IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, and RECEPTOS LLC, Plaintiffs, v. SYNTHON BV, Defendant.	)	C. A. No.: 24-780-GBW

SYNTHON B.V.'S ANSWER TO COMPLAINT

Defendant Synthon B.V. ("Synthon" or "Defendant"), for its Answer and Affirmative Defenses in response to the Complaint of Bristol-Myers Squibb Company and Receptos LLC (collectively "BMS" or "Plaintiffs") in the above-entitled action, states and alleges as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Synthon denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION[1]

COMPLAINT NO. 1

This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Synthon BV ("Synthon"). This action relates to Abbreviated New Drug Application ("ANDA") No. 219236 submitted by Synthon to the U.S. Food and Drug Administration ("FDA").

ANSWER NO. 1

Paragraph 1 contains conclusions of law for which no response is required. To the extent a

[1] To the extent that the headings in Plaintiffs' Complaint contain factual allegations, Synthon denies the contents of the headings.

response is required, Synthon admits that the Complaint purports to set forth claims of patent infringement concerning U.S. Patent No. 11,680,050 ("the '050 patent"). Synthon further admits that it submitted ANDA No. 219236 ("Synthon's ANDA") to the FDA. Synthon denies any patent infringement as alleged by Plaintiffs. Except as expressly admitted, Synthon denies the allegations of Paragraph 1 of the Complaint.

COMPLAINT NO. 2

In ANDA No. 219236, Synthon seeks approval to market capsules containing 0.23 mg, 0.46 mg, and 0.92 mg of ozanimod (the "Synthon ANDA Product") prior to the expiration of U.S. Patent No 11,680,050 (the "'050 patent"). The Synthon ANDA Product is a generic version of Plaintiffs' Zeposia® drug product.

ANSWER NO. 2

Synthon admits that it submitted Synthon's ANDA to the FDA seeking to obtain approval of ozanimod capsules, 0.23 mg, 0.46 mg, and 0.92 mg ("Synthon's ANDA Product") prior to the expiration of the '050 patent. Synthon denies any patent infringement as alleged by Plaintiffs. Except as expressly admitted, Synthon denies the allegations of Paragraph 2 of the Complaint.

PARTIES

COMPLAINT NO. 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.

ANSWER NO. 3

Synthon is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and therefore, Synthon denies the allegations in Paragraph 3.

COMPLAINT NO. 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.

ANSWER NO. 4

Synthon is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint, and therefore, Synthon denies the allegations in Paragraph 4.

COMPLAINT NO. 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.

ANSWER NO. 5

Synthon is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 5 of the Complaint, and therefore, Synthon denies the allegations in Paragraph 5.

COMPLAINT NO. 6

Upon information and belief, Synthon is a corporation organized and existing under the laws of the Netherlands, having a business address at Microweg 22, 6545 CM, Nijmegen, the Netherlands. Upon information and belief, Synthon 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.

ANSWER NO. 6

Synthon admits that it is a corporation organized and existing under the laws of the Netherlands, having a business address at Microweg 22, 6545 CM, Nijmegen, the Netherlands. Synthon admits that certain Synthon entities are in the business of manufacturing pharmaceutical drug products. Synthon denies that it manufactures copies of any branded pharmaceutical products. Except as expressly admitted, Synthon denies the allegations of Paragraph 6 of the Complaint.

JURISDICTION AND VENUE

COMPLAINT NO. 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.

ANSWER NO. 7

Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that this civil action of purported patent infringement arises under the patent laws of the United States, and that this Court has subject matter jurisdiction for Plaintiffs' infringement claim under 35 U.S.C. § 271(e) only. Synthon denies that this Court has subject matter jurisdiction over counts for declaratory judgment seeking judgment that Synthon has infringed or will infringe the '050 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Except as expressly admitted, Synthon denies the allegations of Paragraph 7 of the Complaint.

COMPLAINT NO. 8

Venue is proper in this Court as to Synthon under 28 U.S.C. §§ 1391(c)(3) because Synthon 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.

ANSWER NO. 8

Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that it is a corporation organized and existing under the laws of the Netherlands. Synthon further states that, for the purposes of this action only, Synthon does not contest personal jurisdiction or venue in this Court. Except as expressly admitted, Synthon denies the allegations of Paragraph 8 of the Complaint.

COMPLAINT NO. 9

This Court has personal jurisdiction over Synthon by virtue of, *inter alia*, Synthon's systemic and continuous contacts with this jurisdiction. Upon information and belief, Synthon 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, Synthon has received numerous FDA approvals to market and sell pharmaceutical products throughout the United States, including Delaware. Upon information and belief, Synthon derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

ANSWER NO. 9

Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon states that, for the purposes of this action only, it does not contest personal jurisdiction in this Court. Except as expressly admitted, Synthon denies the allegations of Paragraph 9 of the Complaint.

