IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, ASTRAZENECA PHARMACEUTICALS LP, AND NEKTAR THERAPEUTICS,	)	
Plaintiffs,	)	Civil Action No. 1:18-cv-02010-RGA
v.	)	
APOTEX INC. AND APOTEX CORP.	)	
Defendants.	)	

DEFENDANT APOTEX'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Apotex Inc. and Apotex Corp. ("Apotex"), by their undersigned attorneys, for their Answer to the Complaint filed by Plaintiffs AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and Nektar Therapeutics (all Plaintiffs, collectively, "Plaintiffs" or "AstraZeneca"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

> 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 filing, made by Apotex Inc. and Apotex Corp. (collectively, "Apotex"), of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of MOVANTIK® (naloxegol) in tablet form in doses of 25 mg and 12.5 mg ("Movantik"), prior to the expiration of U.S. Patent No. 9,012,469 ("the '469 patent").

ANSWER: Paragraph 1 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that AstraZeneca's Complaint purports to assert an action for patent infringement based on Apotex's filing of Abbreviated New Drug Application ("ANDA") No. 212534 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic naloxegol tablets, 12.5 mg and

25 mg ("Apotex's ANDA products"), prior to the expiration of United States Patent No. 9,012,469 (the "'469 patent"). Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

> 2. Movantik is an opioid antagonist indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

ANSWER: Apotex admits that, according to the U.S. prescribing information for MOVANTIK®, revised February 2018, MOVANTIK® is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 2 of the Complaint and therefore denies them

> 3. Apotex notified Plaintiff AstraZeneca AB, Plaintiff Nektar Therapeutics, AstraZeneca LP, Plaintiff AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC, by letter dated November 5, 2018 ("Apotex's Notice Letter") that it had submitted to the FDA ANDA No. 212534 ("Apotex's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic "Naloxegol Tablets, 25 mg and 12.5 mg," ("Apotex's ANDA Product") prior to the expiration of the '469 patent.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a letter dated November 5, 2018, to Plaintiff AstraZeneca AB, Plaintiff Nektar Therapeutics, AstraZeneca LP, Plaintiff AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Apotex had filed with FDA ANDA No. 212534 seeking

approval to commercially market naloxegol tablets, 12.5 mg and 25 mg, prior to the expiration of the '469 patent, and that such letter satisfied all statutory, legal, and regulatory requirements. Apotex denies all remaining allegations of Paragraph 3.

4. Upon information and belief, Apotex's ANDA Product is a drug product that is a generic version of Movantik, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it has filed with FDA ANDA No. 212534 seeking approval to commercially market naloxegol tablets, 12.5 mg and 25 mg, as generic to MOVANTIK®. Apotex denies that a generic version of MOVANTIK® would necessarily contain the same or equivalent ingredients in the same or equivalent amounts, denies that Apotex's ANDA products contain the same or equivalent ingredients in the same or equivalent amounts as MOVANTIK®, and denies all remaining allegations of Paragraph 4.

Parties

5. Plaintiff Astrazeneca [sic] AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

ANSWER: Upon information and belief, admitted.

6. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850. AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Application No. 204760, directed to Movantik, and sells and distributes Movantik in the United States.

ANSWER: Upon information and belief, Apotex admits that Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850, and that,

according to the FDA's electronic publication entitled, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), it holds New Drug Application No. 204760 for MOVANTIK®. Apotex is without sufficient information with which to form a belief as to the truth of the remaining allegations in Paragraph 6 and therefore denies all remaining allegations of Paragraph 6.

7. Plaintiff Nektar Therapeutics is a corporation organized under the laws of Delaware with its principal place of business at 455 Mission Bay Boulevard South, San Francisco, California, 94158.

ANSWER: Upon information and belief, admitted.

8. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Apotex Corp.

ANSWER: Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Apotex denies all remaining allegations of Paragraph 8.

9. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

ANSWER: Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex denies all remaining allegations of Paragraph 9.

10. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc. Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex."

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

11. Upon information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit Apotex's ANDA to the FDA.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

Jurisdiction

12. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest that, pursuant to 28 U.S.C. §§ 1331 and 1338(a), this Court has subject matter jurisdiction over AstraZeneca's infringement claims under 35 U.S.C. §271(e)(2)(A) only. Apotex denies that this Court has subject matter jurisdiction over any of AstraZeneca's Declaratory Judgment claims asserting infringement under 35 U.S.C. § 271(a), (b), or (c). Apotex denies all remaining allegations of Paragraph 12.

