

***Ortho Pharmaceutical Corp. v. Smith*: Willful Infringement—Reliance on a Flawed Letter from Counsel**

I. INTRODUCTION

In *Ortho Pharmaceutical Corp. v. Smith*,¹ the Federal Circuit Court of Appeals held that an infringer's reliance on patent counsel's letter is justified if the "opinion [is] thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable."² In crafting this decision, the court focused on the intent and the reasonable beliefs of the infringer.³ By relying on a letter from patent counsel, Ortho Pharmaceutical Corporation ("Ortho") had a reasonable basis for believing that it had not infringed the patent of American Home Products ("AHP"), despite the letter's legal incorrectness.⁴ As a result, the court held that Ortho had not willfully infringed under the totality of the circumstances test used to determine intent.⁵ The *Ortho* case helps clarify what constitutes a competent opinion letter from counsel on which a potential infringer may reasonably rely. Moreover, the competency of such a letter is considered an important factor in determining the infringer's reasonable beliefs and ultimately the infringer's intent.

The patent at issue in *Ortho* concerns the types of steroids used in oral contraceptives.⁶ Ortho filed for a declaratory judgment against AHP to proclaim certain claims of AHP's U.S. Patent No. 3,959,322 ("the '322 patent") invalid.⁷ AHP counterclaimed in the suit for infringement of the '322 patent and named Ortho's parent company Johnson & Johnson Corporation as an additional defendant.⁸

The United States District Court for the Eastern District of Pennsylvania held the claims of the '322 patent not invalid for double patenting or

1. 959 F.2d 936 (Fed. Cir. 1992).

2. *Id.* at 944.

3. *Id.*

4. *Id.* at 945.

5. *Id.*

6. *Id.* at 937.

7. *Id.* at 937-38.

8. *Id.* at 938.

obviousness.⁹ Furthermore, the court found that Ortho infringed claims five and nineteen of the '322 patent under the doctrine of equivalents, and Ortho admitted infringement of claims forty and forty-three.¹⁰ Also, Ortho did not prove inequitable conduct on the part of AHP.¹¹ The district court found that Ortho did not willfully infringe the '322 patent because it had relied on two opinion letters from patent counsel advising that the '322 patent and its parent patent, U.S. Patent No. 3,850,911 ("the '911 patent"), were invalid.¹²

Ortho, while conceding infringement, appealed the decision of the district court holding the '322 patent valid.¹³ AHP cross-appealed the district court's refusal to modify a permanent injunction against Ortho, along with the finding that Ortho did not willfully infringe, resulting in a denial of attorney fees under 35 U.S.C. § 285.¹⁴

The court of appeals addressed the following issues:

1. Is the '322 patent invalid for obviousness-type double patenting?
2. Did the district court clearly err in finding that Ortho's infringement was not willful?
3. Did the trial court abuse its discretion by refusing to enjoin Ortho from using or transmitting infringement generated data and by refusing to extend this prohibition for two years beyond the term of the '322 patent?¹⁵

The court of appeals, finding no abuse of discretion or clear error on the part of the district court, affirmed the district court's decision.¹⁶ This Note will discuss the appellate court's holding that Ortho did not willfully infringe the '322 patent.

9. *Id.*

10. *Id.* at 939. The doctrine of equivalents provides that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape." *Graver Tank & Mfg. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950) (quoting *Union Paper-Bag Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1877)). "What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case A finding of equivalence is a determination of fact." *Id.* at 609. The doctrine of equivalents allows infringement to exist even though the infringing matter is technically outside the wording of the claims of the patent.

11. 959 F.2d at 938.

12. *Id.* at 939-40.

13. *Id.* at 937.

14. *Id.* 35 U.S.C. § 285 (1984) provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party."

15. 959 F.2d at 940.

16. *Id.* at 946.

II. FACTUAL STATEMENT

The contraceptive steroid claimed in the '322 patent is contained in AHP's commercial product, norgestrel. At the time of this appeal, Ortho manufactured norgestimate. Norgestimate had been shown to break down in the body to norgestrel and norgestrel acetate, which cause much of the biological activity of norgestimate.¹⁷ A drug that transforms itself in the body like norgestimate is "often referred to as a 'pro-drug.'"¹⁸ Because of this pro-drug conversion of norgestimate into norgestrel and norgestrel acetate, the district court found claims five and nineteen of AHP's '322 patent infringed by Ortho's norgestimate steroid under the doctrine of equivalents.¹⁹