COMPLAINT NO. 10

This Court also has personal jurisdiction over Synthon because Synthon has been and is engaging in activities directed toward infringement of the '050 patent, including in this District. Synthon has submitted an ANDA for a generic version of Plaintiffs' Zeposia® product, seeking approval from the FDA to market and sell Synthon's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Synthon intends to market and sell Synthon's ANDA Product upon receiving FDA approval. Upon information and belief, if and when the FDA approves Synthon's ANDA, Synthon'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 its ANDA, Synthon has made clear that it intends to use its distribution channels to direct sales of Synthon's ANDA Product in the United States, including Delaware.

ANSWER NO. 10

Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon states that, for the purposes of this action only, it does not contest personal jurisdiction in this Court. Except as expressly admitted, Synthon denies the allegations of Paragraph 10 of the Complaint.

COMPLAINT NO. 11

In addition, this Court has personal jurisdiction over Synthon because Synthon has repeatedly availed itself of the rights, privileges, and protections of this Court as a litigant in this District. For example, Synthon has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District and successfully transferring litigation to this District. *See, e.g.*, Synthon Defendants' Answer, Additional Defenses, and Counterclaims, *Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddy's Laboratories, Ltd. et al.*, Case No. 16-1267 (D. Del. Feb. 16, 2017), D.I. 29; Synthon Defendants' Motion to Dismiss or Alternatively, to Transfer, *Teva Pharmaceuticals, USA, et al., v. Synthon Pharmaceuticals Inc., et al.*, Case No. 17-390 (D. Del. Feb. 20, 2017), D.I. 44 (granting motion to transfer and transferring case to the District of Delaware on Mar. 31, 2017, D.I. 69).

ANSWER NO. 11

Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon states that, for the purposes of this action only, it does not contest personal jurisdiction in this Court. Except as expressly admitted, Synthon denies the allegations of Paragraph 11 of the Complaint.

COMPLAINT NO. 12

This Court also has personal jurisdiction over Synthon pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Synthon is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Synthon 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 Synthon satisfies due process.

ANSWER NO. 12

Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon states that, for the purposes of this action only, it does not contest personal jurisdiction in this Court. Except as expressly admitted, Synthon denies the allegations of Paragraph 12 of the Complaint.

COMPLAINT NO. 13

On June 21, 2024, counsel for Synthon confirmed that Synthon will not contest personal jurisdiction or venue in this Court for purposes of this litigation.

ANSWER NO. 13

Admitted.

THE '050 PATENT

COMPLAINT NO. 14

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.

ANSWER NO. 14

Synthon admits that the '050 patent, on its face, is entitled "Crystalline Forms of Ozanimod and Ozanimod Hydrochloride, and Processes for Preparation Thereof" and states the date of issue as June 20, 2023. Synthon further admits that Exhibit A to the Complaint purports to be a copy of the '050 patent. Synthon denies that the '050 patent was duly and legally issued. Except as expressly admitted, Synthon denies the allegations of Paragraph 14 of the Complaint.

COMPLAINT NO. 15

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

ANSWER NO. 15

Denied.

COMPLAINT NO. 16

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

ANSWER NO. 16

Synthon is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 16 of the Complaint, and therefore, Synthon denies the allegations in Paragraph 16.

PLAINTIFFS' ZEPOSIA® PRODUCT

COMPLAINT NO. 17

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 tablets are marketed in the United States under the trade name "Zeposia®."

ANSWER NO. 17

Synthon admits that Exhibit B, which the Complaint purports to be the complete prescribing information for Zeposia®, states that it is "Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA," and that the FDA website (as of July 24, 2024) identifies BMS as the holder of NDA No. 209899 for capsules containing 0.23 mg, 0.46 mg, and 0.92 mg of ozanimod (expressed as the amount of ozanimod base). Synthon is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations as set forth in Paragraph 17 of the Complaint and therefore denies the remaining allegations in Paragraph 17.

COMPLAINT NO. 18

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.

ANSWER NO. 18

Synthon admits that Exhibit B, which the Complaint purports to be the complete prescribing information for Zeposia®, states that:

> ZEPOSIA is a sphingosine 1-phosphate receptor modulator indicated for the treatment of:
> • Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
> • Moderately to severely active ulcerative colitis (UC) in adults.

Ex. B, Indications and Usage (internal citations omitted). Except as expressly admitted, Synthon denies the allegations of Paragraph 18 of the Complaint.

