

4. Unless otherwise stated, Actavis South Atlantic, LLC and Actavis, Inc. will be collectively referred to as “Actavis.” Upon information and belief, Actavis manufactures generic drugs for sale and use throughout the United States, including this judicial district.

NATURE OF THE ACTION

5. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Letters Patent Nos. 5,326,570 (“the ’570 patent”; Exhibit A hereto) and 5,912,013 (“the ’013 patent”; Exhibit B hereto).

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over defendants Actavis South Atlantic, LLC and Actavis, Inc. based on, *inter alia*, by virtue of their systematic and continuous contacts with Texas.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS COMMON TO ALL COUNTS

9. Shire is the owner of New Drug Application (“NDA”) No. 20-712, which was approved by the Food and Drug Administration (“FDA”) for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia.

10. ASA submitted Abbreviated New Drug Application (“ANDA”) No. 79-207 (“Actavis’ ANDA”) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use,

importation, sale and/or offer for sale of Carbamazepine Extended Release Capsules 200 mg and 300 mg (“ANDA products”).

11. ASA sent Shire a “Notification of Certification for U.S. Patent Nos. 5,326,570 and 5,912,013 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act,” dated December 4, 2007, regarding its ANDA products (“Notice Letter”).

12. Shire did not bring an action for infringement against ASA within 45 days of receipt of the Notice Letter. ASA has since notified Shire, by letter dated July 9, 2008, of its continued intention to proceed with ANDA 79-207 and to manufacture, use, import, sell, and/or offer for sale, in this country, the products described in the ANDA.

FIRST COUNT

(Infringement of the '570 Patent)

13. Shire repeats and realleges paragraphs 1 through 14 above as if fully set forth herein.

14. The '570 patent, entitled “Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine,” was duly and legally issued on July 5, 1994, to Pharmavene, Inc. (“Pharmavene”) upon assignment from Edward M. Rudnic and George W. Belendiuk. Upon Pharmavene’s merger with and into Shire Laboratories Inc. (“Shire Laboratories”), Shire Laboratories became the owner of the '570 patent. Upon Shire Laboratories’ merger with and into Shire, Shire became and remains the owner of the '570 patent. The '570 patent claims, *inter alia*, a drug delivery system for the oral administration of carbamazepine.

15. Pursuant to 21 U.S.C. § 355(b)(1), the '570 patent is listed in “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) as covering Shire’s Carbatrol® drug products.

16. Upon information and belief, ASA filed a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA products before the expiration of the '570 patent.

17. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

18. Upon information and belief, as of the date of the Notice Letter (December 4, 2007), Actavis was aware of the statutory provisions and regulations referred to in paragraph 17, above.

19. ASA’s Notice Letter stated that the ANDA products do not infringe the '570 patent. Nevertheless, the Notice Letter provided Shire with insufficient information regarding the ANDA products that are the subject of ANDA No. 79-207. Until Shire receives sufficient information from Actavis, Shire cannot evaluate, confirm or test the correctness of Actavis Inc.’s certification that the '570 patent has not and would not be infringed. Upon information and belief, therefore, Shire alleges that ASA’s submission to the FDA of ANDA No.

79-207 with a paragraph IV certification for the '570 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, ASA's July 9, 2008, reiteration of its intention to proceed with ANDA 79-207 and to manufacture, use, import, sell, and/or offer for sale, in this country, the products described in the ANDA, coupled with ASA's paragraph IV certification, presents a controversy of sufficient immediacy, adversity, and concreteness to warrant resolution by this court.

20. Upon information and belief, Shire alleges that Actavis' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of ANDA No. 79-207, will infringe one or more claims of the '570 patent.

21. Actavis South Atlantic, LLC and Actavis, Inc. are jointly and severally liable for infringement of one or more claims of the '570 patent. Upon information and belief, Actavis, Inc. actively induced, encouraged, aided, or abetted ASA's submission of ANDA No. 79-207 and its paragraph IV certification to the FDA, and will likewise induce, encourage, aid, and/or abet ASA's manufacture, use, importation, sale, and/or offer for sale of the products described in the ANDA.

22. Actavis Inc.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 79-207 and ASA's paragraph IV certification to the FDA constitutes infringement of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Further Actavis' commercial use, offer for sale, or sale of the ANDA products will infringe the '570 patent.