In deciding to produce norgestimate, Ortho relied on two opinion letters from its patent counsel. The court considered these letters to thoroughly discuss reasons supporting counsel's conclusions, although, as AHP alleged, evidently neither letter contained an analysis under the doctrine of equivalents. The first letter pertained to the '911 patent. This letter found the '911 patent to be invalid and that any claims in potential divisional applications that would encompass norgestimate also would be invalid. Likewise, the second letter, pertaining to both the '911 and the '322 patent, determined those claims that might encompass Ortho's product to be invalid. Counsel admitted that certain narrow claims of the '322 patent specifically drawn for norgestimate might be valid. However, counsel concluded these claims did not include norgestimate. Furthermore, counsel recognized that the pro-drug conversion of norgestimate into norgestrel and norgestrel acetate could be construed as infringement. Nonetheless, Ortho accepted counsel's conclusion of noninfringement.²⁰

III. DETAILS OF THE COURT'S OPINION

The court focused on the intent and the reasonable beliefs of the infringer in determining willfulness.²¹ The core of the court's analysis determined the reasonableness of Ortho's belief that it was not infringing in light of deficiencies in counsel's letters.²²

AHP claimed that Ortho willfully infringed because of two weaknesses in counsel's opinion letters. First, counsel did not include an analysis under the doctrine of equivalents. Second, counsel recognized that the

17. *Id.* at 939.

18. *Id.* at 939 n.4.

19. *Id.* at 939.

20. *Id.* at 944.

21. *Id.*

22. *Id.* at 944-45.

conversion of norgestimate into norgestrel and norgestrel acetate could be construed as infringement.²³

The court reasoned that "[w]hether infringement is 'willful' is by definition a question of the infringer's intent."²⁴ To determine the willfulness or intent of the infringer the court evaluates the totality of the surrounding circumstances.²⁵ One circumstance is when a potential infringer has actual notice of a patentee's rights.²⁶ Then, the possible trespasser has an affirmative duty of due care that ordinarily includes seeking competent legal advisement.²⁷ However, merely receiving a letter from counsel is insufficient. The letter must be thorough and give the infringer a reasonable basis for believing it has the right to do the infringing acts.²⁸

AHP claimed the district court erred in finding Ortho did not willfully infringe because of two deficiencies in the opinion letters relied upon by Ortho that, in retrospect, made the letters legally incorrect.²⁹ The court of appeals first addressed the letters' lack of analysis under the doctrine of equivalents.³⁰ Citing *Datascope Corp. v. SMEC, Inc.*,³¹ AHP argued that the lack of analysis under the doctrine of equivalents should carry great weight in determining Ortho's willfulness.³² Nonetheless, the court rejected AHP's theory, noting that in *Datascope* counsel made no more than conclusory remarks that "on its face defeated the Datascope infringer's claim to having had a reasonable belief that it was not infringing a valid patent."³³ Therefore, the court found that the lack of a doctrine of equivalence analysis does not negate the formation of a reasonable belief of noninfringement per se, as long as the counsel's analysis is thorough enough under the circumstances.³⁴

The court of appeals next addressed AHP's allegation that the letters admitted potential infringement resulting from the pro-drug conversion of norgestimate into AHP's product, norgestrel. Succinctly expressed, the court concluded that "[a] party is not guilty of ignoring patent rights because it resolves a close question of infringement in its favor."³⁵

23. *Id.* at 944.

24. *Id.* (citation omitted).

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. 879 F.2d 820 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 1024 (1990).

32. 959 F.2d at 945.

33. *Id.*

34. *Id.*

35. *Id.*

The court determined that under the circumstances, such as "the letter's overall tone, its discussion of case law, its analysis of the particular facts, and its reference to inequitable conduct," Ortho had formed a reasonable belief it would not infringe.³⁶ Therefore, reasonable reliance on an opinion letter does not depend upon its legal correctness.³⁷ "Rather, counsel's opinion must be thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable."³⁸

IV. ANALYSIS OF THE OPINION

The court of appeals correctly decided that Ortho did not willfully infringe AHP's patents. However, the court's reasoning in *Ortho* is obscure. Instead of expressly deciding whether, under the totality of the circumstances, Ortho intentionally infringed, the court intertwined the issues of willfulness and a breach of the duty to obtain competent counsel. Besides this confusion, the court accurately described the law controlling the duty to obtain competent counsel.

Complying with the duty to obtain the advice of competent counsel and relying on the counsel's opinion is a defense to a charge of willful infringement.³⁹ Usually a competent opinion is one given by an experienced patent attorney that thoroughly discusses reasons for or against potential infringement.⁴⁰

Willfulness is by definition a question of intent.⁴¹ It should be distinguished from the affirmative duty of due care to obtain competent counsel that exists when the infringer has notice of potential infringement. Willfulness is determined by applying the totality of the circumstances test to find whether the infringer's intent is benign or adequately malicious to impose the punitive penalty authorized under 35 U.S.C. § 285.⁴² All of the reasonable beliefs of the infringing party about its activities are relevant in determining willfulness, and the sum of these beliefs form the infringer's intent.⁴³ The duty of care to obtain competent counsel can be breached by acts of negligence, ignorance, or intent. To find a breach of this duty, the court applies an objective reasonableness standard. The potential infringer must act reasonably under the circumstances in deciding

36. *Id.*

37. *Id.* at 944.