13. This Court has personal jurisdiction over each of Apotex Inc. and Apotex Corp.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 13.

14. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex

> Corp., 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, Apotex Inc., itself and through its subsidiary Apotex Corp., 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. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 14.

> 15. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Apotex Corp. 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 related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 15.

> 16. Upon information and belief, Apotex Inc. and Apotex Corp. know and intend that upon approval of Apotex's ANDA, Apotex Inc. will manufacture Apotex's ANDA Product and Apotex Corp. will directly or indirectly market, sell, and distribute Apotex's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Apotex Inc. and Apotex Corp. are agents

of each other and/or operate in concert as integrated parts of the same business group, including with respect to Apotex's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Apotex Corp. participated in, assisted, and cooperated with Apotex Inc. in the acts complained of herein.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 16.

17. Upon information and belief, following any FDA approval of Apotex's ANDA, Apotex Inc. and Apotex Corp. will act in concert to distribute and sell Apotex's ANDA Product throughout the United States, including within Delaware.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 17.

18. Apotex 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.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 18.

19. Upon information and belief, Apotex, with knowledge of the Hatch-Waxman Act process, directed Apotex's Notice Letter to, *inter alia*, AstraZeneca Pharmaceuticals LP and AstraZeneca LP, to addresses in Delaware, and alleged in

Apotex's Notice Letter that the '469 patent is invalid and/or will not be infringed by the commercial manufacture, use or sale of the Apotex's ANDA Product. Upon information and belief, Apotex knowingly and deliberately challenged the '469 patent knowing that when it did so that it was triggering a forty-five day period for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 19.

20. Because AstraZeneca Pharmaceuticals LP is a limited partnership organized in Delaware, it suffers injury and consequences from Apotex's filing of Apotex's ANDA, challenging the '469 patent in Delaware. Upon information and belief, Apotex knew that it was deliberately challenging the patent rights of at least one Delaware entity and seeking to invalidate intellectual property held in Delaware. Apotex has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Apotex's Notice Letter to a Delaware corporation, that it would be sued in Delaware for patent infringement.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 20.

21. This Court has personal jurisdiction over Apotex because Apotex Inc. and Apotex Corp. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Novartis Pharma. Corp. v. Apotex Inc*., No. 18-1038-LPS, D.I. 9 (D. Del. Aug. 8, 2018) (Apotex Inc. and Apotex Corp.); *Vanda Pharma. Inc. v. Apotex Inc*., No. 18-689-CFC (D. Del. July 13, 2018) (same); *Bial-Portela & CA., S.A. v. Apotex Inc*., No. 18-382-CFC, D.I. 11 (D. Del. May 31, 2018) (same); *Onyx Therapeutics, Inc. v. Apotex Inc*., No. 18-132-LPS, D.I. 10 (D. Del. Feb. 26, 2018) (same).

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 21.

22. Upon information and belief, if Apotex's ANDA is approved, Apotex will directly or indirectly manufacture, market, sell, and/or distribute Apotex's ANDA Product within the United States, including in Delaware, consistently with Apotex's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Apotex 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, Apotex's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Apotex'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 the '469 patent in the event that Apotex's ANDA is approved before the patent expires.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 22.

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

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and

the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 23.

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

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 24.

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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this Judicial District for the limited purposes of this action only. Apotex denies all remaining allegations of Paragraph 25.

The '469 Patent

26. Plaintiffs incorporate each of the preceding paragraphs 1–25 as if fully set forth herein.

ANSWER: Apotex incorporates each of its preceding answers to paragraphs 1-25 of the Complaint as if fully set forth herein.

27. The inventors named on the '469 patent are Bengt Leonard Aslund, Carl-Johan Aurell, Martin Hans Bohlin, Eric Thomas Healy, David Richard Jensen, David Thomas Jonaitis, Stephan Parent, Tesfai Sebhatu, and Bo Ingvar Ymen (collectively, "the Named Inventors").

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the cover the of the '469 patent lists Bengt Leonard Aslund, Carl-Johan Aurell, Martin Hans Bohlin, Eric Thomas Healy, David Richard Jensen, David Thomas Jonaitis, Stephan Parent, Tesfai Sebhatu, and Bo Ingvar Ymen as inventors. Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 27 of the Complaint and therefore denies them.

