IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZS PHARMA, INC. and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. SANDOZ INC., Defendant.	)	C.A. No. 1:23-cv-01191-GBW

DEFENDANT SANDOZ INC.'S ANSWER TO PLAINTIFFS' COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant Sandoz Inc. ("Sandoz"), by and through the undersigned attorneys, answers the Complaint of Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca" or "Plaintiffs") as follows:

NATURE OF THE ACTION[1]

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq., and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 217405, filed by and for the benefit of Defendant with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217405, Defendant seek approval to market generic versions of LOKELMA® (sodium zirconium

[1] For ease of reference and organization, Sandoz has adopted the section headers used in the Complaint. For clarity, Sandoz does not agree with the section headers ascribed by Plaintiffs in the Complaint.

cyclosilicate) for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product"), prior to the expiration of U.S. Patent No. 11,738,044 ("the '044 Patent").

RESPONSE: Sandoz admits that Plaintiffs' Complaint against Sandoz purports to bring a claim for patent infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. §§ 271, but denies that Plaintiffs are entitled to any relief. Sandoz further admits that Sandoz submitted an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) seeking approval to market its product that is the subject of this ANDA prior to the expiration of U.S. Patent No. 11,738,044 ("the '044 Patent"). Sandoz denies any remaining allegations of paragraph 1.

THE PARTIES

2. Plaintiff ZS Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

RESPONSE: Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 2, and therefore, denies those allegations.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

RESPONSE: Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 3, and therefore, denies those allegations.

4. On information and belief, Defendant is a corporation organized and existing under the laws of the Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

RESPONSE: Admitted.

JURISDICTION AND VENUE

5. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the submission of Defendant's ANDA No. 217405 to the FDA.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that this action cites the patent laws of the United States and the Declaratory Judgment Act generally. Sandoz denies any remaining allegations in this paragraph.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1, *et seq*.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to subject matter jurisdiction for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

7. This Court has personal jurisdiction over Defendant because, inter alia, it has maintained continuous and systematic contacts with this District and availed itself of the privilege of doing business in this District. On information and belief, Defendant has: (1) filed ANDA No. 217405 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product in the United States, including in this District; (2) regularly and continuously transacted business within this District, including by selling pharmaceutical products in this District either on its own or through its affiliates; and (3) derived substantial revenue from the sale of those products in this District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to personal jurisdiction for

purposes of this action only. Sandoz admits that it filed ANDA No. 217405 and continues to seek FDA approval of that application. Sandoz denies any remaining allegations in this paragraph.

8. This Court also has personal jurisdiction over Defendant because, on information and belief, Defendant is a corporation organized and existing under the laws of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to personal jurisdiction for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

9. On information and belief, if ANDA No. 217405 is approved, the Proposed ANDA Product accused of infringing the '044 Patent will be marketed, distributed, offered for sale, and/or sold in this District, prescribed by physicians practicing in this District, dispensed by pharmacies located within this District, and/or used by patients in this District, all of which would have a substantial effect on this District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to personal jurisdiction for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

10. This Court also has personal jurisdiction over Defendant because it has affirmatively availed itself of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. For example, Defendant did not contest this Court's jurisdiction in Plaintiffs' previously-filed civil action regarding Defendants' ANDA No. 217405, Civil Action No. 22-1101-GBW. *See ZS Pharma, Inc. et al. v. Sandoz Inc.*, Civil Action No. 22-1055, D.I. 21 at ¶¶ 7-11 (D. Del.).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to personal jurisdiction for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

11. For the reasons set forth above, and for additional reasons which will be supplied if Defendant challenges personal jurisdiction in this action, Defendant is subject to personal jurisdiction in this District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to personal jurisdiction for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

12. Venue is proper in this District for Defendant pursuant to 28 U.S.C. § 1400(b) because Defendant is a corporation organized and existing under the laws of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not object to venue for purposes of this action only. Sandoz denies any remaining allegations in this paragraph.

THE '044 PATENT

13. The '044 Patent is assigned to ZS Pharma, Inc.

RESPONSE: Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

14. The '044 Patent, entitled "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof," was duly and legally issued on August 29, 2023. A copy of the '044 Patent is attached as Exhibit A.

