IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, and RECEPTOS LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company ("BMS") and Receptos LLC ("Receptos") (together, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Apotex Inc. ("Apotex"). This action relates to Abbreviated New Drug Application ("ANDA") No. 219450 submitted by Apotex to the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 219450, Apotex seeks approval to market capsules containing 0.23 mg, 0.46 mg, and 0.92 mg of ozanimod (the "Apotex ANDA Product") prior to the expiration of U.S. Patent No 11,680,050 (the "'050 patent"). The Apotex ANDA Product is a generic version of Plaintiffs' Zeposia® drug product.

PARTIES

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543.

4. Receptos is a limited liability company organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543. Receptos is an indirect wholly-owned subsidiary of BMS.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market pharmaceutical products to help patients treat serious diseases, including multiple sclerosis ("MS") and ulcerative colitis ("UC"). Plaintiffs sell Zeposia® in this judicial District and throughout the United States.

6. Upon information and belief, Apotex is a corporation organized and existing under the laws of Canada, having a business address at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the United States market and/or manufacturing active pharmaceutical ingredients for generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court as to Apotex under 28 U.S.C. §§ 1391(c)(3) because Apotex is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

9. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, Apotex's systemic and continuous contacts with this jurisdiction. Upon information and belief, Apotex regularly does and/or solicits business, and derives substantial revenue from selling pharmaceutical products throughout the United States, including Delaware. Upon information and

belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex has received numerous FDA approvals to market and sell pharmaceutical products throughout the United States, including Delaware. Upon information and belief, Apotex derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

10. This Court also has personal jurisdiction over Apotex because Apotex has been and is engaging in activities directed toward infringement of the '050 patent, including in this District. Apotex has submitted an ANDA for a generic version of Plaintiffs' Zeposia® product, seeking approval from the FDA to market and sell Apotex's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Apotex intends to market and sell Apotex's ANDA Product upon receiving FDA approval. Upon information and belief, if and when the FDA approves Apotex's ANDA No. 219450, Apotex's ANDA Product would, among other things, be marketed, distributed, and sold in Delaware, prescribed by physicians practicing in Delaware, and/or dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing ANDA No. 219450, Apotex has made clear that it intends to use its distribution channels to direct sales of Apotex's ANDA Product in the United States, including Delaware.

11. In addition, this Court has personal jurisdiction over Apotex because Apotex has repeatedly availed itself of the rights, privileges, and protections of this Court as a litigant in this District. For example, Apotex has affirmatively availed itself of this Court's jurisdiction by filing complaints and counterclaims in this District. *See, e.g.*, Apotex's Complaint, *Apotex Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, Case No. 23-704 (D. Del. Jun. 28, 2023), D.I. 2; Apotex's Complaint, *Apotex Inc. et al. v. Symplmed Pharmaceuticals LLC et al.*, Case No. 17-

276 (D. Del. Mar. 15, 2017), D.I. 1; Apotex's Answer and Counterclaims, *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc. et al.*, Case. No. 24-549 (D. Del. May 24, 2024), D.I. 14; Apotex's Answer and Counterclaims, *Gilead Sciences, Inc. v. Apotex Inc. et al.*, Case No. 23-0775 (D. Del. Dec. 4, 2023), D.I. 9.

12. This Court also has personal jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Apotex is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Apotex has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

THE '050 PATENT

13. On June 20, 2023, the U.S. Patent and Trademark Office duly and legally issued the '050 patent, titled "Crystalline Forms of Ozanimod and Ozanimod Hydrochloride, and Processes for Preparation Thereof." A true and correct copy of the '050 patent is attached hereto as Exhibit A.

14. The claims of the '050 patent are valid, enforceable, and not expired.

15. Receptos is the assignee of the '050 patent. Plaintiffs have the right to enforce the '050 patent.

PLAINTIFFS' ZEPOSIA® PRODUCT

16. BMS is the current holder of New Drug Application ("NDA") No. 209899, by which the FDA granted approval for the marketing and sale of capsules containing 0.23 mg, 0.46 mg, and 0.92 mg of ozanimod. The ozanimod capsules are marketed in the United States under the trade name "Zeposia®."

17. Zeposia® is a sphingosine 1-phosphate receptor modulator indicated for the treatment of: (1) relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and (2) moderately to severely active UC in adults. A copy of the complete prescribing information for Zeposia® is attached as Exhibit B.

18. The FDA's Orange Book lists U.S. Patent Nos. 8,481,573 ("'573 patent"), 8,796,318 ("'318 patent"), 9,382,217 ("'217 patent"), 10,239,846 ("'846 patent"), and the '050 patent as covering Zeposia® and its use.

INFRINGEMENT BY APOTEX

19. By letter dated June 3, 2024, Apotex notified Plaintiffs that Apotex had submitted ANDA No. 219450 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "Notice Letter"). Plaintiffs received the Notice Letter no earlier than June 4, 2024.

20. The Notice Letter states that Apotex seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Apotex ANDA Product before the expiration of the '050 patent. The Notice Letter does not address any other patent listed in the Orange Book as covering Zeposia® and its use. Upon information and belief, Apotex intends to, directly or indirectly, engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Apotex ANDA Product upon receiving FDA approval and after the expiration of the '573, '318, '217, and '846 patents.