28. The '469 patent, entitled "Crystalline Naloxol-Peg Conjugate," (Exhibit A hereto), was duly and legally issued on April 21, 2015, to AstraZeneca AB and Nektar Therapeutics as assignees of the Named Inventors.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that what purports to be a copy of the '469 patent is attached to the Complaint at Exhibit A; that the '469 patent is entitled "Crystalline Naloxol-Peg Conjugate"; and that the issue date identified on the cover of the '469 patent is April 21, 2015. Apotex denies that the '469 patent was "duly and legally issued." Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 28 of the Complaint and therefore denies them.

29. The '469 patent claims, *inter alia*, a crystalline oxalate salt of mPEG7-O-naloxol, certain naloxol-polyethylene glycol conjugate oxalate salts, methods of producing them, and compositions comprising them.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the claims of the '469 patent are generally directed to a crystalline oxalate salt of mPEG7-O-naloxol, certain naloxol-polyethylene glycol conjugate oxalate salts, methods of producing them, and compositions comprising them. Apotex denies all remaining allegations of Paragraph 29.

30. Plaintiffs are assignees of the ’469 patent, and have the right to enforce the ’469 patent.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 30 of the Complaint and therefore denies them.

31. Movantik, and methods of producing Movantik, are covered by one or more claims of the ’469 patent.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 31 of the Complaint and therefore denies them.

32. The ’469 patent has been listed in connection with Movantik in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

ANSWER: Admitted.

33. Plaintiffs will be substantially and irreparably damaged by infringement of the ’469 patent.

ANSWER: Denied.

Count I – Apotex’s [Alleged] Infringement of the ’469 Patent

34. Plaintiffs incorporate each of the preceding paragraphs 1–33 as if fully set forth herein.

ANSWER: Apotex incorporates each of its preceding answers to paragraphs 1-33 of the Complaint as if fully set forth herein.

35. In Apotex's Notice Letter, Apotex notified Plaintiffs that it had submitted Apotex's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product prior to the expiration of the patent-in-suit.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a letter dated November 5, 2018, to Plaintiff AstraZeneca AB, Plaintiff Nektar Therapeutics, AstraZeneca LP, Plaintiff AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Apotex had filed with FDA ANDA No. 212534 seeking approval to commercially market naloxegol tablets, 12.5 mg and 25 mg, prior to the expiration of the '469 patent, and that such letter satisfied all statutory, legal, and regulatory requirements. Apotex denies all remaining allegations of Paragraph 35.

36. In its Notice Letter, Apotex also notified Plaintiffs that, as part of its ANDA, Apotex had filed certifications 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), with respect to the '469 patent. Upon information and belief, Apotex submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '469 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a letter dated November 5, 2018, to Plaintiff AstraZeneca AB, Plaintiff Nektar Therapeutics, AstraZeneca LP, Plaintiff AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Apotex had filed with FDA ANDA No. 212534 and that Apotex's ANDA No. 212534 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification(s)") asserting that the '469 patent is invalid, unenforceable, and/or will not be infringed by Apotex's ANDA No. 212534 and the naloxegol tablets, 12.5 mg and 25

mg, described therein, and that such letter satisfied all statutory, legal, and regulatory requirements. Apotex denies all remaining allegations of paragraph 36.

37. Apotex's ANDA Product, and the manufacture and/or use of Apotex's ANDA Product, are covered by one or more claims of the '469 patent, including at least the following: claims 1, 2, 4–6, and 8–14.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

38. In its Notice Letter, Apotex did not contest infringement of claims 1, 2, 4–6, and 8–14 of the '469 patent.

ANSWER: Denied.

39. Apotex has knowledge of the '469 patent.

ANSWER: Admitted.

40. Apotex's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product before the expiration of the '469 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

41. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product immediately and imminently upon approval of its ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the Movantik product.

ANSWER: Denied.

42. The manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe one or more claims of each of the '469 patent, including at least the claims listed in above paragraph 37.

ANSWER: Denied.

43. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product in accordance with, and as directed by Apotex's proposed product labeling would infringe one or more claims of each of the '469 patent, including at least the claims listed in above paragraph 37.

ANSWER: Denied.

44. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '469 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Denied.

45. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '469 patent, that Apotex's ANDA Product is not a staple article or commodity of commerce, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '469 patent immediately and imminently upon approval of Apotex's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the Movantik product.

ANSWER: Denied.

46. Notwithstanding Apotex's knowledge of the claims of the '469 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following upon FDA approval of Apotex's ANDA and prior to the expiration of the '469 patent.

