IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PF PRISM IMB B.V.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
SANDOZ INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc. and PF PRISM IMB B.V. (collectively "Pfizer"), file this Complaint for patent infringement against Sandoz Inc. ("Defendant" or "Sandoz"), and by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission of Abbreviated New Drug Application ("ANDA") No. 219705 submitted to the U.S. Food and Drug Administration ("FDA") in the name of Sandoz Inc. seeking approval to manufacture and sell a generic version of Pfizer's Inlyta® (axitinib) tablets, 1 mg and 5 mg ("Inlyta®"), prior to the expiration of U.S. Patent No. 8,791,140 ("the '140 patent").

2. Sandoz Inc. notified Pfizer by letter dated October 1, 2024, and received by Pfizer on October 2, 2024 ("Sandoz's Notice Letter"), that it had submitted to the FDA ANDA No. 219705 ("Sandoz's ANDA"), with a Paragraph IV certification, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic axitinib tablets, 1 mg and 5 mg ("Sandoz's ANDA Product"), prior to the expiration of the '140 patent.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

4. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

5. Upon information and belief, Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540, United States.

6. Upon information and belief, Sandoz is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States by itself and/or through its affiliates or agents.

7. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 219705, Sandoz will distribute and sell the generic product described in ANDA No. 219705 throughout the United States and within Delaware.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Sandoz is subject to personal jurisdiction in Delaware because, among other things, Sandoz is a corporation organized and existing under the laws of the State of Delaware, and Sandoz has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief,

Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

10. Sandoz has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing 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)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

11. Upon information and belief, Sandoz, with knowledge of the Hatch-Waxman Act process, directed Sandoz's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Sandoz's Notice Letter that Sandoz's ANDA Product will not infringe Pfizer's '140 patent and that the '140 patent is invalid and/or unenforceable. Upon information and belief, Sandoz knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

12. Because Pfizer is incorporated in Delaware, Pfizer suffers injury and consequences from Sandoz's filing of Sandoz's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, Sandoz knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Sandoz has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Sandoz's Notice Letter to Pfizer Inc., a Delaware corporation, that it would be sued in Delaware for patent infringement.

13. Upon information and belief, if Sandoz's ANDA is approved, Sandoz will directly or indirectly manufacture, market, sell, and/or distribute Sandoz's ANDA Product within the United States, including in Delaware, consistent with Sandoz's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sandoz regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Sandoz's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Sandoz's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patents in the event that Sandoz's ANDA Product is approved before the patents expire.

14. Upon information and belief, Sandoz derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Sandoz and/or for which Sandoz is the named applicant on approved ANDAs. Upon information and belief, various products for which Sandoz is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

15. Venue is proper in this district for Sandoz pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Sandoz is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

16. Venue is proper in this district as to Sandoz because Sandoz (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this

District, and (2) does not contest that venue is proper in this District. *See, e.g.*, *ZS Pharma, Inc. et al. v. Sandoz Inc.*, C.A. No. 23-01191-GBW, D.I. 11 (D Del. Jan. 5, 2024); *Array Biopharma Inc. v. Sandoz Inc.*, C.A. No. 22-1316-GBW, D.I. 12 (D. Del. Nov. 2, 2022).

BACKGROUND

17. PF PRISM C.V., a subsidiary of Pfizer Inc., is the holder of approved NDA No. 202324 for the manufacture and sale of axitinib tablets, 1 mg and 5 mg, approved by the FDA for the treatment of advanced renal cell carcinoma. Pfizer markets and sells axitinib tablets, 1 mg and 5 mg, under the trade name Inlyta®. Inlyta® was approved by the FDA on January 27, 2012.

18. The ’140 patent, entitled “Crystalline Forms of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyondazole Suitable for the Treatment of Abnormal Cell Growth in Mammals” (Exhibit A hereto), and owned by Pfizer Inc., was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on July 29, 2014. The ’140 patent is listed in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as “the Orange Book”) in connection with Inlyta®.

19. Pfizer has all right, title, and interest in the ’140 patent, including the right to sue for infringement thereof.

20. Upon information and belief, Sandoz filed or caused to be filed with the FDA ANDA No. 219705 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Sandoz’s ANDA Product in the United States before the expiration of the ’140 patent.

21. Upon information and belief, Sandoz’s ANDA No. 219705 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certification”), alleging that the

claims of the '140 patent are invalid, unenforceable and/or not infringed by Sandoz's ANDA Product.

