the best mode requirement.<sup>300</sup> In *International Telephone* the court again made this distinction, however here it found the undisclosed elements to be nonessential to the production of the invention, and their disclosure was not required.<sup>301</sup>

In *Bayer*, the Klauke compound and synthesis of 6-FQA upon which the production of Cipro depends and from which it is synthesized can be analogized to the fuel of *Randomex* and the special tool of *Flick-Reedy*. Without these two compounds, Cipro would not exist as synthesized under Dr. Grohe.<sup>302</sup> These two intermediates of Cipro are needed for its efficient production; therefore they must be disclosed under the Federal Court's analyses and holdings in *Randomex*, *Flick-Reedy*, and *International Telephone* and its articulation of the essential element requirement.<sup>303</sup>

The Federal Circuit has articulated further broad circumstances when information must be disclosed. In *Chemcast*, in addition to establishing the two-prong analysis that the Federal Circuit currently follows,<sup>304</sup> the court further held that any information necessary to practice the best mode of the invention must be disclosed.<sup>305</sup> This holding is simply another way of stating the distinction made in *Randomex*. In *Chemcast*, the patentee did not disclose a preferred ingredient for making an element of the invention and the court held that the best mode requirement was not satisfied.<sup>306</sup> Likewise, in *Bayer*, the patentee failed to disclose a preferred ingredient—the Klauke compound necessary to make an element of the intermediate, 6-FQA.<sup>307</sup> Under the Federal Circuit's precedent in *Chemcast*, Bayer violated the best mode requirement.

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299. See *supra* notes 64-69 and accompanying text.

300. See *supra* notes 64-69 and accompanying text.

301. See *supra* notes 70-80 and accompanying text.

302. See *supra* notes 296-301 and accompanying text.

303. See *supra* note 296 and accompanying text.

304. See *supra* notes 112-25 and accompanying text.

305. See *supra* note 131 and accompanying text.

306. See *supra* notes 127-30 and accompanying text.

307. See *supra* notes 265-68 and accompanying text.



Finally, in *United States Gypsum*, the Federal Circuit held that in addition to the disclosure of essential aspects of the claimed invention, disclosure of the best mode of *practicing* an invention is required under 35 U.S.C. § 112.<sup>308</sup> Thus, the court interpreted the text of the best mode requirement as requiring disclosure of methods of producing or bringing the claimed invention to fruition. In *Bayer*, the method of practicing the claimed invention was to use the Klauke compound to produce 6-FQA and then to use 6-FQA to synthesize Cipro.<sup>309</sup> This was the best mode of practicing the claimed invention as conceived by Dr. Grohe at the time of patent application.<sup>310</sup> Therefore, its disclosure is required according to *Gypsum* and the text of 35 U.S.C. § 112.

#### E. 35 U.S.C. § 112 MAY NOT PERTAIN ONLY TO CLAIMED SUBJECT MATTER

The Federal Circuit in *Bayer* held that 35 U.S.C. § 112 “only demands disclosure of ‘the best mode contemplated by the inventor of *carrying out his invention*.’”<sup>311</sup> However, the court previously found the phrase “carrying out his invention” in § 112 ambiguous.<sup>312</sup> In *Wahl Instruments*, the court found that the phrases “mode” and “carrying out the invention” were not precisely definable.<sup>313</sup> However, a second judicial interpretation held that the phrase applied only to the claimed invention.<sup>314</sup> The first case to address the issue of whether the best mode requirement is limited to the claimed invention was *Christianson*.<sup>315</sup> However, this decision was made in reference to mass production and sales to customers only.<sup>316</sup> Therefore, it was a limited holding that has gained widespread recognition in the Federal Circuit as binding law in a variety of cases that do not involve mass production or sales to customers.

Therefore, since the phrases “carrying out the invention” and “mode” are ambiguous, there is support for the contention

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308. See *supra* notes 34, 143-51 and accompanying text.

309. See *supra* notes 265-68 and accompanying text.

310. See *supra* notes 265-68 and accompanying text.

311. *Bayer*, 301 F.3d at 1315 (quoting 35 U.S.C. § 112 (1994)) (alteration in original).

