

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., and C.P.)	
PHARMACEUTICALS INTERNATIONAL)	
C.V.)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
BRECKENRIDGE PHARMACEUTICAL,)	
INC., PENSA PHARMA S.A., and)	
LABORATORIOS DEL DR. ESTEVE, S.A.,)	
)	
Defendants.)	

COMPLAINT

Pfizer Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V. (collectively “Plaintiffs” or “Pfizer”), for their Complaint against Defendants Breckenridge Pharmaceutical, Inc., Pensa Pharma S.A., and Laboratorios del Dr. Esteve, S.A. (collectively “Breckenridge”) allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Breckenridge for infringement of United States Patent No. 6,965,027 (the “’027 patent”) and United States Patent No. 7,301,023 (the “’023 patent”).
2. This action arises out of Breckenridge Pharmaceutical, Inc.’s filing of Abbreviated New Drug Application (“ANDA”) No. 209633 seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic copies of Pfizer’s Xeljanz[®] prior to the expiration of the ’027 and ’023 patents.

THE PARTIES

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

4. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, 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 company of PF PRISM C.V.

5. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

6. On information and belief, defendant Breckenridge Pharmaceutical, Inc. is a company organized and existing under the laws of Florida, having its principal place of business at 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, Florida 33487.

7. On information and belief, defendant Pensa Pharma S.A. is a corporation organized and existing under the laws of Spain, having a place of business at Rambla Catalunya, 123, At. 1^a. 08008 Barcelona, Spain. On information and belief, Breckenridge Pharmaceutical, Inc. is a wholly-owned subsidiary of Pensa Pharma S.A. On information and belief, Breckenridge Pharmaceutical, Inc. is the U.S. agent for Pensa Pharma S.A.

8. On information and belief, defendant Laboratorios del Dr. Esteve, S.A. is a joint stock company organized and existing under the laws of Spain, with a place of business at Av. Mare de Déu de Montserrat, 221, 08041 Barcelona, Spain. On information and belief, Breckenridge Pharmaceutical, Inc. is member of the Esteve Group. On information and belief,

Laboratorios del Dr. Esteve, S.A. manufactures pharmaceutical products distributed by Breckenridge Pharmaceutical Inc.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Breckenridge.

12. This Court has personal jurisdiction over Breckenridge by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware. In particular, this suit arises out of Breckenridge Pharmaceutical, Inc.'s filing of ANDA No. 209633 seeking FDA approval to sell tofacitinib citrate tablets (eq. 5 mg base) ("Breckenridge Generic Tablets") prior to the expiration of the '027 and '023 patents, throughout the United States, including in Delaware.

13. On information and belief, Breckenridge Pharmaceutical, Inc., Pensa Pharma S.A., and Laboratorios del Dr. Esteve, S.A. are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, manufacture, sale, and/or distribution of generic drugs, including Breckenridge Generic Tablets, throughout the United States, including in or into Delaware. On information and belief, Pensa Pharma S.A. and Laboratorios del Dr. Esteve, S.A., directly or through Pensa Pharma S.A.'s subsidiary Breckenridge Pharmaceutical, Inc., manufacture, market, import, and sell generic drugs for distribution in Delaware and throughout the United States.

14. On information and belief, if ANDA No. 209633 is approved, Breckenridge Generic Tablets will, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

15. Breckenridge's infringing activities with respect to its filing of ANDA No. 209633 and its intent to commercialize and sell Breckenridge Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

16. On information and belief, Breckenridge maintains substantial, systematic, and continuous contacts throughout the United States, including with Delaware. Breckenridge's website states that it "has 30 approved Abbreviated New Drug Applications (ANDA's) approved by the Food and Drug Administration (FDA)" and it has "over 80 products in [its] pipeline; including 25 that contain Paragraph IV patent challenges." (<http://www.bpirx.com/html/index.aspx?page=home> (last visited Mar. 13, 2017)).