ANSWER: Denied.

47. The foregoing actions by Apotex constitute and/or will constitute infringement of the '469 patent; active inducement of infringement of the '469 patent; and contribution to the infringement by others of the '469 patent.

ANSWER: Denied.

48. Upon information and belief, Apotex has acted with full knowledge of the '469 patent and without a reasonable basis for believing that it would not be liable for infringement of the '469 patent; active inducement of infringement of the '469 patent; and/or contribution to the infringement by others of the '469 patent.

ANSWER: Denied.

49. Unless Apotex is enjoined from infringing the '469 patent, actively inducing infringement of the '469 patent, and contributing to the infringement by others of the '469 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count II – Declaratory Judgment of [Alleged] Infringement by Apotex of the '469 Patent

50. Plaintiffs incorporate each of the preceding paragraphs 1–49 as if fully set forth herein.

ANSWER: Apotex incorporates each of its preceding answers to paragraphs 1-49 of the Complaint as if fully set forth herein.

51. 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 Plaintiffs on the one hand and Apotex on the other regarding Apotex's infringement, active inducement of infringement, and contribution to the infringement by others of the '469 patent.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Apotex denies that this Court has subject matter jurisdiction over Plaintiffs' Declaratory Judgment claims against Apotex. Apotex denies all remaining allegations of Paragraph 51 of the Complaint.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the '469 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Apotex denies that this

Court has subject matter jurisdiction over Plaintiffs' Declaratory Judgment claims against Apotex.

Apotex denies all remaining allegations of Paragraph 52 of the Complaint.

[Prayer for Relief]

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that each claim of the '469 patent has been infringed under 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of Apotex's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Apotex's ANDA Product, or any other drug product that infringes or the use of which infringes one or more claims of the '469 patent, be not earlier than the expiration of the '469 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the claims of the '469 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the claims of the '469 patent, prior to its expiration, will infringe, induce the infringement of, and contribute to the infringement by others of, the '469 patent;

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

(f) Costs and expenses in this action; and

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

RESPONSE TO PRAYER FOR RELIEF: Apotex denies Plaintiffs are entitled to any of the relief requested in their prayer for relief or otherwise.

APOTEX'S ADDITIONAL DEFENSES

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint filed by Plaintiffs AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and Nektar Therapeutics (all Plaintiffs, collectively, "Plaintiffs" or "AstraZeneca") not otherwise admitted.

First Additional Defense
(Invalidity of U.S. Patent No. 9,012,469 B2)

The claims of the U.S. Patent No. 9,012,469 B2 ("'469 patent") are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.*, including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Second Additional Defense
(Non-infringement of the '469 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in Apotex's Abbreviated New Drug Application ("ANDA") No. 212534 do not and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '469 patent.

Third Additional Defense
(Failure to State a Claim)

Plaintiffs' Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

Fourth Additional Defense
(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over Plaintiffs' claims asserted under the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202.

Fifth Additional Defense
(Failure to State a Claim for Exceptional Case or Willful Infringement)

Plaintiffs fails to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Apotex reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants/Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by way of their attorneys, hereby state for their Counterclaims against Plaintiffs/Counterclaim-Defendants AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and Nektar Therapeutics (all Plaintiffs/Counterclaim-Defendants, collectively, "Plaintiffs" or "AstraZeneca"), the following:

1. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent No. 9,012,469 ("'469 patent"). Upon information and belief, a true and correct copy of the '469 patent is attached to the Complaint as Exhibit A.

2. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Additional Defenses to the Complaint.

The Parties

3. Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida, 33326.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

6. Upon information and belief, Plaintiff/Counterclaim-Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850.

7. Upon information and belief, Plaintiff/Counterclaim-Defendant Nektar Therapeutics is a corporation organized under the laws of Delaware with its principal place of business at 455 Mission Bay Boulevard South, San Francisco, California, 94158.

Jurisdiction and Venue

8. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (codified in relevant part at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

10. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Apotex and Plaintiffs arising under the Patent Laws of the United States, 35 U.S.C. § *1 et seq*.

11. This court has personal jurisdiction Plaintiffs based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiffs are doing business in this jurisdiction.

12. Venue is proper over Apotex's Counterclaims in this judicial district under 28 U.S.C. § 1391(b) and (c).

Facts Common to All Counts

13. On or about April 21, 2015, the U.S. Patent and Trademark Office ("PTO") issued the '469 patent.

14. Plaintiffs purport to own and have the right to enforce the '469 patent.

15. Plaintiff/Counterclaim-Defendant AstraZeneca Pharmaceuticals LP purports to be the holder of New Drug Application ("NDA") No. 204760 for naloxegol tablets, 12.5 mg and 25 mg, sold in the United States under the trademark MOVANTIK®.

