Eli Lilly v. Barr: Double Patenting Analysis Can Be Anything But Obvious

I. INTRODUCTION

The pharmaceutical manufacturer Eli Lilly (Lilly) brought suit against four drug manufacturers (collectively referred to as Barr)[1] for infringement upon two patents assigned to Lilly.[2] Of the patents at issue, claim 5 of U.S. Patent No. 4,314,081 (the '081 patent) concerns the pharmaceutical compound fluoxetine hydrochloride.[3] Claim 7 of U.S. Patent No. 4,626,549 (the '549 patent) concerns a method of delivering fluoxetine hydrochloride to inhibit serotonin uptake in animal brain neurons.[4] Both patents relate to the active ingredient in the widely prescribed antidepressant Prozac.[5] As an affirmative defense, Barr argued that Lilly's patents were invalid for both failure to comply with the best mode requirement of 35 U.S.C. § 112 and for obviousness-type double patenting.[6]

The United States District Court for the Southern District of Indiana granted Lilly summary judgment, dismissing Barr's patent validity challenges.[7] In dismissing the double patent claim, the court found that Barr failed to provide any evidence that claim 7 of the '549 patent was a mere scientific explanation of prior art.[8] As to the best mode claim, the court held that the specific disclosures argued by Barr as best mode requirements were not necessary under 35 U.S.C. § 112.[9] The court

1. Barr Laboratories, Inc. was the first party named. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 958 (Fed. Cir. 2001). The other defendants include Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman. *Id.*
2. *Id.*
3. *Id.* at 960.
4. *Id.* at 960-61.
5. *Id.* at 958.
6. *Id.*
7. Eli Lilly & Co. v. Barr Labs., Inc., 100 F. Supp. 2d 917, 934 (S.D. Ind. 1999).
8. *Eli Lilly*, 251 F.3d at 973.
9. *Eli Lilly*, 100 F. Supp. 2d at 933-34.

based its reasoning on findings that the quality of the invention was not impacted by the disclosure and that the additional disclosures would amount to routine details not required by the statute.[10]

Barr appealed the district court's summary judgment to the Federal Circuit. A panel assembled from the Federal Circuit issued an initial opinion on August 9, 2000.[11] Upon granting a petition for rehearing en banc, the court vacated the panel's decision and reassigned the issue of double patenting.[12] The court accepted the panel's second decision,[13] holding, (1) failure to disclose an unclaimed method of synthesizing an intermediate compound did not violate the best mode requirement of 35 U.S.C. § 112, (2) failure to disclose the unclaimed preferred solvent for a recrystallization process did not violate the best mode requirement of 35 U.S.C. § 112, and (3) a patentable distinction does not exist when the difference between claims is a natural biological process occurring in humans rather than animals.[14] *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001), *reh'g & reh'g en banc denied*, 251 F.3d 955 (Fed. Cir. 2001).

II. BACKGROUND

Pursuant to Article I, section 8, clause 8 of the United States Constitution, Congress grants inventors the right to patent their inventions.[15] A patent grants the inventor, or assignee, the right to exclude all others from making, using, or selling the invention for a specified period of time.[16] In exchange for patent rights, the public obtains a full disclosure of the invention.[17] Congress has established requirements for the actual disclosure in 35 U.S.C. § 112, which reads in part:

> 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

10. *Id.* at 923.
11. *Eli Lilly*, 251 F.3d at 958.
12. *Id.*
13. *Id.* at 955. A second request for *rehearing and rehearing en banc* was denied July 18, 2001.
14. *See id.* at 972.
15. U.S. CONST. art. I, § 8, cl. 8.
16. *See, e.g.*, Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990).
17. Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 418 (Fed. Cir. 1988).

> same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[18]

The statute's specific mandate of "the best mode contemplated by the inventor" has been termed the best mode requirement by the courts. The purpose of the best mode language is to prevent the grant of a patent right to an inventor without the exchange of the preferred embodiment of the invention to the public.[19] In other words, the inventor must publicly disclose the best mode known to him in order to obtain the right to exclude others from practicing the invention.[20]

A claim of best mode violation is a question of fact which is reviewed by the court for clear error.[21] The court's review requires a two-step analysis.[22] First, a court must determine if the inventor knew of a better mode for carrying out the invention.[23] Second, the court must determine if the disclosure is adequate for one skilled in the art to practice the preferred embodiment (best mode) of the patent.[24]