RESPONSE: Sandoz admits that the title on the face of the '044 Patent is "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof." Sandoz admits that the '044

Patent was issued on August 29, 2023, but specifically denies that the patent was duly and legally issued. Sandoz admits that a purported copy of the '044 Patent was attached to Plaintiffs' Complaint as Exhibit A. Sandoz denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

LOKELMA® (sodium zirconium cyclosilicate)

15. LOKELMA® (sodium zirconium cyclosilicate) is a drug used to treat hyperkalemia. Marked elevations in serum potassium can cause fatal heart arrhythmias and abnormalities in conduction (progression of electrical impulses through the heart) and muscle weakness and paralysis. LOKELMA® (sodium zirconium cyclosilicate) is a non-absorbed zirconium silicate that preferentially captures potassium in exchange for hydrogen and sodium, thereby lowering serum potassium levels.

RESPONSE: Sandoz admits that the prescribing information for LOKELMA® states that "LOKELMA is a potassium binder indicated for the treatment of hyperkalemia in adults." Sandoz further admits that section 12.1 of the prescribing information for LOKELMA® states that "LOKELMA (sodium zirconium cyclosilicate) is a non-absorbed zirconium silicate that preferentially captures potassium in exchange for hydrogen and sodium. In vitro, LOKELMA has a high affinity for potassium ions, even in the presence of other cations such as calcium and magnesium." Sandoz denies any remaining allegations in this paragraph.

16. AstraZeneca is the holder of approved New Drug Application ("NDA") No. 207078 for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. Pursuant to NDA No. 207078, AstraZeneca markets and distributes LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet in the United States.

RESPONSE: Sandoz admits that the FDA's database lists AstraZeneca as the holder of New Drug Application ("NDA") No. 207078 for LOKELMA®, 5 g and 10 g sodium zirconium cyclosilicate packets. Sandoz denies any remaining allegations in this paragraph.

17. LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet, the active pharmaceutical ingredient sodium zirconium cyclosilicate, the method of manufacture, and/or their use are covered by one or more claims of the '044 Patent. The '044 Patent has been listed for NDA No. 207078 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that the FDA's database lists AstraZeneca as the holder of NDA No. 207078 for LOKELMA®, 5 g and 10 g sodium zirconium cyclosilicate packets. Sandoz admits that the '044 Patent is listed in the Orange Book for LOKELMA®. Sandoz denies any remaining allegations in this paragraph.

Defendant's ANDA No. 217405

18. In a letter dated July 15, 2022 (the "First Notice Letter"), Defendant stated that it had submitted ANDA No. 217405 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product. The First Notice Letter further stated that ANDA No. 217405 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that U.S. Patent Nos. 8,802,152 ("the '152 Patent"), 8,808,750 ("the '750 Patent"), 8,877,255 ("the '255 Patent"), 9,592,253 ("the '253 Patent"), 9,844,567 ("the '567 Patent"), 9,861,658 ("the '658 Patent"), 9,913,860 ("the '860 Patent"), 10,300,087 ("the '087 Patent"), 10,335,432 ("the '432 Patent"), 10,398,730 ("the '730 Patent"), 10,413,569 ("the '569 Patent"), and 10,695,365 ("the '365 Patent") are invalid,

unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product. Plaintiffs timely filed suit with respect to those patents on August 22, 2022. *See ZS Pharma, Inc. et al. v. Sandoz Inc.*, Civil Action No. 22-1101, D.I. 1 (D. Del.).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217405 to the FDA under Section 505(j) of the FFDCA, seeking the FDA's approval of Sandoz's ANDA Product before the expiration of the '152, '750, '255, '253, '567, '658, '860, '087, '432, '730, '569, and '365 Patents. Sandoz admits that it sent AstraZeneca and ZS Pharma a letter dated July 15, 2022 (the "First Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz further admits that Sandoz's First Notice Letter notified AstraZeneca and ZS Pharma that Sandoz's ANDA No. 217405 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '152, '750, '255, '253, '567, '658, '860, '087, '432, '730, '569, and '365 Patents. Sandoz admits that on August 22, 2022, Plaintiffs filed Civil Action No. 22-1101 against Sandoz in the District of Delaware asserting the '152, '750, '255, '253, '567, '658, '860, '087, '432, '730, '569, and '365 Patents. Sandoz denies any remaining allegations in this paragraph.