21. By submitting ANDA No. 219450, Apotex has necessarily represented to the FDA that the Apotex ANDA Product has the same active ingredient as Zeposia®, has the same dosage form, route of administration, and strength as Zeposia®, and is bioequivalent to Zeposia®.

22. Upon information and belief, Apotex is seeking approval to market the Apotex ANDA Product for the same approved indications as Zeposia®.

23. In the Notice Letter, Apotex states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the '050 Patent are invalid under 35 U.S.C. §§ 102 and 103. The Notice Letter does not contest that the commercial manufacture, use, offer to sell, sale, and/or importation of the Apotex ANDA Product will infringe at least claims 1-3, 5, and 7 of the '050 patent, to the extent that the claims are valid.

24. Apotex offered confidential access to portions of its ANDA No. 219450, on terms and conditions set forth in the Notice Letter (the "Apotex Offer"). Apotex requested that Plaintiffs accept the Apotex Offer before receiving access to Apotex's ANDA No. 219450. The Apotex Offer contains unreasonable restrictions well beyond those that would apply to an ANDA under a protective order. For example, the Apotex Offer does not extend to any in-house counsel, and for outside counsel, it contains broad bars on patent prosecution, FDA counseling, and litigation involving ozanimod. The Apotex Offer unreasonably restricts the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts. The restrictions that Apotex has placed on access to ANDA No. 219450 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

25. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

CLAIM FOR RELIEF
(INFRINGEMENT OF THE '050 PATENT)

26. Plaintiffs incorporate each of the above paragraphs 1 to 25 as though fully set forth herein.

27. Upon information and belief, Apotex's submission of ANDA No. 219450 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Apotex ANDA Product for use in accordance with its proposed label prior to the expiration of the '050 patent infringed one or more claims of the '050 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Apotex has not contested the infringement of claims 1-3, 5, and 7 of the '050 patent to the extent that the patent's claims are valid.

28. Upon information and belief, Apotex's commercial manufacture, use, offer to sell, sale, and/or importation of the Apotex ANDA Product for use in accordance with its proposed label prior to the expiration of the '050 patent, and/or its inducement or contribution to such conduct, would further infringe one or more claims of the '050 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. §§ 271(a), (b), and/or (c). Those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claim 1 the '050 patent.

29. Upon information and belief, upon FDA approval of Apotex's ANDA No. 219450, Apotex will infringe, either literally or under the doctrine of equivalents, one or more claims of the '050 patent, by making, using, offering to sell, selling, and/or importing the Apotex ANDA Product for use in accordance with its proposed label, or by actively inducing and contributing to infringement of the '050 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless

enjoined by the Court. Unless enjoined, those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claim 1 of the '050 patent.

30. Upon information and belief, the Apotex ANDA Product or its use in accordance with its proposed label satisfies each and every element of at least claim 1 of the '050 patent.

31. Claim 1 of the '050 patent, which is representative for purposes of Apotex's infringement of the patent's claims, recites:

> A crystalline Form CS1 of ozanimod hydrochloride, wherein the X-ray powder diffraction pattern shows characteristic peaks at 2theta values of 26.1°±0.20°, 24.4°±0.20° and 20.1°±0.20° using CuKα radiation.

32. Upon information and belief, the Apotex ANDA Product contains a crystalline Form CS1 of ozanimod hydrochloride, wherein the X-ray powder diffraction pattern shows characteristic peaks at 2theta values of 26.1°±0.20°, 24.4°±0.20° and 20.1°±0.20° using CuKα radiation. For example, the Notice Letter states that "the active ingredient in the proposed drug product is ozanimod," Notice Letter at 2, and nowhere in the Notice Letter does Apotex contend that it does not infringe claim 1 of the '050 patent to the extent it is valid.

33. Upon information and belief, Apotex does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Apotex ANDA Product would infringe claims 1-3, 5, and 7 of the '050 patent to the extent they are valid.

34. Upon information and belief, Apotex, upon FDA approval, would promote the use of the Apotex ANDA Product to infringe one or more claims of the '050 patent, including by encouraging the use of the Apotex ANDA Product in accordance with its proposed label.

35. Apotex had knowledge of the '050 patent prior to the submission of its ANDA. For example, the '050 patent is listed in the FDA's Orange Book under the entry for Zeposia®, and Apotex cites both the '050 patent and the Orange Book listing in the Notice Letter.

36. Upon information and belief, Apotex is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or medical practitioners will prescribe and/or administer the Apotex ANDA Product in accordance with its proposed label and therefore will directly infringe one or more claims of the '050 patent.

37. The Apotex ANDA Product constitutes a material part of the invention claimed in the '050 patent, is especially adapted for use in infringing the claims of the '050 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the '050 patent are not invalid, are not unenforceable, and are infringed by Apotex's submission of ANDA No. 219450 under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, and that Apotex's making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, the Apotex ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the claims of the '050 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 219450 shall be a date which is not earlier than the expiration date of the '050 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Apotex, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States

the Apotex ANDA Product until after the expiration date of the '050 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

4. An order awarding Plaintiffs their costs in this litigation;

5. A finding that this is an exceptional case and awarding Plaintiffs their reasonable attorneys' fees, including under 35 U.S.C. § 285; and

6. Such further and other relief as this Court deems just and proper.

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