COMPLAINT NO. 19

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.

ANSWER NO. 19

Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that the '573, '318, '217, '846, and '050 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book") in connection with Zeposia®. Except as expressly admitted, Synthon denies the allegations of Paragraph 19 of the Complaint.

INFRINGEMENT BY SYNTHON

COMPLAINT NO. 20

By letter dated May 20, 2024, Synthon notified Plaintiff BMS that Synthon had submitted ANDA No. 219236 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "Notice Letter"). Plaintiff BMS received the Notice Letter no earlier than May 21, 2024.

ANSWER NO. 20

Synthon admits that it sent a letter to Plaintiff BMS dated May 20, 2024 (the "Notice Letter"), notifying BMS that it had submitted Synthon's ANDA to the FDA pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Synthon admits that it received a delivery notification showing that the Notice Letter was delivered to BMS on May 21, 2024. Synthon is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 20 of the Complaint, and therefore, Synthon denies the remaining allegations in Paragraph 20.

COMPLAINT NO. 21

The Notice Letter states that Synthon seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Synthon 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, Synthon intends to, directly or indirectly, engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product upon receiving FDA approval and after the expiration of the '573, '318, '217, and '846 patents.

ANSWER NO. 21

Synthon admits that the Notice Letter states that Synthon submitted Synthon's ANDA to the FDA to obtain approval of Synthon's ANDA Product prior to expiration of the '050 patent. Synthon further admits that the '573, '318, '217, and '846 patents listed in the Orange Book in connection with Zeposia® are not addressed in the Notice Letter. Except as expressly admitted, Synthon denies the allegations of Paragraph 21 of the Complaint.

COMPLAINT NO. 22

By submitting ANDA No. 219236, Synthon has necessarily represented to the FDA that the Synthon 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®.

ANSWER NO. 22

Paragraph 22 of the Complaint contains legal conclusions to which no answer is required.

COMPLAINT NO. 23

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

ANSWER NO. 23

The allegations of Paragraph 23 of the Complaint are too vague and ambiguous to permit a response. To the extent a response is required, Synthon denies the allegations of Paragraph 23 of the Complaint.

COMPLAINT NO. 24

In the Notice Letter, Synthon 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 Synthon ANDA Product will infringe all claims of the '050 patent, including at least claim 1, to the extent that the claims are valid. Synthon did not offer confidential access to its ANDA No. 219236 in the Notice Letter.

ANSWER NO. 24

Synthon admits that the Notice Letter states that Synthon's 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. Synthon admits that the Notice Letter states that the claims of the '050 patent are invalid, unenforceable, and/or will not be infringed by Synthon's ANDA Product. Synthon admits that the Notice Letter states that Synthon reserves the right to assert non-infringement of the '050 patent in any subsequent patent infringement suit. Synthon further admits that it did not offer confidential access to its ANDA No. 219236 in the Notice Letter. Except as expressly admitted, Synthon denies the allegations of Paragraph 24 of the Complaint.

COMPLAINT NO. 25

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

ANSWER NO. 25

Admitted.

CLAIM FOR RELIEF

(INFRINGEMENT OF THE '050 PATENT)

COMPLAINT NO. 26

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

ANSWER NO. 26

Synthon incorporates by reference each of its responses to Paragraphs 1 through 25 of the Complaint as though fully set forth herein.

COMPLAINT NO. 27

Upon information and belief, Synthon's submission of ANDA No. 219236 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon 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, Synthon has not contested the infringement of any claim of the '050 patent to the extent that the patent's claims are valid.

ANSWER NO. 27

Paragraph 27 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that the Notice Letter states that the claims of the '050 patent are invalid, unenforceable, and/or will not be infringed by Synthon's ANDA Product. Synthon admits that the Notice Letter states that Synthon reserves the right to assert non-infringement of the '050 patent in any subsequent patent infringement suit. Except as expressly admitted, Synthon denies the allegations of Paragraph 27 of the Complaint.

COMPLAINT NO. 28

Upon information and belief, Synthon's commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon 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.

ANSWER NO. 28

Denied.

COMPLAINT NO. 29

Upon information and belief, upon FDA approval of Synthon's ANDA No. 219236, Synthon 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 Synthon 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.

ANSWER NO. 29

Denied.

COMPLAINT NO. 30

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

ANSWER NO. 30

Denied.

COMPLAINT NO. 31

Claim 1 of the '050 patent, which is representative for purposes of Synthon'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.

ANSWER NO. 31

Paragraph 31 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that claim 1 of the '050 patent 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." Except as expressly admitted, Synthon denies the allegations of Paragraph 31 of the Complaint.