16. On or about September 16, 2014, the U.S. Food and Drug Administration ("FDA") approved NDA No. 204760.

17. Plaintiffs purport and claim to have the right to enforce the '469 patent, and have listed that patent in the FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, otherwise known as the "Orange Book," for MOVANTIK®.

18. By listing the '469 patent in the Orange Book, Plaintiffs maintain that an infringement suit could be reasonably asserted against any sponsor of Abbreviated New Drug Application ("ANDA"), including Apotex, who attempts to seek approval for, and market, a generic version of MOVANTIK® before expiration of that patent.

19. Apotex has filed ANDA No. 212534 with the FDA seeking approval for naloxegol tablets, 12.5 mg and 25 mg ("Apotex's ANDA products"), identifying MOVANTIK® as approved in NDA No. 204760 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("Apotex's ANDA").

20. Because Apotex's ANDA seeks FDA approval to market Apotex's ANDA products prior to the expiration of the '469 patent, Apotex's ANDA includes a Paragraph IV certification for that patent.

21. Plaintiffs have sued Apotex in this District for alleged infringement of the '469 patent.

Count I
(Declaratory Judgment of Invalidity of the '469 Patent)

22. Apotex re-alleges and incorporates by reference the allegations of Paragraphs 1-21

of these Counterclaims as if fully set forth herein.

23. There is an actual, substantial, and continuing case or controversy between Apotex and Plaintiffs regarding, *inter alia*, the invalidity of the '469 patent.

24. The claims of the '469 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

25. The claims of the '469 patent are directed to unpatentable subject matter, as they cover laws of nature, natural phenomenon, and/or abstract ideas, and do not include any inventive concept.

26. The claims of the '469 patent are directed to a natural phenomenon or law of nature—the naturally occurring formation of a salt between naloxegol and oxalic acid—and do not include any inventive concept.

27. The claims of the '469 patent are anticipated by the prior art because each and every element of each and every claim of the '469 patent is disclosed, expressly and/or inherently, in one or more references and/or products which were publicly available before the earliest possible priority date of the '469 patent, including, but not limited to, those references and/or products disclosed in Apotex's Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95, dated November 5, 2018 ("Apotex's Paragraph IV Certification Notice Letter").

28. The claims of the '469 patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '469 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '469 patent, including, but not limited to, those references and/or

products disclosed in Apotex's Paragraph IV Certification Notice Letter, and the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '469 patent, and would have had a reasonable expectation of success in doing so.

29. There is no objective evidence of non-obviousness of the claims of the '469 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '469 patent.

30. The specification of the '469 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the same.

31. The '469 patent does not describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation.

32. Apotex is entitled to a judicial declaration that the claims of the '469 patent are invalid.

Count II
(Declaratory Judgment of Non-Infringement of the '469 Patent)

33. Apotex re-alleges and incorporates by reference the allegations of Paragraphs 1-32 of these Counterclaims as if fully set forth herein.

34. There is an actual, substantial, and continuing case or controversy between Apotex and Plaintiffs regarding, *inter alia*, non-infringement of the claims of the '469 patent.

35. The manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex's ANDA products has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or

enforceable claim of the ’469 patent, either literally or under the doctrine of equivalents.

36. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex’s ANDA products has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’469 patent, either literally or under the doctrine of equivalents.

Prayer for Relief

WHEREFORE, Apotex respectfully prays for judgment in its favor and against Plaintiffs:

A. Declaring that the claims of the ’469 patent are invalid;

B. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Apotex’s ANDA products has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the ’469 patent either literally or under the doctrine of equivalents;

C. Ordering that Plaintiffs’ Complaint be dismissed with prejudice and judgment entered in favor of Apotex;

D. Declaring this case exceptional and awarding Apotex its reasonable attorneys’ fees and costs under 35 U.S.C. § 285;

E. Ordering that Plaintiffs, and their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it, be preliminarily and permanently enjoined from using the ’469 patent to block, hamper, hinder or obstruct FDA approval of Apotex’s ANDA products; and

F. Awarding such other and further relief as the Court may deem just and proper.

Dated: January 2, 2019

/s/ Kenneth L. Dorsney

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