IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UROVANT SCIENCES GMBH and SUMITOMO PHARMA AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Urovant Sciences GmbH ("Urovant") and Sumitomo Pharma America, Inc. ("SMPA") (collectively, "Plaintiffs"), by and through their attorneys, for their Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 12,102,638 ("the '638 patent" or "patent-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 100, *et seq.*, and in particular under 35 U.S.C. § 271, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This action relates to Apotex's filing of Abbreviated New Drug Application ("ANDA") No. 220169 under 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell, and/or sell in the United States vibegron tablet (75 mg) ("Defendants' Generic Product"), which is a generic version of Plaintiffs' GEMTESA® (vibegron), before the expiration of the patent-in-suit.

THE PARTIES

2. Urovant is a Switzerland limited liability company having its principal place of business at Aeschengraben 27, 4051 Basel, Switzerland.

3. SMPA is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

4. Plaintiffs are in the business of developing innovative treatments, science, and technology to address patient needs in the critical areas of oncology, women's health, urology, rare disease, neurology & psychiatry, and cell & gene therapies. The patent-in-suit covers GEMTESA®, which is marketed and sold by SMPA in this judicial district and throughout the United States for the treatment of overactive bladder ("OAB") with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults, and in adult males on pharmacological therapy for benign prostatic hyperplasia ("BPH").

5. On information and belief, 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, M9L 1T9, Canada.

6. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

7. On information and belief, Apotex Corp. is the U.S. affiliate of Apotex Inc.

8. On information and belief, Apotex Inc. and Apotex Corp., in coordination with each other or at the direction of Apotex Inc., are in the business of, among other things, manufacturing,

marketing, distributing, importing for sale, and/or selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

9. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 220169, Defendants will make, use, offer to sell, and/or sell Defendants' Generic Product throughout the United States, including in the State of Delaware, and/or import such generic products into the United States, including into the State of Delaware.

JURISDICTION AND VENUE

10. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

11. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Apotex Inc., inter alia, under Federal Rule of Civil Procedure 4(k)(1) or (k)(2), because Apotex Inc. is a foreign corporation and: (a) Apotex Inc. is subject to the general jurisdiction of the laws of Delaware; and (b) to the extent that Apotex Inc. is not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and Apotex Inc. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

14. This Court also has personal jurisdiction over Apotex Inc. because, on information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products, throughout the United States, including in Delaware. On information and belief, Apotex Inc. directly or indirectly develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Apotex Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

15. This Court also has personal jurisdiction over Apotex Inc. because, inter alia, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Apotex Inc. has previously invoked this Court's jurisdiction by bringing claims, *see, e.g.*, *Apotex Inc. v. Boehringer Ingelheim Pharms., Inc. et al*, C.A. No. 24-577 (D. Del. May 13, 2024) and *Apotex Inc. v. Boehringer lngelheim Pharms., Inc. et al*, C.A. No. 23-704 (D. Del. Jun. 28, 2023); and by bringing counterclaims, *see, e.g., Otsuka Pharm. Co., Ltd. et al v. Apotex Inc. et al*, C.A. No. 24-1004 (D. Del. Aug. 30, 2024) .

16. On information and belief, Apotex Inc., either directly or indirectly, currently sells significant quantities of generic drug products in the United States and in this judicial district. Apotex Inc.'s website states: "With Canadian roots and a broad portfolio of generic, biosimilar, and innovative branded pharmaceuticals and consumer health products, we are the largest Canadian-based pharmaceutical company and a health partner of choice for the Americas for pharmaceutical licensing and product acquisitions." https://www.apotex.com/global/about-us/our-purpose (accessed Mar. 25, 2025). Further, Apotex Inc. states that by 2020, it was a "[t]op 10

player in the US generics market." https://www.apotex.com/global/about-us/our-story (accessed Mar. 25, 2025).