Compliance with the best mode requirement is primarily a subjective matter.[25] Section 112 requires disclosure of the "best mode [specifically] *contemplated by the inventor*."[26] Thus, the inventor's belief of whether a best mode exists in carrying out an invention is highly relevant to compliance with the disclosure requirement.[27] However, the subjective understanding of the inventor does not exist in a vacuum. "[W]hether the inventor concealed a better mode of practicing his invention than he disclosed, is a function of not only what the inventor knew but also how one skilled in the art would have understood his disclosure."[28] The disclosure required by the statute is limited by an objective determination of both the level of skill in the art and the scope of the inventor's claims.[29]

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18. 35 U.S.C. § 112 (1994).
19. *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962).
20. *See id.*
21. N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 940 (Fed. Cir. 1990).
22. Engel Indus. v. Lockformer Co., 946 F.2d 1528, 1531 (Fed. Cir. 1991).
23. *Id.*
24. *Id.*
25. Chemcast Corp. v. Arco Indus., 913 F.2d 923, 926 (Fed. Cir. 1990).
26. 35 U.S.C. § 112 (1994) (emphasis added).
27. *Engel*, 946 F.2d at 1533.
28. *Chemcast*, 913 F.2d at 927.
29. *Id.* at 926; *see* Randomex, Inc. v. Scopus Corp., 849 F.2d 585 (Fed. Cir. 1988) (holding that best mode analysis is measured by those persons skilled in the claimed invention, not the end user of the device).

The doctrine of double patenting also works to limit the rights granted by a patent.[30] A double patent violation occurs when a patent owner attempts to obtain a second patent for either (1) the same invention or (2) an obvious modification.[31] The purpose of the double patent doctrine is to allow the public open access to the protected invention and any obvious modifications at the expiration of the protected term.[32] Without such protection a patent holder could indefinitely extend exclusive ownership of the invention by obtaining subsequent patents that cover the same basic invention.

Double patenting analysis necessarily involves two steps.[33] First, the court must determine if the scope of the claims are the same.[34] If this is so, rejection is the proper remedy under 35 U.S.C. § 101, which allows *a* patent to issue to the inventor.[35] If the claims are not alike, the court must determine if there is a patentable distinction by comparing the claims for nonobvious variations.[36]

Whether the claims of a patent application were an obvious modification of an earlier patent owned by the plaintiff was a question presented to the Federal Circuit in *In re Goodman*.[37] The court held that the more "generic" invention of the application was anticipated by the narrow "species" invention of the patent and, therefore, invalid for obviousness-type double patenting.[38] The application claimed a method for producing mammalian peptides in plant cells, while the earlier patent specified dicotyledonous plant cells.[39] In other words, the invention applying for patent protection was a broader application of the discovery in the existing patent. The *Goodman* court found it unnecessary to reverse the analysis and compare the obviousness of the patent in light of the application.[40] The more deferential "two way" analysis was found unjustified since the applicant determined the early issuance of the narrow "species" patent.[41] The court reasoned that granting a patent on

30. *See In re* Longi, 759 F.2d 887, 892 (Fed. Cir. 1985).
31. *Id.*
32. *Id.* at 892-93.
33. *In re* Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993).
34. *Id.*
35. *Id.* at 1053. "A person shall be entitled to *a* patent unless . . . ." 35 U.S.C. § 102 (1994) (emphasis added).
36. *Goodman*, 11 F.3d at 1052.
37. *Id.* at 1053.
38. *Id.*
39. *Id.* at 1048.
40. *Id.*
41. *Id.*

the broader application would result in a time extension of the narrow terms of the existing patent.[42]

In another obviousness-type double patenting case, the Federal Circuit applied a two-way test to determine whether the claims in both the patent and the application would be obvious in light of each other.[43] The *Braat* court held, when a later filed improvement patent issues before an earlier filed application, a two-way analysis must be conducted if the United States Patent and Trademark Office was solely responsible for the rate of progress of the patent applications.[44] The court reasoned that extending the time of exclusive rights to the patent was justifiable if the inventor was not responsible for determining which patent (the narrower species, or broader genus) issued first.[45]