17. Breckenridge has previously availed itself of the United States District Court for the District of Delaware by consenting to the court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Onyx Therapeutics, Inc. v. Breckenridge Pharm., Inc.*, No. 1:16-cv-01001-LPS (D. Del.) (D.I. 11); *Amgen Inc. v. Breckenridge Pharm., Inc.*, No. 1:16-cv-00927-GMS (D. Del.) (D.I. 17); *Novartis Pharm. Corp. et al. v. Breckenridge Pharm., Inc.*, No. 1:16-cv-00431-RGA (D. Del.) (D.I. 8); *OSI Pharm., LLC et al. v. Breckenridge Pharm., Inc. et al.*, No. 1:15-cv-01063-SLR (D. Del.) (D.I. 10); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al.*, No. 1:15-cv-00902-RGA (D. Del.) (D.I. 53); *Forest Labs., LLC et al. v. Breckenridge Pharm., Inc.*, No. 1:14-cv-01504-SLR-SRF (D. Del.)

(D.I. 6); *Novartis Pharm Corp. et al. v. Breckenridge Pharm., Inc.*, No. 1:14-cv-01043-RGA (D. Del.) (D.I. 10); *Cephalon, Inc. v. Breckenridge Pharm., Inc. et al.*, No. 1:14-cv-00671-GMS (D. Del.) (D.I. 12); *UCB, Inc. et al. v. Breckenridge Pharm. Inc. et al.*, No. 1:13-cv-01211-LPS (D. Del.) (D.I. 12); *UCB, Inc. et al. v. Accord Healthcare, Inc. et al.*, No. 1:13-cv-01206-LPS (D. Del.) (D.I. 100); *Par Pharm., Inc. et al. v. Breckenridge Pharm. Inc.*, No. 1:13-cv-01114-SLR-SRF (D. Del.) (D.I. 9); *Pfizer Inc. et al. v. Breckenridge Pharm., Inc. et al.*, No. 1:12-cv-00810-SLR (D. Del.) (D.I. 15).

18. In the alternative, this Court has jurisdiction over Pensa Pharma S.A. and Laboratorios del Dr. Esteve, S.A. under Federal Rule of Civil Procedure 4(k)(2). Pensa Pharma S.A. and Laboratorios del Dr. Esteve, S.A. have contacts with the United States by, *inter alia*, having caused the filing of Breckenridge Pharmaceutical, Inc.’s ANDA with the FDA.

BACKGROUND

Xeljanz[®]

19. Tofacitinib citrate is an inhibitor of Janus kinases (“JAKs”) and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

20. The active ingredient in Xeljanz[®] is tofacitinib citrate. Xeljanz[®] contains tofacitinib citrate in an amount equivalent to 5 mg of tofacitinib base in a tablet formulated for twice-daily administration.

21. The FDA-approved Prescribing Information for Xeljanz[®] states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz®

22. PF PRISM C.V. holds approved New Drug Application (“NDA”) No. 203214 for EQ 5 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz®.

23. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the ’027 and ’023 patents are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for the Xeljanz® NDA.

24. The Orange Book lists the expiration date for the ’027 patent as March 25, 2023, and the ’023 patent as May 23, 2022.

25. The Orange Book also lists four additional patents for Xeljanz® that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); and RE41,783 (expiring December 8, 2020). On December 14, 2016, the United States Patent and Trademark Office (“USPTO”) issued a Notice of Final Determination extending the expiration date of the RE’783 patent to December 8, 2025.

The ’027 Patent

26. On November 15, 2005, the USPTO issued the ’027 patent, titled “Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile citrate.” The ’027 patent is duly and legally assigned to Pfizer Inc. A copy of the ’027 patent is attached hereto as Exhibit A.

27. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’027 patent.

The '023 Patent

28. On November 27, 2007, the USPTO issued the '023 patent, titled "Chiral Salt Resolution." The '023 patent is duly and legally assigned to Pfizer Inc. A copy of the '023 patent is attached hereto as Exhibit B.

29. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '023 patent.

Breckenridge's ANDA

30. By letter dated February 1, 2017, (the "Breckenridge Notice Letter") and received by Pfizer on February 6, 2017, Breckenridge notified Pfizer that it had filed ANDA No. 209633 with the FDA, seeking approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to market and sell Breckenridge Generic Tablets prior to the expiration of the '027 and '023 patents.

31. The Breckenridge Notice Letter asserts that ANDA No. 209633 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) alleging that each of the '027 and '023 Patents is "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale" of Breckenridge Generic Tablets.

32. The Breckenridge Notice Letter indicates that Breckenridge Generic Tablets will contain tofacitinib citrate as the active ingredient.

33. The Breckenridge Notice Letter states that ANDA No. 209633 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Breckenridge Generic Tablets prior to the expiration of the '027 and '023 patents.