38. *Id.*

39. *Studiengesellschaft Kohle v. Dart Indus.*, 862 F.2d 1564, 1576 (Fed. Cir. 1988).

40. *See infra* text accompanying notes 50 and 51.

41. 959 F.2d at 944.

42. *Id.* at 944. *See supra* note 14 and accompanying text.

43. 959 F.2d at 944.

if an opinion of counsel is needed and, if obtained, whether the advice of counsel qualifies as competent.⁴⁴

The breach of the duty to obtain competent counsel is only one factor, although an important one, in determining willfulness and not a determinative rule conclusively establishing intent.⁴⁵ In *Underwater Devices, Inc. v. Morrison-Knudsen Co.*,⁴⁶ the court clearly stated the controlling law to be the totality of the circumstances test to find willful infringement.⁴⁷ The court maintained that whether the infringer "knew or should have known" that it had not sought competent counsel is a fact that should be weighed in determining willfulness, but does not control.⁴⁸

In this case, the court first set out the test for finding willful infringement, evaluating the totality of the circumstances to find or infer intent.⁴⁹ The court, however, then proceeds to discuss the issue of reasonable reliance on counsel's letter in the context of determining willful infringement.⁵⁰ The court states that "Ortho's intent and reasonable beliefs are the primary focus of a willful infringement inquiry,"⁵¹ but, carelessly, the court does not express that an opinion letter which does not instill a reasonable belief in the infringer does not necessarily equate to a finding of willfulness. Rather, Ortho's reasonable beliefs are factors in inferring the requisite intent to find willfulness, with the ultimate decision being determined by the totality of the circumstances.⁵² The court should have delineated that intent is the primary focus in a willfulness inquiry, and reasonable beliefs are the primary focus in a breach of duty inquiry.

Nonetheless, the court appropriately focuses on the question of Ortho's reasonable reliance on counsel's letter in assessing AHP's argument on appeal. Previous cases have established that "[m]ere bald, conclusory statements do not satisfy one's affirmative duty to obtain competent legal

44. See *id.* at 944-45. The objective standard of reasonableness is applied throughout this segment of the court's opinion to determine if the letters offer competent advice. For instance the court concludes that "[i]n light of the letter's overall tone, its discussion of case law, its analysis of the particular facts and its reference to inequitable conduct, we cannot say the district court clearly erred in finding that Ortho reasonably relied upon opinions by its counsel." *Id.* at 945.

45. *Machinery Corp. of Am. v. Gullfiber AB*, 774 F.2d 467, 472 (Fed. Cir. 1985).

46. 717 F.2d 1380 (Fed. Cir. 1983).

47. *Id.* at 1390.

48. *Id.*

49. 959 F.2d at 944.

50. The court held that Ortho did not willfully infringe as a result of its reasonable reliance on counsel's letter. Thus, Ortho had obtained competent counsel. However, the court never addresses the fact that even had it not found Ortho's reliance to be reasonable, the circumstances may still have led to a finding of non-willfulness. *Id.* at 945.

51. *Id.* at 944.

52. See *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 867 (Fed. Cir. 1985).

advice before infringement."⁵³ To be competent, counsel's letter should be thorough and "based on an evaluation of the validity or infringement" of the potentially infringed patent.⁵⁴

In this case, the court correctly applies the law in finding that the lack of analysis under the doctrine of equivalents did not make the letters conclusory in nature.⁵⁵ Instead, the court looked at the letter on its face, including the letter's tone, analysis of case law, and discussion of facts, to determine if the letter could have instilled a reasonable belief in Ortho that it would not infringe the AHP patent.⁵⁶ Given a competent opinion to rely upon, Ortho could decide close questions of infringement in its favor without exhibiting the aggressive behavior and intent necessary to comprise willfulness.⁵⁷

V. CONCLUSION

35 U.S.C. § 285 is a statute designed to prevent those who have knowledge of potential infringement from aggressively and intentionally undertaking the risk of infringement without support of competent advice of counsel.⁵⁸ Altogether, the court's decision is sound and the rule of law is clear. "[C]ounsel's opinion must be thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable."⁵⁹ When counsel's opinion is not thorough, but conclusory, and other factors could not reasonably have instilled beliefs in the infringer that a court might reasonably hold the patent invalid, the court may find willfulness under those circumstances.

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53. *Studiengesellschaft Kohle v. Dart Indus.*, 862 F.2d 1564, 1577 (Fed. Cir. 1988).

54. *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390 (Fed. Cir. 1983).

55. 959 F.2d at 945.

56. *Id.*

57. *Id.*

58. *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1566 (Fed. Cir. 1988).

59. 959 F.2d at 944.