III. COURT'S DECISION

In the noted case, the court held that failure to disclose a method of synthesizing an intermediate compound that was not claimed in the patent did not violate the best mode requirement of 35 U.S.C. § 112.[46] Barr argued that claim 5 of the '081 patent and claim 7 of the '549 patent violated the best mode requirement by not disclosing the inventor's method for synthesizing p-trifluoromethylphenol.[47] In its analysis the court first noted that Lilly's patents made no claim upon p-trifluoromethylphenol.[48] Neither the compound nor the method of synthesis are protected by Lilly's patents.[49] Secondly, the court found that Lilly's particular method of synthesizing p-trifluoromethylphenol was not necessary to carrying out the best mode of the invention.[50] To support its finding the court referred to the record of the trial court establishing the commercial availability of p-trifluoromethylphenol.[51] P-trifluoromethyl-phenol was described in prior art and available for purchase from at least one manufacturer.[52] The court denied Barr's claim that *Clayton v. Akiba* applied to its dispute with Lilly by distinguishing *Clayton* from the facts

42. *Id.* at 1053.
43. *In re* Braat, 937 F.2d 589, 593 (Fed. Cir. 1991).
44. *Id.*
45. *See id.*
46. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 964 (Fed. Cir. 2001).
47. *Id.*
48. *Id.*
49. *Id.*
50. *Id.*
51. *Id.* at 964-65.
52. *Id.* at 965.

at issue in the noted case.[53] Specifically, the necessary intermediate compound in *Clayton* was not found to be a novel concept.[54] Thus, without its disclosure the patent would still remain a secret. While p-trifluoromethylphenol is a necessary component of both the '081 and '549 patents, production of the compound is not novel.[55] The court reasoned that Lilly's particular method of synthesis amounted to a production detail, which need not be disclosed.[56] Furthermore, the court found no evidence that Lilly's method affected the quality of the p-trifluoromethylphenol or, ultimately, the patents.[57]

In the second claim relating to 35 U.S.C. § 112, the court held that failure to disclose the preferred solvent for the unclaimed recrystallization process did not violate the best mode requirement.[58] Lilly's '081 and '549 patents state that the preferred condition of the fluoxetine hydrochloride utilized in the respective patents is found by purifying the compound through recrystallization.[59] Again, the court noted that the preferred solvent to achieve such recrystallization was not claimed in Lilly's patents.[60] Thus, Lilly had no right to exclude others from practicing the recrystallization process with the particular solvent it prefers.[61] In addition to being unclaimed, the court found that selection of a preferred solvent for a recrystallization process was a routine detail.[62] The court noted that Barr's own expert witness classified the selection of a solvent for recrystallization as a routine detail.[63] Because a routine detail is something that a person of ordinary skill in the art possesses the knowledge to determine, the best mode requirement does not require its disclosure.[64] Furthermore, the court reasoned that the best mode requirement does not guarantee that experimentation will not be necessary to carry out the patent.[65]

Addressing the claim of obviousness-type double patenting, the court held that a patentable distinction does not exist when either the

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53. *Id.*; *see* Clayton v. Akiba, 214 U.S.P.Q. (BNA) 374, 380 (Feb. 2, 1982) (holding the inventor's failure to disclose a method for preparing a necessary intermediate compound violated the best mode requirement).
54. *Eli Lilly*, 251 F.3d at 965.
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.* at 966.
60. *Id.*
61. *Id.*
62. *Id.*
63. *Id.*
64. *Id.*
65. *Id.* at 966-67.

difference in claims is a natural biological process or when occurring in animals rather than humans.[66] In its analysis, the court examined whether the claims of the '549 patent were obvious over the claims of the earlier issued '213 patent.[67] The obviousness-type double patenting analysis first requires a determination of the differences between the patents.[68] The court determined that the '213 patent differs only in describing a method of treating anxiety in humans with fluoxetine hydrochloride and the '549 patent describes a method of using fluoxetine hydrochloride to block serotonin uptake in animals.[69]

The second step of obviousness-type double patent analysis is the determination of whether such differences are patentably distinct.[70] In making this determination, the court divided its analysis between the differences related to the claims on fluoxetine hydrochloride and its use on specific subjects.[71] As to whether a method of treating anxiety with fluoxetine hydrochloride differs from using fluoxetine hydrochloride to block serotonin uptake, the court accepted the evidence presented by Barr that indicated blocking the uptake of serotonin is the natural result of taking fluoxetine hydrochloride.[72] As for the difference between the '213 patent's utilization on humans and the '549 patent's application to animals, the court again found that the '213 patent anticipated the claims of the '549 patent.[73] The holding relied on the fact that humans are a species of the animal genus.[74]

IV. ANALYSIS

In the noted case, the court's best mode analysis gave great credence to the unclaimed nature of the method of synthesis and preferred solvent. However, this emphasis should not be mistaken as determinative of the issue. The best mode requirement is a test of whether the disclosure is adequate to enable others to repeat the invention at the same level of quality.[75] The court properly resolved the best mode issue by comparing the inventor's subjective understanding of the best mode with the ability