22. Sandoz sent or caused to be sent to Pfizer Sandoz's Notice Letter dated October 1, 2024, received by Pfizer on October 2, 2024, notifying Pfizer that Sandoz's ANDA No. 219705 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Sandoz's ANDA Product before the expiration of the '140 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz's Notice Letter states "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(l) and (2)(A), and contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(viii)(IV) ('Paragraph IV certifications') to obtain approval to engage in the commercial manufacture, use or sale of axitinib tablets, 1 mg and 5 mg, before the expiration of the '140 patent . . . ."

23. The purpose of Sandoz's submission of ANDA No. 219705 was to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '140 patent.

24. Upon information and belief, Sandoz's ANDA Product is covered by one or more claims of the '140 patent.

25. The submission of ANDA No. 219705 to the FDA constituted infringement by Sandoz of the '140 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe the '140 patent under 35 U.S.C. § 271(a), (b) and/or (c).

26. In Sandoz's Notice Letter, Sandoz included an Offer of Confidential Access to portions of ANDA No. 219705. The terms of Sandoz's Offer of Confidential Access were unreasonably restrictive.

27. In an exchange of correspondence, counsel for Pfizer and counsel for Sandoz negotiated the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms under which Pfizer could review, among other things, Sandoz's unredacted ANDA, any Drug Master File referred to therein, or relevant characterization data. Sandoz further refused to produce samples of Sandoz's ANDA Product.

28. An actual case or controversy exists between Pfizer and Sandoz with respect to infringement of the '140 patent.

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

COUNT I – INFRINGEMENT OF THE '140 PATENT

30. Pfizer incorporates each of the preceding paragraphs as if fully set forth herein.

31. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '140 patent either literally or under the doctrine of equivalents.

32. As an example, claim 1 of the '140 patent recites a compound comprising: "[a] crystalline form of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl] indazole, wherein said crystalline form has a powder X-ray diffraction pattern comprising a peak at diffraction angle (2θ) of 6.0±0.1 and further comprising at least one peak at diffraction angle (2θ) selected from 11.5±0.1, 21.0±0.1 and 26.9±0.1."

33. Upon information and belief, Sandoz's ANDA Product contains "[a] crystalline form of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl] indazole, wherein said crystalline form has a powder X-ray diffraction pattern comprising a peak at diffraction angle (2θ) of 6.0±0.1 and further comprising at least one peak at diffraction angle (2θ) selected from 11.5±0.1, 21.0±0.1 and 26.9±0.1."

34. Upon information and belief, Sandoz's ANDA Product infringes claims 1–6 of the '140 patent literally or under the doctrine of equivalents.

35. Sandoz's submission of ANDA No. 219705 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '140 patent infringes the '140 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of ANDA No. 219705.

37. Upon information and belief, the manufacture, use, offer for sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '140 patent under 35 U.S.C. § 271.

38. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '140 patent when ANDA No. 219705 is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '140 patent and specific intent to infringe the '140 patent.

39. Upon FDA approval of ANDA No. 219705, Sandoz will intentionally encourage acts of direct infringement of one of more claims of the '140 patent by others, with knowledge that their acts are encouraging infringement.

40. Upon information and belief, Sandoz knows that Sandoz's ANDA Product is especially made or adapted for use in infringing the '140 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and

will, contribute to infringement of the '140 patent immediately and imminently upon approval of Sandoz's ANDA.

41. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '140 patent, active inducement of infringement of the '140 patent, and/or contribution to the infringement by others of the '140 patent.

42. Upon information and belief, Sandoz has acted with full knowledge of the '140 patent and without a reasonable basis for believing that Sandoz would not be liable for infringing the '140 patent, actively inducing infringement of the '140 patent, and/or contributing to the infringement by others of the '140 patent.

43. Unless Sandoz is enjoined from infringing the '140 patent, actively inducing infringement of the '140 patent, and/or contributing to the infringement by others of the '140 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

44. Sandoz's submission of ANDA No. 219705 with knowledge of the '140 patent and its infringement of that patent makes this case exceptional.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '140 PATENT

45. Pfizer incorporate each of the preceding paragraphs as if fully set forth herein.

46. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '140 patent, and/or the validity of the '140 patent.

47. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's ANDA Product or any other Sandoz drug product that is covered

by or whose use is covered by the '140 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '140 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Sandoz has infringed the '140 patent;

(b) A judgment ordering that the effective date of any FDA approval for Sandoz to make, use, offer for sale, sell, market, distribute, or import Sandoz's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '140 patent be not earlier than the expiration date of the '140 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sandoz, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Sandoz's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '140 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '140 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Sandoz's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing,

distributing, or importation of which infringes the '140 patent prior to the expiration date of the '140 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '140 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. §§ 285;

(f) An award of Pfizer's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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