

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PRODUCTS INC., PF)
PRISM C.V. and C.P. PHARMACEUTICALS)
INTERNATIONAL C.V.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
VIWIT PHARMACEUTICAL CO., LTD.,)
)
Defendant.)

COMPLAINT

Plaintiffs Pfizer Inc., Pfizer Products Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V. (collectively, “Plaintiffs”), for their Complaint against Defendant Viwit Pharmaceutical Co., Ltd. (“Viwit”), allege as follows:

NATURE OF ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising out of Viwit’s submission of Abbreviated New Drug Application (“ANDA”) No. 212879 to the United States Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic copy of Plaintiffs’ breakthrough smoking-cessation product, Chantix®, prior to the expiration of the U.S. Patent Nos. 6,410,550 (the “550 patent”), 6,890,927 (the “927 patent”), and 7,265,119 (the “119 patent”), which cover, *inter alia*, Chantix® and/or its use.

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having its principal place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Pfizer Products Inc. is a corporation organized and existing under the laws of the State of Connecticut and having a place of business at Eastern Point Road, Groton, Connecticut 06340. Pfizer Inc. is the ultimate parent of Pfizer Products Inc.

4. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized and existing under the laws of the Netherlands, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent of PF PRISM C.V.

5. Plaintiff C.P. Pharmaceuticals International C.V. (“CPPI C.V.”) is a limited partnership (*commanditaire vennootschap*) organized and existing under the laws of the Netherlands, having its registered seat in Rotterdam, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 24280998. Pfizer Inc. is the ultimate parent of C.P. Pharmaceuticals International C.V.

6. On information and belief, Viwit is a corporation organized and existing under the laws of China and having a place of business at 500 Caobao Rd Building 2, Room 404, Xuhui Qu, Shanghai Shi, China.

JURISDICTION AND VENUE

7. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Upon information and belief, Viwit is not resident in the United States and may therefore be sued in any judicial district, including this one.

10. If Viwit commercially markets, uses, offers for sale, or sells Viwit's ANDA Product in the United States, before the expiration of the '550, '927, and '119 patents, Viwit will infringe and/or actively induce or contribute to the infringement of the '550, '927, and '119 patents, causing harm to the Plaintiffs in the State of Delaware.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c)(3).

PATENTS-IN-SUIT

12. On June 25, 2002, the United States Patent and Trademark Office duly and legally issued the '550 patent, entitled "Aryl fused azapolycyclic compounds." (Exh. A.) Pfizer Inc. owns the '550 patent.

13. On May 10, 2005, the United States Patent and Trademark Office duly and legally issued the '927 patent, entitled "Tartrate Salts of 5,8,14-Triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-Hexadeca-2(11),3,5,7,9-Pentaene and Pharmaceutical Compositions Thereof." (Exh. B.) Pfizer Inc. and Pfizer Products Inc. own the '927 patent.

14. Pfizer Inc. has exclusively licensed the '927 patent to C.P. Pharmaceuticals International C.V.

15. On September 4, 2007, the United States Patent and Trademark Office duly and legally issued the '119 patent, entitled "Tartrate Salts of 5,8,14-Triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-Hexadeca-2(11),3,5,7,9-Pentaene and Pharmaceutical Compositions Thereof." (Exh. C.) Pfizer Inc. and Pfizer Products Inc. own the '119 patent.

16. Pfizer Inc. has exclusively licensed the '119 patent to C.P. Pharmaceuticals International C.V.

17. Pfizer Inc., Pfizer Products Inc., and C.P. Pharmaceuticals International C.V. have all right, title, and interest in the '550, '927, and '119 patents, including the right to sue for infringement.

CHANTIX

18. PF PRISM C.V. holds approved New Drug Application No. 021928 for varenicline tartrate tablets, in 0.5 mg and 1.0 mg dosages, which Plaintiffs sell under the trade name Chantix®.

19. Chantix® is a nicotinic receptor partial agonist indicated for use as an aid to smoking cessation treatment.

20. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '550, '927, and '119 patents are listed in the FDA publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (the "Orange Book"), with respect to Chantix®.

