IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Civil Action No. 5:25-cv-163

UROVANT SCIENCES GMBH and SUMITOMO PHARMA AMERICA, INC.,	)
Plaintiffs,	)
v.	)
INTAS PHARMACEUTICALS LIMITED and ACCORD HEALTHCARE INC.,	)
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 Intas Pharmaceuticals Limited ("Intas") and Accord Healthcare Inc. ("Accord Inc.") (collectively, "Accord" 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 "the 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 Judgement Act 28 U.S.C. §§ 2201-2202. This action relates to Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 220254 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 Tablets (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, Intas is a corporation organized and existing under the laws of India, with its principal place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad, Gujarat, India, 380054.

6. On information and belief, Intas is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of North Carolina.

7. On information and belief, Accord Inc. is a corporation organized and existing under the laws of North Carolina, with its principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617.

8. On information and belief, Accord Inc. is the wholly-owned U.S. subsidiary of Intas.

9. On information and belief, Accord Inc. and Intas, in coordination with each other or at the direction of Intas, 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 North Carolina.

10. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 220254, Defendants will make, use, offer to sell, and/or sell Defendants' Generic Product throughout the United States, including in the State of North Carolina, and/or import such generic products into the United States, including into the State of North Carolina.

JURISDICTION AND VENUE

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

12. 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.

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

14. Plaintiffs believe this case belongs in Delaware, but are concurrently filing a case in this district out of an abundance of caution.

15. This Court has personal jurisdiction over Intas, *inter alia*, under Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2), because Intas is organized under the laws of India.

16. This Court has personal jurisdiction over Intas because, on information and belief, Intas is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Intas directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district.

17. This Court has personal jurisdiction over Accord Inc. Accord Inc. is incorporated in the State of North Carolina. On information and belief, Accord Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Accord Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district.

18. 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.

19. On information and belief, Accord Inc. and Intas have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 220254 and intend to benefit from the ANDA.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Accord is incorporated in North Carolina.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Intas is incorporated in India and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

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

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

24. 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

25. 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.

26. Urovant Sciences GmbH owns the '638 patent.

27. 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.

28. 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

29. On information and belief, Defendants submitted ANDA No. 220254 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 Tablets with the proposed strength of 75 mg ("Defendants' Generic Product"), which is a generic version of Urovant's GEMTESA® (vibegron) tablets.

30. In a letter dated February 10, 2025 ("Accord's Notice Letter"), Defendants notified Plaintiffs that ANDA No. 220254 was submitted to the FDA under 21 U.S.C. § 355(j) to obtain approval to manufacture, use, import, offer to sell, and/or sell Defendants' generic products. Accord's Notice Letter identified Accord's ANDA as ANDA No. 220254.

31. Accord's Notice Letter purports to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" and includes an enclosure purporting to be a "detailed statement of the legal and factual basis for the Paragraph IV certification with respect to the ['638] Patent" titled "Detailed Statement for ANDA No. 220254."

32. Accord's Notice Letter states that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(l) and (2)(A), and contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Accord ANDA product, before the expiration of the ['638] Patent."

33. Accord's Notice Letter also asserts that "the ['638] Patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Accord's ANDA."

34. Plaintiffs commenced this action within 45 days of receiving Accord's Notice Letter.

COUNT I

(INFRINGEMENT OF THE '638 PATENT)

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

36. On information and belief, Defendants filed ANDA No. 220254 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.

37. On information and belief, Defendants 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.

38. On information and belief, Defendants do not contest infringement of the '638 patent because Accord's Notice Letter did not provide non-infringement allegations addressing infringement for any claims of the '638 patent.

39. On information and belief, in its ANDA No. 220254, Defendants have represented to the FDA that Defendants' Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' GEMTESA®.

40. Defendants have had actual knowledge of the '638 patent, at least as of the date of Accord's Notice Letter.

41. On information and belief, if ANDA No. 220254 is approved, Defendants intend to and will manufacture, use, import, offer to sell, and/or sell Defendants' Generic Product in the United States.

42. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 220254 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.

43. On information and belief, if ANDA No. 220254 is approved, Defendants 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. 220254 shall be no earlier than the expiration of the '638 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled.

44. On information and belief, Defendants know and intend that healthcare professionals will prescribe, and patients will take, Defendants' Generic Product for which approval is sought in ANDA No. 220254, 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.

45. On information and belief, Defendants have knowledge of the '638 patent and, by their 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.

46. On information and belief, Defendants are aware and/or have knowledge that their 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.

47. On information and belief, Defendants have had and continue 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.

48. On information and belief, Defendants have had and continue 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.

49. On information and belief, Defendants’ actions relating to Defendants’ ANDA No. 220254 complained of herein were done by and for the benefit of Defendants.

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

51. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ 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).

52. On information and belief, Defendants acted, and upon FDA approval of ANDA No. 220254, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the ’638 patent. This is an exceptional case.

53. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless this Court enjoins those activities.

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

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '638 patent through Defendants' submission of ANDA No. 220254 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 Defendants' 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 Defendants and all persons and entities acting in concert with Defendants 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 Defendants and all persons and entities acting in concert with Defendants 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.

Dated: March 27, 2025

/s/ Paul W. Browning, Ph.D.

Paul W. Browning, Ph.D.
District of Columbia Bar No. 468703
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorney for Plaintiffs Urovant Sciences GmbH and Sumitomo Pharma America, Inc.

Notice of Special Appearance Forthcoming

/s/ Allison Mullins
Allison Mullins
N.C. State Bar No. 23430
L. Cooper Harrell
N.C. State Bar No. 27875
TURNING POINT LITIGATION
MULLINS DUNCAN HARRELL & RUSSELL PLLC
300 North Greene Street, Suite 2000
Greensboro, NC 27401
Telephone: 336-645-3320
Facsimile: 336-645-3330
amullins@turningpointlit.com
charrell@turningpointlit.com

Local Civil Rule 83.1(d) Attorneys for Plaintiffs Urovant Sciences GmbH and Sumitomo Pharma America, Inc.