UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

BAUSCH HEALTH IRELAND LIMITED, and SALIX PHARMACEUTICALS, INC. Plaintiffs, v. MYLAN PHARMACEUTICALS INC. Defendant.	Civil Action No. 1:22-CV-20 (Kleeh) *Document Electronically Filed*

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Plaintiffs") filed their original Complaint in this Civil Action against Mylan Laboratories Ltd., Agila Specialties Inc., Mylan API US LLC, Mylan Inc., Viatris Inc. and Mylan Pharmaceuticals Inc. – a Viatris Company; and now, pursuant to the terms of the Stipulation to File Amended Complaint and Amend Case Caption (ECF No. ___), which was entered into by and among the aforementioned entities subject to the approval of the Court, and which is hereby incorporated by reference, Plaintiffs by way of First Amended Complaint against Defendant Mylan Pharmaceuticals Inc. allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd.,

Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 208745, which covers Trulance®.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware having a place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg Pennsylvania 15317, and Defendant Mylan Pharmaceuticals Inc. purports to have a place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Nos. 7,041,786 ("the '786 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231 patent") and 10,011,637 ("the '637 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Defendant's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic plecanatide oral tablets, 3 mg ("Defendant's generic plecanatide oral tablets").

JURISDICTION AND VENUE

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

6. Upon information and belief, this Court has jurisdiction over Defendant Mylan Pharmaceuticals Inc. Upon information and belief, Mylan Pharmaceuticals Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely

destination for Defendant's generic plecanatide oral tablets. Upon information and belief, Mylan Pharmaceuticals Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Pharmaceuticals Inc. is registered to do business in this judicial district. Upon information and belief, Mylan Pharmaceuticals Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Mylan Pharmaceuticals Inc. purports to have a place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

7. Defendant has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, this judicial district and elsewhere. Defendant's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of its proposed generic drugs. Upon information and belief, Defendant intends to direct sales of its drugs into this judicial district, among other places, once it has the requested FDA approval to market them. Upon information and belief, Defendant will engage in marketing of Defendant's generic plecanatide oral tablets in this judicial district upon approval of its ANDA.

8. Defendant knows or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, New Jersey 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

9. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

10. The U.S. Patent and Trademark Office ("PTO") issued the '786 patent on May 9,

2006. The '786 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the '786 patent and have the right to sue for infringement thereof. A copy of the '786 patent is attached hereto as Exhibit A.

11. The PTO issued the '321 patent on April 4, 2017. The '321 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the '321 patent and have the right to sue for infringement thereof. A copy of the '321 patent is attached hereto as Exhibit B.

12. The PTO issued the '097 patent on April 11, 2017. The '097 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the '097 patent and have the right to sue for infringement thereof. A copy of the '097 patent is attached hereto as Exhibit C.

13. The PTO issued the '024 patent on March 20, 2018. The '024 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the '024 patent and have the right to sue for infringement thereof. A copy of the '024 patent is attached hereto as Exhibit D.

14. The PTO issued the '231 patent on March 27, 2018. The '231 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the '231 patent and have the right to sue for infringement thereof. A copy of the '231 patent is attached hereto as Exhibit E.

15. The PTO issued the '637 patent on July 3, 2018. The '637 patent claims, *inter alia*, purified peptides and processes of purifying peptides. Plaintiffs hold all substantial rights in the '637 patent and have the right to sue for infringement thereof. A copy of the '637 patent is attached

hereto as Exhibit F.

16. Salix is the holder of NDA No. 208745 for Trulance®, which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the '786, '321, '097, '024, '231 and '637 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

17. Plecanatide oral tablets, 3 mg, are sold in the United States under the trademark Trulance®.

DEFENDANT'S INFRINGING ANDA SUBMISSION

18. Upon information and belief, Defendant filed or caused to be filed with the FDA ANDA No. 215686, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

19. Upon information and belief, Defendant's ANDA No. 215686 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Defendant's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

20. Plaintiffs received a letter dated March 18, 2021, purporting to be a Notice of ANDA No. 215686 with Paragraph IV Certifications ("Defendant's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Defendant's Notice Letter was addressed to Salix and Bausch.

21. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. acted in concert with Mylan Laboratories Ltd., Agila Specialties Inc., Mylan API US LLC, Mylan Inc. and Viatris Inc. to prepare and submit Defendant's ANDA No. 215686 and Defendant's Notice Letter.

22. Defendant's Notice Letter alleges that ANDA No. 215686 has been submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Defendant's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

23. Defendant's Notice Letter states that Defendant's ANDA No. 215686 "contains any

required bioavailability or bioequivalence data or information," for Defendant's generic plecanatide oral tablets.

24. Defendant's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, provides no explanation of any non-infringement defense related to the '786 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent or the '637 patent.

25. Upon information and belief, ANDA No. 215686 seeks approval of Defendant's generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '786 Patent Under § 271(e)(2)

26. Paragraphs 1–25 are incorporated herein as set forth above.

27. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '786 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant's generic plecanatide oral tablets before the expiration date of the '786 patent.

28. Upon information and belief, Defendant's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '786 patent.

29. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

30. If Defendant's marketing and sale of Defendant's generic plecanatide oral tablets prior to the expiration of the '786 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Infringement of the '321 Patent Under § 271(e)(2)

31. Paragraphs 1–30 are incorporated herein as set forth above.

32. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '321 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant's generic plecanatide oral tablets before the expiration date of the '321 patent.

33. Upon information and belief, Defendant's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '321 patent.

34. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '321 patent.

35. If Defendant's marketing and sale of Defendant's generic plecanatide oral tablets prior to the expiration of the '321 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '097 Patent Under § 271(e)(2)

36. Paragraphs 1–35 are incorporated herein as set forth above.

37. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '097 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant's generic plecanatide oral tablets before the expiration date of the '097 patent.

38. Upon information and belief, Defendant's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '097 patent.

39. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '097 patent.

40. If Defendant's marketing and sale of Defendant's generic plecanatide oral tablets prior to the expiration of the '097 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Infringement of the '024 Patent Under § 271(e)(2)

41. Paragraphs 1–40 are incorporated herein as set forth above.

42. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '024 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant's generic plecanatide oral tablets before the expiration date of the '024 patent.

43. Upon information and belief, Defendant's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '024 patent.

44. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '024 patent.

45. If Defendant's marketing and sale of Defendant's generic plecanatide oral tablets prior to the expiration of the '024 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '231 Patent Under § 271(e)(2)

46. Paragraphs 1–45 are incorporated herein as set forth above.

47. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the ’231 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant’s generic plecanatide oral tablets before the expiration date of the ’231 patent.

48. Upon information and belief, Defendant’s generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’231 patent.

49. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant’s generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’231 patent.

50. If Defendant’s marketing and sale of Defendant’s generic plecanatide oral tablets prior to the expiration of the ’231 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI FOR PATENT INFRINGEMENT

Infringement of the ’637 Patent Under § 271(e)(2)

51. Paragraphs 1–50 are incorporated herein as set forth above.

52. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the ’637 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendant’s generic plecanatide oral tablets before the expiration date of the ’637 patent.

53. Upon information and belief, Defendant’s generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’637 patent.

54. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Defendant’s generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’637 patent.

55. If Defendant's marketing and sale of Defendant's generic plecanatide oral tablets prior to the expiration of the '637 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendant on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '786 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '786 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '321 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '321 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '097 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '097 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '024 patent by submitting or causing to be submitted ANDA No. 215686 to the

FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '024 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '231 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '231 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '637 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendant's generic plecanatide oral tablets before the expiration of the '637 patent;

7. Order that the effective date of any approval by the FDA of Defendant's generic plecanatide oral tablets be a date that is not earlier than the expiration of the '786 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent, or such later date as the Court may determine;

8. Enjoin Defendant from the commercial manufacture, use, import, offer for sale, and/or sale of Defendant's generic plecanatide oral tablets until expiration of the '786 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent, or such later date as the Court may determine;

9. Enjoin Defendant and all persons acting in concert with Defendant from seeking, obtaining, or maintaining approval of Defendant's ANDA No. 215686 until expiration of the '786 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent;

10. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

11. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: May 5, 2022

/s/*Daniel R. Higginbotham*

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