17. This Court has personal jurisdiction over Apotex Corp. Apotex Corp. is incorporated in the State of Delaware.

18. Additionally, on information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Apotex Corp. directly or indirectly develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

19. On information and belief, Apotex Corp. maintains continuous and systematic contacts with Delaware through holding an active pharmacy wholesale license in the State of Delaware with the license number A4-0001921, and an active controlled substances distributor/manufacturer license in the State of Delaware with the license number DM-0008873.

20. On information and belief, Apotex Corp. is a generic pharmaceutical company that, in coordination with or at the direction of Apotex Inc., develops, manufactures, markets, imports, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

21. On information and belief, and consistent with its role with respect to other of Apotex Inc.'s generic products, Apotex Corp. is the U.S. Agent for ANDA No. 220169. *See, e.g.*, *Otsuka Pharm. Co., Ltd. v. Apotex Inc.*, C.A. No. 24-1004-JLH (D. Del.); *Pfizer Inc. v. Apotex*

Inc., C.A. No. 24-00621-CFC (D. Del.); *H. Lundbeck A/S v. Apotex Inc.*, C.A. No. 18-00088-LPS (D. Del.).

22. On information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

23. On information and belief, Apotex Inc. and Apotex Corp. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 220169 and intend to benefit from the ANDA.

24. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 220169, Defendants will market, distribute, and sell Defendants' Generic Product described in ANDA No. 220169 throughout the United States, including in Delaware.

25. Defendants state in their Notice Letter, as defined below, that they "will not object to personal jurisdiction in the District of Delaware."

26. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), as to Apotex Corp., because Apotex Corp. is incorporated in the State of Delaware.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), as to Apotex Inc., because Apotex Inc. is incorporated in Canada and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

28. Urovant is the holder of New Drug Application ("NDA") No. 213006 for GEMTESA® (vibegron) tablets in a strength of 75 mg.

29. The FDA approved NDA No. 213006 on December 23, 2020.

30. GEMTESA® is a prescription drug approved for the treatment of overactive bladder ("OAB") with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults, and OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia ("BPH"). Vibegron is the active ingredient in GEMTESA®.

The Patent-in-Suit

31. United States Patent No. 12,102,638 ("the '638 patent"), titled "Use of Vibegron to Treat Overactive Bladder," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 1, 2024. A true and correct copy of the '638 patent is attached as Exhibit A.

32. Urovant Sciences GmbH owns the '638 patent.

33. The '638 patent currently expires on March 22, 2040, by virtue of 655 days of patent term adjustment granted to the '638 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit B.

34. The '638 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the FDA Orange Book") in connection with NDA No. 213006 for GEMTESA®.

The ANDA

35. On information and belief, Apotex submitted ANDA No. 220169 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval to manufacture, use, import, offer for sale, and/or sell in the United States vibegron tablet (75 mg) (defined above as "Defendants' Generic Product"), which is a generic version of Urovant's GEMTESA® (vibegron) tablets.

36. In a letter dated February 14, 2025 ("Apotex's Notice Letter"), Apotex notified Plaintiffs that "ANDA [No. 220169] was submitted under 21 U.S.C. § 355(j)(1) and (2)(A) with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of vibegron tablet, 75 mg before the expiration of the '638 patent." Apotex's Notice Letter identified Apotex's ANDA as "ANDA No. 220169."

37. Apotex's Notice Letter purports to be a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335(j)(2)(B)(ii) and 21 C.F.R. § 314.95)" and included an enclosure purporting to be a "detailed statement of the legal and factual bases for the certification set forth in Apotex's ANDA" titled "Factual and Legal Bases for Apotex's ANDA Certification that the Claims of U.S. Patent No. 12,102,638 Are Invalid, Unenforceable, and/or Will Not Be Infringed by Apotex's Vibegron Product Described in ANDA No. 220169."

38. Apotex's Notice Letter asserts that "each claim of the '638 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Apotex's ANDA."

39. Plaintiffs commenced this action within 45 days of receiving Apotex's Notice Letter.

COUNT I

(INFRINGEMENT OF THE '638 PATENT)

40. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

41. On information and belief, Apotex filed ANDA No. 220169 seeking approval to manufacture, use, import, offer to sell, and/or sell Defendants' Generic Product in the United States before the expiration of the '638 patent.