COMPLAINT NO. 32

Upon information and belief, the Synthon 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 the "[t]he drug product is a capsule that contains the hydrochloride salt of ozanimod as the active ingredient," Notice Letter at 1, and nowhere in the Notice Letter does Synthon contend that it does not infringe any valid claim of the '050 patent.

ANSWER NO. 32

Paragraph 32 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Synthon admits that the Notice Letter states that the claims of the '050 patent are invalid, unenforceable, and/or will not be infringed by Synthon's ANDA Product. Synthon admits that the Notice Letter states that Synthon reserves the right to assert non-infringement of the '050 patent in any subsequent patent infringement suit. Except as expressly admitted, Synthon denies the allegations of Paragraph 32 of the Complaint.

COMPLAINT NO. 33

Upon information and belief, Synthon does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product would infringe a valid claim of the '050 patent.

ANSWER NO. 33

Synthon admits that the Notice Letter states that the claims of the '050 patent are invalid, unenforceable, and/or will not be infringed by Synthon's ANDA Product. Synthon admits that the Notice Letter states that Synthon reserves the right to assert non-infringement of the '050 patent in any subsequent patent infringement suit. Except as expressly admitted, Synthon denies the allegations of Paragraph 33 of the Complaint.

COMPLAINT NO. 34

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

ANSWER NO. 34

Paragraph 34 of the Complaint calls for speculation and contains legal conclusions to which no answer is required. To the extent a further response is required, denied.

COMPLAINT NO. 35

Synthon 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 Synthon cites both the '050 patent and the Orange Book listing in the Notice Letter.

ANSWER NO. 35

Synthon admits that it had knowledge of the '050 patent prior to the submission of its ANDA. Synthon admits that its Notice Letter cites both the '050 patent and the Orange Book listing. Except as expressly admitted, Synthon denies the allegations of Paragraph 35 of the Complaint.

COMPLAINT NO. 36

Upon information and belief, Synthon 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 Synthon ANDA Product in accordance with its proposed label and therefore will directly infringe one or more claims of the '050 patent.

ANSWER NO. 36

Paragraph 36 of the Complaint calls for speculation and contains legal conclusions to which no answer is required. To the extent a further response is required, denied.

COMPLAINT NO. 37

The Synthon 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.

ANSWER NO. 37

Paragraph 37 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, denied.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Synthon denies that Plaintiffs are entitled to the relief sought against Synthon in Paragraphs (1)–(6) of the Prayer for Relief set forth in the Complaint or any relief at all for the allegations relating to Synthon made in the Complaint.

SEPARATE DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Synthon states the following defenses:

FIRST SEPARATE DEFENSE

(Invalidity of U.S. Patent No. 11,680,050)

The claims of the '050 patent are invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially created bases for invalidity or unenforceability.

SECOND SEPARATE DEFENSE

(*Non-infringement of U.S. Patent No. 11,680,050*)

The submission of ANDA No. 219236 and/or manufacture, use, sale, offer for sale and/or importation into the United States of the product covered by ANDA No. 219236 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent No. 11,680,050.

THIRD SEPARATE DEFENSE

(*No Injunction*)

Plaintiffs have planned for, and in fact anticipated, the filing of several ANDA applications with the FDA for the approval of generic forms of its Zeposia® product for many years. Accordingly, should Synthon's ANDA Product be approved and should it further be sold in the United States market, Plaintiffs would not be irreparably harmed as a result of such anticipated competition. Further, should such sales occur, there are adequate remedies at law available, assuming such sales are found to infringe the '050 patent. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

FOURTH SEPARATE DEFENSE

(*Failure to State a Claim for Declaratory Judgement Causes of Action*)

The Complaint fails to state a claim upon which relief may be granted on the declaratory judgment causes of action or any action brought pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

FIFTH SEPARATE DEFENSE

(*Lack of Subject Matter Jurisdiction*)

The Court does not have subject matter jurisdiction over the declaratory judgment causes of action or any action brought pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

SIXTH SEPARATE DEFENSE

(*Not an Exceptional Case*)

Plaintiffs fail to state a proper claim for an exceptional case, or to assert any facts supporting an exceptional case.

SEVENTH SEPARATE DEFENSE

(*Failure to State a Claim*)

The Complaint fails to state a claim upon which relief can be granted.

EIGHTH SEPARATE DEFENSE

(*Equitable Doctrines*)

Plaintiffs' claims of patent infringement are barred in whole or in part by the equitable doctrines of waiver, estoppel, unclean hands, and/or patent misuse.

