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. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Pfizer Products Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V. (collectively, "Plaintiffs"), for their Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), 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 Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 201962 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. 6,890,927 (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. 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. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

7. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

8. Upon information and belief, Apotex Inc. is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly owned subsidiaries and agents, including Apotex Corp.

PATENTS-IN-SUIT

9. 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. A.) Pfizer Inc. and Pfizer Products Inc. own all right, title, and interest to the inventions claimed in the '927 patent.

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

11. 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. B.) Pfizer Inc. and Pfizer Products Inc. own all right, title, and interest to the inventions claimed in the '119 patent.

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

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

CHANTIX

14. 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®.

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

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

APOTEX'S ANDA

17. Apotex Inc. and Apotex Corp. jointly notified Pfizer Inc., by letter dated August 4, 2010, that they had submitted ANDA No. 201962 to the FDA, for Apotex's Varenicline Tartrate Tablets, in 0.5mg and 1mg dosages, a generic copy of Chantix® ("Apotex's ANDA Product").

18. By letter dated August 17, 2021 (the "2021 Notice Letter"), Apotex Inc. individually notified Pfizer Inc., PF PRISM C.V., and Pfizer Products Inc., that it had amended ANDA No. 201962. The purpose of the amendment of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product prior to the expiration of the '927 and '119 patents.

19. In the 2021 Notice Letter, Apotex also stated that Apotex had amended its ANDA to include a certification 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 the '927 and '119 patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale" of Apotex's ANDA Product.

20. This action is being commenced before the expiration of forty-five days from the date of the receipt by Plaintiffs of the 2021 Notice Letter.

JURISDICTION AND VENUE

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

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

23. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*, (1) its presence in Delaware, Apotex Inc. having conducted business in Delaware by way of marketing, selling and distributing drug products in Delaware; (2) its systematic and continuous contacts with Delaware, including its substantial and ongoing sale of generic drugs in Delaware; (3) its business transactions with companies located and/or headquartered in Delaware; (4) its intention to offer to sell and sell Apotex's Product in Delaware upon receiving FDA approval; and (5) its prior consent to personal jurisdiction in this judicial district and its filing of suit in this judicial district, having availed itself of the rights and benefits of Delaware law, *see, e.g.*, *Apotex Inc. et al v. Lupin Ltd. et al*, C.A. No. 15-357-LPS (D. Del. May 04, 2015); *Astellas Pharma Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-976-JFB, D.I. 17 (D. Del. Jan. 17, 2017); *Onyx Therapeutics, Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-1039-LPS, D.I. 14 (D. Del. Jan. 31, 2017); *Apotex Inc. et al v. Symplmed Pharmaceuticals, LLC et al*, C.A. No. 17-276-CFC-MPT (D. Del. Mar 15, 2017); *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-399-LPS, D.I. 8 (D. Del. May 4, 2017); *Bayer Healthcare LLC v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-334-LPS, D.I. 10 (D. Del. May 22, 2017); *Teva Pharms. Int'l GmbH, et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-1164-GMS, D.I. 17 (D. Del. Nov. 27, 2017); *Merck Sharp & Dohme Corp. v. Apotex Inc. & Apotex Corp.*, C.A. No. 20-749-RGA, D.I. 7 (D. Del. Jun. 26, 2020).

24. Alternatively, this Court has jurisdiction over Apotex Inc. under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Plaintiffs' claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, not least through its

development of drug products for sale in the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

25. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process at 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, Delaware 19810. Apotex Corp. has thus consented to jurisdiction in Delaware.

26. Venue is proper in this Court for Defendant Apotex Inc. under 28 U.S.C. § 1391(c)(3) because Apotex Inc., on information and belief, is not a resident of the United States and may thus be sued in any judicial district.

27. Venue is proper in this Court for Defendant Apotex Corp. under 28 U.S.C. § 1400(b) because, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

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

28. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-27 of this Complaint, as if fully set forth herein.

29. Apotex's ANDA Product and/or certain uses thereof are covered by one or more claims of the '927 patent, including at least claim 1.

30. Apotex has infringed the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, amending, and maintaining ANDA No. 201962, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's ANDA Product prior to the expiration of the '927 patent.

31. If Apotex commercially makes, uses, offers to sell, or sells Apotex's ANDA Product within the United States, or imports Apotex'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, induce the infringement, and/or contribute to the infringement of one or more claims of the '927 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

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

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

34. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-33 of this Complaint, as if fully set forth herein.

35. Apotex's ANDA Product and/or certain uses thereof are covered by one or more claims of the '119 patent, including at least claims 1, 4 and 7.

36. Apotex has infringed the '119 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, amending, and maintaining ANDA No. 201962, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's ANDA Product prior to the expiration of the '119 patent.

37. If Apotex commercially makes, uses, offers to sell, or sells Apotex's ANDA Product within the United States, or imports Apotex'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, induce the infringement, and/or contribute to the infringement of one or more claims of the '119 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

39. 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 Apotex;

b. That Apotex has infringed U.S. Patent Nos. 6,890,927 and 7,265,119;

c. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Apotex, 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 Apotex's ANDA Product within the United States, or importing Apotex's ANDA Product into the United States, prior to the expiration of the '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. 201962 under § 505(j) of the FDCA (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '927 and '119 patents; including any extensions thereof;

e. That Plaintiffs be awarded monetary relief if Apotex commercially makes, uses, sells, or offers to sell Apotex's ANDA Product within the United States, or imports Apotex's ANDA Product into the United States, prior to the expiration of the '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

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Dimitrios Drivas
Alison Hanstead
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020-1095
(212) 819-8200

Hallie Kiernan
WHITE & CASE LLP
3000 El Camino Real
Two Palo Alto Square, Suite 900
Palo Alto, CA 94306
(650) 213-0300

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