19. In a letter dated October 13, 2022 (the "Second Notice Letter"), Defendant stated that it had submitted ANDA No. 217405 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product. The Second Notice Letter further stated that ANDA No. 217405 contained a Paragraph IV Certification that U.S. Patent No. 11,406,662 ("the '662 Patent") is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the

Proposed ANDA Product. Plaintiffs timely filed suit with respect to this patent on October 5, 2022. *See ZS Pharma, Inc. et al. v. Sandoz Inc.*, Civil Action No. 22-1101, D.I. 18 (D. Del.).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217405 to the FDA under Section 505(j) of the FFDCA, seeking the FDA's approval of Sandoz's ANDA Product before the expiration of the '662 Patent. Sandoz admits that it sent AstraZeneca and ZS Pharma a letter dated October 13, 2022 (the "Second Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz further admits that Sandoz's Second Notice Letter notified AstraZeneca and ZS Pharma that Sandoz's ANDA No. 217405 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '662 Patent. Sandoz admits that on October 5, 2022, Plaintiffs filed an amended complaint in Civil Action No. 22-1101, asserting the '662 Patent in addition to the '152, '750, '255, '253, '567, '658, '860, '087, '432, '730, '569, and '365 Patents. Sandoz denies any remaining allegations in this paragraph.

20. On information and belief, Defendant has amended or will amend ANDA No. 217405 to include a Paragraph IV Certification that the '044 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies that it has submitted an amendment to ANDA No. 217405 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '044 Patent.

21. Defendant' submission of ANDA No. 217405 to the FDA constitutes infringement of one or more claims of the '044 Patent under 35 U.S.C. § 271(e)(2)(A). Although the '044 Patent

did not issue until after ANDA No. 217405 was filed, this does not preclude Defendant from infringement liability under 35 U.S.C. § 271(e)(2). *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1127 (Fed. Cir. 2018).

RESPONSE: Denied.

22. On information and belief, sodium zirconium cyclosilicate is the active ingredient in the Proposed ANDA Product.

RESPONSE: Sandoz admits that it submitted ANDA No. 217405 for a drug product having sodium zirconium cyclosilicate as the active ingredient. Sandoz denies any remaining allegations in this paragraph.

23. On information and belief, the Proposed ANDA Product exhibits sodium zirconium cyclosilicate as patented by the '044 Patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217405 for a drug product having sodium zirconium cyclosilicate as the active ingredient. Sandoz denies any remaining allegations in this paragraph.

24. On information and belief, ANDA No. 217405 refers to and relies upon the NDA for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet and contains data that, according to Defendant, demonstrate the bioequivalence of the Proposed ANDA Product and LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217405

seeking approval of the drug product for which LOKELMA® is the reference listed drug. Sandoz denies any remaining allegations in this paragraph.

25. On information and belief, Defendant intends to have healthcare providers use the Proposed ANDA Product, if approved, as set forth in the Proposed ANDA Product label.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that its drug product that is the subject of ANDA No. 217405, if approved, will be provided with a product label containing information required by the FDA. Sandoz denies any remaining allegations in this paragraph.

26. On information and belief, Defendant's Proposed ANDA Product label will instruct healthcare providers to prescribe the Proposed ANDA Product in the manner set forth in the label.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that its drug product that is subject of ANDA No. 217405, if approved, will be provided with a product label containing information required by the FDA. Sandoz denies any remaining allegations in this paragraph.

27. On information and belief, the FDA has not yet approved ANDA No. 217405.

RESPONSE: Sandoz admits that as of the date of this answer, ANDA No. 217405 has not been approved by the FDA. Sandoz denies any remaining allegations in this paragraph.

COUNT I: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 11,738,044

28. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 27 of this Complaint.

RESPONSE: To the extent an answer to this paragraph is required, Sandoz repeats and incorporates by reference its Answers to paragraphs 1 – 27.

29. On information and belief, the Proposed ANDA Product infringes one or more claims of the ’044 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the ’044 Patent.

RESPONSE: Denied.

30. Defendant’ submission of ANDA No. 217405 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the ’044 Patent constitutes infringement of the ’044 Patent under 35 U.S.C. § 271(e)(2).

RESPONSE: Denied.

31. On information and belief, Defendant plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217405 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

RESPONSE: Denied.

32. On information and belief, upon FDA approval of ANDA No. 217405, Defendant will infringe the ’044 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

RESPONSE: Denied.

33. On information and belief, Defendant has or will have knowledge that if it were to receive approval from the FDA to market the Proposed ANDA Product described in ANDA No. 217405 and make the Proposed ANDA Product available for sale and/or use by others, e.g., by

doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '044 Patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Defendant has or will have knowledge of such infringement and/or such infringing use and also knows or will know that the Proposed ANDA Product described in ANDA No. 217405 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '044 Patent.

RESPONSE: Denied.

34. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

RESPONSE: Denied.

PRAYER FOR RELIEF

Sandoz denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or to any relief whatsoever, including those specifically requested as against Sandoz.