34. Attached to the Breckenridge Notice Letter was Breckenridge's Detailed Statement ("Breckenridge's Detailed Statement") asserting the purported factual and legal bases for Breckenridge's contention that the '027 and '023 patents are invalid, unenforceable, and/or

will not be infringed by the manufacture, use, offer for sale, and/or sale of Breckenridge Generic Tablets.

35. Breckenridge's Detailed Statement alleges that all claims of the '027 and '023 patents are invalid. Breckenridge's Detailed Statement does not contain a noninfringement argument with respect to any claim of the '027 and '023 patents, other than that all claims are invalid.

36. On information and belief, Pensa Pharma S.A., Laboratorios del Dr. Esteve, S.A., and Breckenridge Pharmaceutical, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209633.

37. On information and belief, upon approval of ANDA No. 209633, Breckenridge will distribute Breckenridge Generic Tablets throughout the United States.

COUNT I
(Infringement of the '027 Patent by Breckenridge Generic Tablets)

38. The allegations of paragraphs 1-37 above are repeated and re-alleged as if set forth fully herein.

39. Pursuant to 35 U.S.C. § 271(e)(2)(A), Breckenridge Pharmaceutical, Inc.'s filing of ANDA No. 209633 seeking approval to market Breckenridge Generic Tablets is an act of infringement of one or more claims of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209633 be a date which is not earlier than the expiration date of the '027 patent.

40. Breckenridge had knowledge of the '027 patent when it submitted ANDA No. 209633 to the FDA.

41. On information and belief, upon FDA approval, Breckenridge intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Breckenridge Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

42. The foregoing actions by Breckenridge constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

43. Pfizer will be substantially and irreparably harmed if Breckenridge is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the '023 Patent by Breckenridge Generic Tablets)

44. The allegations of paragraphs 1-43 above are repeated and re-alleged as if set forth fully herein.

45. Pursuant to 35 U.S.C. § 271(e)(2)(A), Breckenridge Pharmaceutical, Inc.'s filing of ANDA No. 209633 seeking approval to market Breckenridge Generic Tablets is an act of infringement of claim 1 of the '023 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209633 be a date which is not earlier than the expiration date of the '023 patent.

46. Breckenridge had knowledge of the '023 patent when it submitted ANDA No. 209633 to the FDA.

47. On information and belief, upon FDA approval, Breckenridge intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Breckenridge Generic Tablets and will thereby infringe claim 1 of the '023 patent.

48. The foregoing actions by Breckenridge constitute and/or would constitute infringement of claim 1 of the '023 patent.

49. Pfizer will be substantially and irreparably harmed if Breckenridge is not enjoined from infringing the '023 patent. Pfizer has no adequate remedy at law.

COUNT III

(Pensa Pharma S.A.'s Inducing of Infringement by Breckenridge Pharmaceutical, Inc.)

50. The allegations of paragraphs 1-49 above are repeated and re-alleged as if set forth fully herein.

51. On information and belief, Pensa Pharma S.A. and Laboratorios del Dr. Esteve, S.A. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Breckenridge Pharmaceutical, Inc. of ANDA No. 209633 to the FDA, knowing of the '027 and '023 patents.

52. The filing of ANDA No. 209633 by Breckenridge Pharmaceutical, Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Pensa Pharma S.A. and Laboratorios del Dr. Esteve, S.A. induced the infringement of the '027 and '023 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 209633 to the FDA knowing that the submission of ANDA No. 209633 would constitute direct infringement of the '027 and '023 patents.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Breckenridge Pharmaceutical, Inc.'s submission of ANDA No. 209633 was an act of infringement and that Breckenridge's making, using, offering to sell, selling, or importing Breckenridge Generic Tablets prior to the expiration of the '027 and '023 patents will infringe each of those patents;

B. A judgment that defendants Pensa Pharma S.A.'s and Laboratorios del Dr. Esteve, S.A.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 209633, knowing that its submission would constitute direct infringement, induced infringement of the '027 and '023 patents;

C. A judgment that the effective date of any FDA approval for Breckenridge to make, use offer for sale, sell, market, distribute, or import the Breckenridge Generic Tablets be no earlier than the dates on which the '027 and '023 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A permanent injunction enjoining Breckenridge, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Breckenridge Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '027 and '023 patents, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

F. An award of Pfizer's costs and expenses in this action; and

G. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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