NINTH SEPARATE DEFENSE

(*Safe Harbor Defense of 35 U.S.C. § 271(e)(1)*)

Synthon is not liable for infringement of the '050 patent because Synthon is exempt from liability under the safe harbor of 35 U.S.C. § 271(e)(1), which provides: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

TENTH SEPARATE DEFENSE

(*Costs Barred Under 35 U.S.C. § 288*)

Plaintiffs' demand for costs is barred or limited under 35 U.S.C. § 288.

ELEVENTH SEPARATE DEFENSE

(*Lack of Willful Infringement*)

The Complaint fails to state a claim for willful infringement upon which relief can be granted. Even if such claim were proper, the Complaint fails to allege facts supporting a claim for willful infringement.

RESERVATION OF ADDITIONAL SEPARATE AND/OR AFFIRMATIVE DEFENSES

Synthon reserves the right to assert defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

DEFENDANT SYNTHON B.V.'S COUNTERCLAIMS

Counterclaim-Plaintiff Synthon B.V. ("Synthon" or "Counterclaim-Plaintiff") hereby alleges the following Counterclaims against Bristol-Myers Squibb Company and Receptos LLC (collectively "BMS" or "Counterclaim-Defendants"):

1. Synthon repeats and incorporates by reference each of the foregoing Paragraphs of Synthon B.V.'s Answer to Plaintiffs' Complaint.

THE PARTIES

2. Synthon is a corporation organized and existing under the laws of the Netherlands, having a business address at Microweg 22, 6545 CM, Nijmegen, the Netherlands.

3. Upon information and belief, 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. Upon information and belief, 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. Upon information and belief, Receptos is an indirect wholly-owned subsidiary of BMS.

JURISDICTION

5. Synthon's non-infringement and invalidity counterclaims arise under the patent laws of the United States, 35 U.S.C. § 100 et seq. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have subjected to the jurisdiction of this Court by filing the Complaint.

7. Venue as to these Counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

FIRST COUNTERCLAIM

(Declaratory Judgment of Non-infringement of U.S. Patent No. 11,680,050)

8. Synthon hereby incorporates by reference each and every allegation set forth in its Answer to the Complaint and in Paragraphs 1 through 7 of its Counterclaims above.

9. Synthon has filed Abbreviated New Drug Application ("ANDA") No. 219236 seeking approval to engage in the commercial manufacture, use, and sale of ozanimod capsules, 0.23 mg, 0.46 mg, and 0.92 mg ("Synthon's ANDA Product") prior to the expiration of U.S. Patent No. 11,680,050 (the "'050 patent").

10. In the Complaint, Counterclaim-Defendants assert, and continue to assert, that Synthon has infringed the '050 patent by filing ANDA No. 219236 seeking approval of Synthon's ANDA Product.

11. There is a substantial and continuing controversy between Synthon and

Counterclaim-Defendants as to infringement, invalidity, and unenforceability of the '050 patent.

12. Synthon's filing of ANDA No. 219236 did not infringe any valid and enforceable claim of the '050 patent directly or indirectly, either literally or by the doctrine of equivalents.

SECOND COUNTERCLAIM

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,680,050)

13. Synthon hereby incorporates by reference each and every allegation set forth in its Answer to the Complaint and in Paragraphs 1 through 12 of its Counterclaims above.

14. There is a substantial and continuing controversy between Synthon and Counterclaim-Defendants as to infringement, invalidity, and unenforceability of the '050 patent.

15. The '050 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation. In particular, the claims of the '050 patent are invalid under §§ 102 and 103 in light of, but not limited to, U.S. Patent Publication No. 2011/0172202 (Martinborough).

THIRD COUNTERCLAIM

(Miscellaneous Reservation of Rights)

16. Synthon asserts the above Counterclaims without the benefit of full discovery and investigation, and reserves the right to supplement or amend these Counterclaims as necessary.

PRAYER FOR RELIEF

WHEREFORE, Synthon prays for the following relief:

A. An order dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. An order declaring that no valid and enforceable claim of the '050 patent is infringed by the submission of Synthon's ANDA or by the making, use, sale, offer for sale, marketing or importation into the United States of the product described in Synthon's ANDA No. 219236;

C. An order declaring that the claims of the '050 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code;

D. An order declaring that this case is exceptional under 35 U.S.C. § 285, and awarding costs and reasonable attorneys' fees to Synthon;

E. An order awarding costs and expenses in this action to Synthon; and

F. Awarding Synthon such other and further relief as the Court deems just and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

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**Pro hac vice* admission to be filed

Dated: July 24, 2024

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