312. See *supra* notes 135-41 and accompanying text.

313. See *supra* notes 135-37 and accompanying text.

314. See *supra* notes 135-41 and accompanying text.

315. See *supra* notes 81-84 and accompanying text.

316. See *supra* notes 81-84 and accompanying text.

that they need not apply only to the claimed invention. There is no direct language in 35 U.S.C. § 112, ¶ 1, which explicitly refers to the "claimed invention." This statute refers only to "the best mode of carrying out the invention."<sup>317</sup> Further, there is no legislative history that mandates the restriction of § 112 to the claimed invention.<sup>318</sup>

Therefore, Bayer Corp. may have violated the best mode requirement under 35 U.S.C. § 112, ¶ 1, regardless of whether the Klauke compound or 6-FQA synthesis were or were not undisclosed preferred embodiments or undisclosed intermediates which materially affected the production of Cipro. According to the text of § 112 and the legislative history of the Patent Act, Bayer is required to disclose any preferred method of producing Cipro without regard to its remoteness to the claimed invention.

#### F. THE IMPACT OF *ELI LILLY* ON *BAYER*

Novel subject matter alone may require disclosure. The facts of *Eli Lilly* are similar to those of *Bayer*.<sup>319</sup> The inventor in *Eli Lilly* disclosed the claimed invention, Prozac, but did not disclose the inventor's preferred method for synthesizing the starting material needed to make Prozac.<sup>320</sup> The Federal Circuit held that any best mode involving novel subject matter must be disclosed even if the novel subject matter is unclaimed<sup>321</sup> and held, in this case, that the unclaimed subject matter was not novel, because it was commercially available from more than one supplier.<sup>322</sup>

In *Bayer*, however, the starting materials for the synthesis of Cipro were not commercially available.<sup>323</sup> In fact, the Klauke compound had to be synthesized by another scientist at Bayer because Dr. Grohe was having difficulty synthesizing a precursor to 6-FQA.<sup>324</sup> If the Klauke compound had been commercially available, Dr. Grohe most likely would have been able to obtain it with more ease than actually occurred. Therefore, since the two intermediates of Cipro were novel

317. 35 U.S.C. § 112, ¶ 1.

318. See *supra* notes 47-61 and accompanying text.

319. See *supra* notes 163-70 and accompanying text.

320. See *supra* note 165 and accompanying text.

321. See *supra* notes 170-71 and accompanying text.

322. See *supra* notes 170-74 and accompanying text.

323. See *Bayer*, 301 F.3d at 1310.

324. *Id.*

under the Federal Circuit's analysis in *Eli Lilly*, they were required to be disclosed in the specification in order to comply with the best mode requirement of 35 U.S.C. § 112, ¶1.

G. THE FEDERAL CIRCUIT'S INTERPRETATION OF THE BEST MODE REQUIREMENT IN *BAYER* COMPARED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE'S INTERPRETATION OF 35 U.S.C. § 112, ¶ 1.

The USPTO's interpretation of the best mode requirement is quite similar to the Federal Circuit's interpretation of the best mode requirement.<sup>325</sup> However, the USPTO expressly recognizes that if the patent applicant develops specific techniques that he or she recognizes as the best mode of carrying out the invention, these must be disclosed in the specification under the patentee's obligation to the public to disclose this preferred technique.<sup>326</sup>

Therefore, under the USPTO guidelines, Bayer Corp would likely be required to disclose the Klauke compound and synthetic route of 6-FQA in the '560 patent, since these intermediates were developed by Dr. Grohe as specific techniques to synthesize Cipro.

#### IV. CONCLUSION

In *Bayer v. Schein*, the Federal Circuit held that a pharmaceutical company did not violate the best mode requirement of 35 U.S.C. § 112, ¶ 1, when it failed to disclose two intermediates in the synthesis of Cipro. The court relied on past precedent to conclude that unclaimed subject matter need only be disclosed for best mode purposes when it is a concealed preferred embodiment of the claimed invention or when it materially affects the making or using of the claimed invention. The Federal Circuit held that the two intermediates, the Klauke compound and the synthetic route of 6-FQA, both unclaimed, were neither a preferred embodiment nor did they materially affect the claimed invention, Cipro.

A closer analysis of the facts of precedent cases suggests that the Federal Circuit erred in its holding. As analogized to *Spectra-Physics*, *Dana*, *Great Northern*, and *Nobelpharma*, the two intermediates in question in *Bayer* do materially affect the making or using of Cipro. Further, like the invention in

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325. See *supra* notes 175-83 and accompanying text.

326. See *supra* note 178 and accompanying text.

*Northern Telecom*, they are both preferred embodiments of the claimed invention. Analysis of Federal Circuit precedent leads to these two conclusions. Additionally, other Federal Circuit precedent, and USPTO rules, mandate the disclosure of the Klauke compound and 6-FQA under 35 U.S.C. § 112, ¶ 1. Finally, there is good social policy behind the best mode requirement of disclosure of all necessary and important subject matter. For these reasons, the public should be given the chance to know how to synthesize Cipro from the Klauke compound and the synthesis of 6-FQA.