GENERAL DENIAL

Sandoz denies all remaining allegations not specifically admitted herein. Sandoz further denies that Plaintiffs are entitled to any judgement or relief requested in the Complaint, or to any relief whatsoever.

SANDOZ'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Sandoz asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required

by law, regardless of how such defenses are denominated below. Sandoz reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Sandoz asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE

(Invalidity or Unenforceability of the '044 Patent)

The '044 Patent and each of the claims thereof are invalid or unenforceable for failure to comply with one or 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.

SECOND AFFIRMATIVE DEFENSE

(No Direct or Indirect Infringement of the '044 Patent)

Sandoz does not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '044 Patent.

THIRD AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Sandoz for exceptional case under 35 U.S.C. § 285.

FOURTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

Wherefore, Sandoz respectfully requests that Plaintiffs take nothing by way of their Complaint, that judgment be entered in favor of Sandoz, that Sandoz be awarded its attorneys' fees and costs, and all other just and proper relief.

SANDOZ INC.'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP (collectively, "Counterclaim Defendants" or "AstraZeneca"), Defendant Sandoz ("Counterclaim Plaintiff" or "Sandoz") states as follows:

THE PARTIES

1. On information and belief, Plaintiff ZS Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

2. On information and belief, Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

3. Sandoz Inc. is a corporation organized and existing under the laws of the Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

4. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Counterclaim Defendants on the basis of, *inter alia*, their contacts with Delaware relating to the subject matter of this action, including having filed suit.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

7. Upon information and belief, AstraZeneca is the holder of approved New Drug Application ("NDA") No. 207078 for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. Pursuant to NDA No. 207078, AstraZeneca markets and distributes LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet in the United States.

8. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

9. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

10. U.S. Patent No. 11,738,044 ("the '044 Patent") is entitled "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof," and issued on August 29, 2023. A purported copy of the '044 Patent was attached as Exhibit A to Counterclaim Defendants' Complaint.

11. Upon information and belief, ZS Pharma is the assignee of the '044 Patent.

12. Upon information and belief, Counterclaim Defendants caused the '044 Patent to be listed in the Orange Book as a patent that claims a drug for which AstraZeneca holds NDA No. 207078.

13. Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 217405 to obtain FDA approval prior to the expiration of the '044 Patent.

14. On October 20, 2023, Counterclaim Defendants filed this instant lawsuit alleging infringement of the '044 Patent.

COUNTERCLAIM I

(Declaratory Judgment of Noninfringement of the '044 Patent)

15. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1-14 of its Counterclaims.

16. ZS Pharma alleges ownership of the '044 Patent, and Counterclaim Defendants have brought claims against Sandoz alleging infringement of the '044 Patent.

17. The manufacture, use, or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '044 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

18. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA No. 217405 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Sandoz's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '044 Patent.

19. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '044 Patent and is not liable for such infringement.

20. Sandoz is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe any valid or enforceable claim of the '044 Patent.

COUNTERCLAIM II

(Declaratory Judgment of Invalidity or Unenforceability of the '044 Patent)

21. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1-20 of its Counterclaims.

22. ZS Pharma alleges ownership of the '044 Patent, and Counterclaim Defendants have brought claims against Sandoz alleging infringement of the '044 Patent.

23. One or more claims of the '044 Patent are invalid or unenforceable under one or more provisions of 35 §§ U.S.C. 101, 102, 103, 112 and /or in view of defenses recognized in 35 U.S.C. § 282 (b).

24. The '044 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

25. The alleged invention of the '044 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '044 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '044 Patent and would have had a reasonable expectation of success in doing so.

26. Moreover, the alleged invention of the '044 Patent does no more than claim compositions and properties that were inherently disclosed in the prior art.

27. The subject matter claimed in the '044 Patent fails to comply with at least 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

28. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA No. 217405 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Sandoz's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '044 Patent.

29. Sandoz is entitled to a declaration that all claims of the '044 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Sandoz requests judgment in its favor and against Counterclaim Defendants as follows:

a. Declaring that all claims of the '044 Patent are invalid or unenforceable.

b. Declaring that the filing of Sandoz's ANDA No. 217405 has not infringed and does not infringe any valid and enforceable claim of the '044 Patent.

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Sandoz's ANDA Product does not, and would not, infringe any valid and enforceable claim of the '044 Patent.

d. Declaring this an exceptional case in favor of Sandoz and awarding its attorneys' fees pursuant to 35 U.S.C. § 285.

e. Awarding costs and expenses; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

DATED: January 5, 2024

PHILLIPS, MCLAUGHLIN & HALL, P.A.

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