66. *Id.* at 971.
67. *Id.* at 968.
68. *Id.*
69. *Id.* at 969.
70. *Id.*
71. *See id.* at 969-70.
72. *Id.* at 970.
73. *Id.* at 971.
74. *Id.*
75. *See* Chemcast Corp. v. Arco Indus., 913 F.2d 923, 928 (Fed. Cir. 1990) (rejecting the argument that because the patent did not claim any specific material failure to disclose the material the inventor thought worked best was not a best mode violation).

of someone skilled in the art to repeat the invention at the same level of quality, given the description.[76]

Invalidation for obviousness-type double patenting has a particularly harsh impact given the fact that the conflicting patent was terminally disclaimed prior to litigation.[77] Consequently, Lilly has no exclusive right to either the broad method of delivering fluoxetine hydrochloride to animals or the narrow patent of treating anxiety in humans with fluoxetine hydrochloride.[78] Terminal disclaimers are typically used to refute the double patenting objections to a patent application whose claims are generic to an earlier species patent.[79] The terminal disclaimer allows the broader patent to expire at the same time as the earlier filed, narrow patent.[80] In the noted case, the terminally disclaimed patent rendered obvious and invalidated an earlier filed, but later issued, patent.[81]

The dissent is particularly disturbed by this unusual result and argues that double patenting analysis does not apply to the facts of the case.[82] The dissent interprets the double patenting analysis to situations where neither patent is prior art to the other.[83] This interpretation is based on the assumption that double patenting is exclusively concerned with rejecting a patent owner's attempt to extend the period of exclusive right to the patent.[84] The dissent focuses on the fact that the '549 patent (method of fluoxetine hydrochloride delivery to animals) was initially filed in 1974, nine years prior to the '213 patent (treating humans with fluoxetine hydrochloride for anxiety).[85] In addition, the '213 patent referenced the '549 patent in its application.[86] The dissent would hold that a later discovery could not retroactively deny the patentability of an earlier work.[87]

The majority determined that a one-way comparison of the later issued, but earlier filed '549 patent to the '213 patent was appropriate because the delay in issuing the '549 patent was not exclusively the fault

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76. *Eli Lilly*, 251 F.3d at 963.
77. *Id.* at 967 n.5.
78. *Id.* at 971.
79. *In re* Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993).
80. *Id.* at 1053.
81. *Eli Lilly*, 251 F.3d at 967 n.5.
82. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 973 (Fed. Cir. 2001) (Newman, J., dissenting).
83. *Id.*
84. *Id.* at 974-75.
85. *Id.* at 973.
86. *Id.*
87. *See id.* at 974.

of the United States Patent and Trademark Office.[88] The only evidence offered by the majority to support the use of a one-way comparison is a Lilly expert's statement that "it is true that the claim could have been presented earlier."[89] This presents a question of whether a vague reference indicating the delay was caused by Lilly is significant enough to require the more strict one-way analysis. The evidence does not indicate whether Lilly was at fault for the entire nine-year delay or only a portion thereof. Without a significant or purposeful delay by Lilly, the result of the case appears extraordinarily punitive. Perhaps a better examination of the issue would include whether the record supports any evidence showing that Lilly intended to extend the period of its patent by delaying the issuance of the broader patent.

If a two-way test had been applied, it is not clear whether the analysis would have impacted the majority's decision. The court found no evidence, contrary to Barr's assertion, that blocking serotonin uptake is a natural result of administration of fluoxetine hydrochloride for any purpose.[90] The court would likely have found the '213 patent obvious over the '549 patent as easily as it found the reverse true.[91]

The dissent also takes issue with the majority's holding that a patentable distinction does not exist when the difference in claims is a natural biological process.[92] The dissent argues that such a rule oversimplifies the science involved in the discovery. "[E]very biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered."[93] It is easy to imagine how the majority's holding could be used in future cases to invalidate a wide range of patents based on biological processes.

V. CONCLUSION

The noted case presents a concise application of the best mode requirement of 35 U.S.C. § 112. The court applied the facts of the case to a well-developed area of the law. However, their discussion of obviousness-type double patenting is less convincing. The draconian

88. *Id.* at 968 n.7.
89. *Id.*
90. *Id.* at 970.
91. *See id.*
92. *See id.* at 976.
93. *Id.*

outcome of the court's decision is difficult to accept with a set of facts that show no bad faith or ill intent on the part of the inventor.

Paul Pitts