VIWIT'S ANDA

21. By letter dated December 19, 2019 (the "Notice Letter"), Viwit notified Pfizer Inc., PF PRISM C.V., and Pfizer Products Inc., that it had submitted ANDA No. 212879 to the FDA, for Viwit's varenicline tartrate tablets, in 0.5mg and 1mg dosages, a generic copy of Chantix® ("Viwit's ANDA Product"). The purpose of the submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Viwit's ANDA Product prior to the expiration of the '550, '927, and '119 patents.

22. In the Notice Letter, Viwit also stated that, as part of its ANDA, it had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(VI) (“Paragraph IV certification”) asserting that each claim of the ’550, ’927, and ’119 patents is “invalid, unenforceable, and/or will be infringed by the manufacture, use, or sale” of Viwit’s ANDA Product.

23. This action is being commenced before the expiration of forty-five days from the date of the receipt by Plaintiffs of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT 6,410,550

24. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 23 hereof, as if more fully set forth herein.

25. Viwit’s ANDA Product and/or certain uses thereof are covered by one or more claims of the ’550 patent.

26. Viwit has infringed the ’550 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 212879, by which Viwit seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Viwit’s ANDA Product prior to the expiration of the ’550 patent.

27. If Viwit commercially makes, uses, offers to sell, or sells Viwit’s ANDA Product within the United States, or imports Viwit’s ANDA Product into the United States, or induces or contributes to any such conduct during the term of the ’550 patent, it would further infringe the ’550 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. In the Notice Letter, Viwit does not dispute that Viwit’s ANDA Product infringes claims 1 and 8 of the ’550 patent.

29. Plaintiffs will be substantially and irreparably harmed if Viwit is not enjoined from infringing the '550 patent.

30. Plaintiffs do not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT 6,890,927

31. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 23 hereof, as if more fully set forth herein.

32. Viwit's ANDA Product and/or certain uses thereof are covered by one or more claims of the '927 patent.

33. Viwit has infringed the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 212879, by which Viwit seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Viwit's ANDA Product prior to the expiration of the '927 patent.

34. If Viwit commercially makes, uses, offers to sell, or sells Viwit's ANDA Product within the United States, or imports Viwit's ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '927 patent, it would further infringe the '927 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

35. In the Notice Letter, Viwit does not dispute that Viwit's ANDA Product infringes claims 1-3, 13-15, and 19-26 of the '927 patent.

36. Plaintiffs will be substantially and irreparably harmed if Viwit is not enjoined from infringing the '927 patent.

37. Plaintiffs do not have an adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT 7,265,119

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 23 hereof, as if more fully set forth herein.

39. Viwit's ANDA Product and/or certain uses thereof are covered by one or more claims of the '119 patent.

40. Viwit has infringed the '119 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 212879, by which Viwit seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Viwit's ANDA Product prior to the expiration of the '119 patent.

41. If Viwit commercially makes, uses, offers to sell, or sells Viwit's ANDA Product within the United States, or imports Viwit's ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '119 patent, it would further infringe the '119 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

42. The Notice Letter, Viwit does not dispute that Viwit's ANDA Product infringes claims 4-9, 11-12, and 14-15 of the '119 patent.

43. Plaintiffs will be substantially and irreparably harmed if Viwit is not enjoined from infringing the '119 patent.

44. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- a. That the Court enter judgment in favor of Plaintiffs and against Viwit;
- b. That Viwit has infringed U.S. Patent Nos. 6,410,550, 6,890,927, and 7,265,119;

c. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Viwit, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from making, using, selling, or offering to sell Viwit's ANDA Product within the United States, or importing Viwit's ANDA Product into the United States, prior to the expiration of the '550, '927, and '119 patents, including any extensions thereof;

d. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 212879 under § 505(j) of the FDCA (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '550, '927, and '119 patents; including any extensions thereof;

e. That Plaintiffs be awarded monetary relief if Viwit commercially makes, uses, sells, or offers to sell Viwit's ANDA Product within the United States, or imports Viwit's ANDA Product into the United States, prior to the expiration of the '550, '927, and '119 patents, including any extensions thereof, and that Plaintiffs be awarded prejudgment interest on any such relief;

f. That the Court award Plaintiffs their attorneys' fees and other costs reasonably incurred in the defense of this action; and

g. That the Court order such other and further relief to Plaintiffs as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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