42. On information and belief, Apotex filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '638 patent are purportedly invalid, unenforceable, and/or will not be infringed.

43. On information and belief, Apotex does not contest infringement of at least one claim of the '638 patent because Apotex's Notice Letter did not provide non-infringement allegations addressing indirect infringement for multiple claims.

44. On information and belief, in its ANDA No. 220169, Apotex has represented to the FDA that Defendants' Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' GEMTESA®.

45. Apotex has had actual knowledge of the '638 patent, at least as of the date of Apotex's Notice Letter.

46. On information and belief, if ANDA No. 220169 is approved, Apotex intends to and will manufacture, use, import, offer to sell, and/or sell Defendants' Generic Product in the United States.

47. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 220169 seeking approval to manufacture, use, import, offer to sell, or sell Defendants' Generic Product

before the expiration date of the '638 patent constitutes infringement, either literally or under the doctrine of equivalents.

48. On information and belief, if ANDA No. 220169 is approved, Apotex will infringe one or more claims of the '638 patent, including at least claim 1, either literally or under the doctrine of equivalents under § 271(a), by making, using, offering to sell, selling, and/or importing Defendants' Generic Product, and/or by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 220169 shall be no earlier than the expiration of the '638 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled.

49. On information and belief, Apotex knows and intends that healthcare professionals will prescribe, and patients will take, Defendants' Generic Product for which approval is sought in ANDA No. 220169, and therefore will infringe at least one claim of the '638 patent, including at least claim 1, either literally or under the doctrine of equivalents.

50. On information and belief, Apotex has knowledge of the '638 patent and, by its proposed package insert for Defendants' Generic Product, will knowingly induce direct infringement of at least one claim of the '638 patent, including at least claim 1, either literally or under the doctrine of equivalents.

51. On information and belief, Apotex is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' Generic Product according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '638 patent, including at least claim 1.

52. On information and belief, Apotex has had and continues to have knowledge that Defendants' Generic Product constitutes a material part of the invention and is especially adapted for a use that infringes at least one claim of the '638 patent, including at least claim 1.

53. On information and belief, Apotex has had and continues to have knowledge that Defendants' Generic Product is not a staple article or commodity of commerce suitable for substantial non-infringing use for at least one claim of the '638 patent, including at least claim 1.

54. On information and belief, Apotex's actions relating to Apotex's ANDA No. 220169 complained of herein were done by and for the benefit of Apotex.

55. A substantial and justiciable controversy exists between the parties as to the infringement of the '638 patent.

56. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Apotex's making, using, offering to sell, selling, and/or importing of the ANDA Product, inducement thereof or contribution thereto, will infringe the '638 patent's asserted claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

57. On information and belief, Apotex acted, and upon FDA approval of ANDA No. 220169, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '638 patent. This is an exceptional case.

58. Plaintiffs will be irreparably harmed by Apotex's infringing activities unless this Court enjoins those activities.

59. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement.

60. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Apotex has infringed at least one claim of the '638 patent through Apotex's submission of ANDA No. 220169 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Defendants' Generic Product in the United States before the expiration of the '638 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Apotex's making, using, offering to sell, selling, or importing of Defendants' Generic Product before the expiration of the '638 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '638 patent under 35 U.S.C. § 271(a), (b), and/or (c);

C. The entry of judgment that the claims of the '638 patent are not invalid.

D. The issuance of an order that the effective date of any FDA approval of Defendants' Generic Product shall be no earlier than the expiration date of the '638 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a preliminary and/or permanent injunction, enjoining Apotex and all persons and entities acting in concert with Apotex from manufacturing, using, offering for sale, or selling Defendants' Generic Product within the United States, or importing Defendants' Generic Product into the United States, until the expiration of the '638 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a preliminary and/or permanent injunction, enjoining Apotex and all persons and entities acting in concert with Apotex from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '638 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

H. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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