23. Upon information and belief, Actavis has been aware of the existence of the '570 patent, making the acts of infringement set forth above deliberate and willful, thus

rendering this case “exceptional” under 35 U.S.C. § 285.

24. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Infringement of the '013 Patent)

25. Shire repeats and realleges paragraphs 1 through 26 above as if fully set forth herein.

26. The '013 patent, entitled “Advanced Drug Delivery System and Method of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine,” was duly and legally issued on June 15, 1999, to Shire Laboratories upon assignment from Edward M. Rudnic, George W. Belendiuk, John McCarty, Sandra Wassink, and Richard A. Couch. Upon Shire Laboratories’ merger with and into Shire, Shire became and remains the owner of the '013 patent. The '013 patent claims, *inter alia*, a pharmaceutical formulation containing carbamazepine.

27. Pursuant to 21 U.S.C. § 355(b)(1), the '013 patent is listed in “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) as covering Shire’s Carbatrol® drug products.

28. Upon information and belief, ASA filed a paragraph IV certification for the '013 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA products before the expiration of the '013 patent.

29. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed

statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

30. Upon information and belief, as of the date of ASA’s Notice Letter (December 4, 2007), Actavis was aware of the statutory provisions and regulations referred to in paragraph 29, above.

31. ASA’s Notice Letter stated that the ANDA products do not infringe the ’013 patent. Nevertheless, the Notice Letter provided Shire with insufficient information regarding the ANDA products that are the subject of ANDA No. 79-207. Until Shire receives sufficient information from Actavis, Shire cannot evaluate, confirm or test the correctness of Actavis Inc.’s certification that the ’013 patent has not and would not be infringed. Upon information and belief, therefore, Shire alleges that ASA’s submission to the FDA of ANDA No. 79-207 with a paragraph IV certification for the ’013 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the ’013 patent is an act of infringement of one or more claims of the ’013 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, ASA’s July 9, 2008, reiteration of its intention to proceed with ANDA 79-207 and to manufacture, use, import, sell, and/or offer for sale, in this country, the products described in the ANDA, coupled with ASA’s paragraph IV certification,

presents a controversy of sufficient immediacy, adversity, and concreteness to warrant resolution by this court.

32. Upon information and belief, Shire alleges that Actavis' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of ANDA No. 79-207, will infringe one or more claims of the '013 patent.

33. Actavis South Atlantic, LLC and Actavis, Inc. are jointly and severally liable for infringement of one or more claims of the '013 patent. Upon information and belief, Actavis Inc. actively induced, encouraged, aided, or abetted ASA's submission of ANDA No. 79-207 and its paragraph IV certification to the FDA, and will likewise induce, encourage, aid, and/or abet ASA's manufacture, use, importation, sale, and/or offer for sale of the products described in the ANDA.

34. Actavis Inc.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 79-207 and ADA's paragraph IV certification to the FDA constitutes infringement of the '013 patent under 35 U.S.C. § 271(e)(2)(A). Further Actavis' commercial use, offer for sale, or sale of the ANDA products will infringe the '013 patent.

35. Upon information and belief, Actavis has been aware of the existence of the '013 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

36. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), ASA's

submission to the FDA of ANDA No. 79-207 with a paragraph IV certification to obtain approval for the commercial manufacture, use, importation, sale and/or offer for sale in the United States of the ANDA products was an act of infringement of the '570 and '013 patents;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Actavis Inc.'s active inducement, encouragement, aiding, or abetting of the submission to the FDA of ANDA No. 79-207 with a paragraph IV certification to obtain approval for the commercial manufacture, use, importation, sale and/or offer for sale in the United States of the ANDA products was an act of infringement of the '570 and '013 patents;

(c) A judgment declaring that defendants' infringement of the '570 and '013 patents was willful;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the ANDA products that are the subject of ANDA No. 79-207 shall be no earlier than the date on which the last of the '570 and '013 patents expires;

(e) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States, of the ANDA products that are the subject of ANDA No. 79-207 until the expiration of the last of the '570 and '013 patents;

(f) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if defendants commercially manufacture, use, offer for sale, sell or import any product that infringes either the '570 or '013 patents;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees;

(h) A judgment awarding Shire its costs and expenses in this action; and

(i) A judgment awarding Shire such other and further relief as this Court may deem just and proper.

Dated: July 24, 2008

Respectfully submitted,

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