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. **1:24-CV-36 (Kleeh)**

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Plaintiffs") by way of 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 principal 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. ("Defendant" or "Mylan") 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 No. 11,834,521 ("the 521 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 for purposes of this particular case 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 '521 patent on December 5, 2023. The '521 patent claims, *inter alia*, oral formulations of a purified peptide. Plaintiffs hold all substantial rights in the '521 patent and have the right to sue for infringement thereof. A copy of the '521 patent is attached hereto as Exhibit A.

11. 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 '521 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

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

MYLAN'S INFRINGING ANDA SUBMISSION

13. Upon information and belief, Mylan Pharmaceuticals Inc. 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).

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

15. Plaintiffs received a letter from Mylan Pharmaceuticals Inc. dated March 6, 2024, purporting to be a Notice of ANDA No. 215686 with Paragraph IV Certifications ("Mylan's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Mylan's Notice Letter was addressed to Salix and Bausch.

16. 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.

17. 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®.

18. 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 '521 patent.

19. 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 '521 patent.

20. 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 '521 Patent Under § 271(e)(2)

21. Paragraphs 1-20 are incorporated herein as set forth above.

22. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '521 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Mylan's generic plecanatide oral tablets before the expiration date of the '521 patent.

23. Upon information and belief, Mylan's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '521 patent.

24. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '521 patent.

25. If Mylan's marketing and sale of Mylan's generic plecanatide oral tablets prior to the expiration of the '521 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 Mylan 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), Mylan has infringed at least one claim of the '521 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 Mylan's generic plecanatide oral tablets before the expiration of the '521 patent;

2. Order that the effective date of any approval by the FDA of Mylan's generic plecanatide oral tablets be a date that is not earlier than the expiration of the '521 patent, or such later date as the Court may determine;

3. Enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic plecanatide oral tablets until expiration of the '521 patent, or such later date as the Court may determine;

4. Enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 215686 until expiration of the '521 patent;

5. 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

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

Dated: April 5, 2024

s/*Daniel R. Higginbotham*
Daniel R. Higginbotham (WV Bar No.11680)
THOMAS COMBS & SPANN, PLLC
300 Summers Street, Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Tel: (304) 414-1800
dhigginbotham@tcspllc.com

Attorneys for Plaintiffs
Bausch Health Ireland Limited
and Salix Pharmaceuticals, Inc.