

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BRISTOL-MYERS SQUIBB COMPANY
AND PFIZER INC.,

Plaintiffs,

V.

UMEDICA LABORATORIES PVT.
LTD.,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company (“BMS”) and Pfizer Inc. (“Pfizer”) (BMS and Pfizer, collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Umedica Laboratories Pvt. Ltd. (“Umedica”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 219640 filed by Umedica with the U.S. Food and Drug Administration (“FDA”).

2. In ANDA No. 219640, Umedica seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs’ Eliquis® drug product (the “Umedica ANDA product”), prior to expiration of U.S. Patent No. 9,326,945 (the “’945 patent”) (the “patent-in-suit”).

PARTIES

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543.

4. Pfizer is a corporation organized and existing under the laws of Delaware, having a place of business at 66 Hudson Boulevard East, New York, New York 10001.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for thromboembolic disorders. Plaintiffs sell Eliquis® in this judicial district and throughout the United States.

6. Upon information and belief, Umedica Laboratories Pvt. Ltd. is a corporation organized and existing under the laws of India, having a place of business at 3rd Floor, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai, Maharashtra 400021, India.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Umedica because, *inter alia*, upon information and belief: (1) Umedica has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Umedica's ANDA product in the United States, including in Delaware; and (2) Umedica will market, distribute, offer for sale, and/or sell Umedica's ANDA product in the United States, including in Delaware, upon approval of ANDA No. 219640, and will derive substantial revenue from the use or consumption of Umedica's ANDA product in the State of Delaware. Umedica, through its counsel, by e-mail dated September 25, 2024, agreed that it consents to jurisdiction in this Court for this matter.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Umedica is a company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

PATENT-IN-SUIT

10. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued the '945 patent, titled "Apixaban Formulations." A true and correct copy of the '945 patent is attached hereto as Exhibit A. The claims of the '945 patent are valid, enforceable, and not expired. Plaintiffs are the joint owners of the '945 patent and have the right to enforce it.

11. The '945 patent was previously the subject of litigation under the Hatch-Waxman Act in this Court. *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, C.A. No. 17-374-LPS (consolidated), 447 F. Supp. 3d 306 (D. Del. 2020). In that litigation, the '945 patent was found valid, *id.* at 353-356, and infringed by all three defendants who went to trial, *id.* at 342-351. Those findings were affirmed on appeal. *Bristol-Myers Squibb Co. v. Sigmapharm Labs., LLC*, 858 F. App'x 359 (Fed. Cir. 2021).

12. BMS is the holder of New Drug Application ("NDA") No. 202155, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength apixaban tablets. Plaintiffs market apixaban tablets in the United States, under the trade name "Eliquis®." The FDA's official publication of approved drugs (the "Orange Book") includes Eliquis® together with the patent-in-suit. Eliquis® is a factor Xa inhibitor indicated: (1) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the prophylaxis of deep vein thrombosis ("DVT"), which may lead to pulmonary embolism ("PE"), in patients who have undergone hip or knee replacement surgery; and (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. A copy of the complete prescribing information for Eliquis® approved in NDA No. 202155 is attached as Exhibit B.

INFRINGEMENT BY UMEDICA

13. By letter dated September 4, 2024, Umedica notified Plaintiffs that Umedica had submitted ANDA No. 219640 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (“the Eliquis Notice Letter”). Plaintiffs received the Eliquis Notice Letter by Federal Express no earlier than September 6, 2024.

14. The Eliquis Notice Letter states that Umedica seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Umedica ANDA product before the expiration of the patent-in-suit. Upon information and belief, Umedica intends to—directly or indirectly—engage in the commercial manufacture, use, and sale of the Umedica ANDA product promptly upon receiving FDA approval to do so.

15. By filing ANDA No. 219640, Umedica has necessarily represented to the FDA that the Umedica ANDA product has the same active ingredient as Eliquis[®], has the same dosage form and strength as Eliquis[®], and is bioequivalent to Eliquis[®].

16. Upon information and belief, Umedica is seeking approval to market the Umedica ANDA product for the same approved indications as Eliquis[®].

17. In the Eliquis Notice Letter, Umedica states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Umedica ANDA product.

18. In the Eliquis Notice Letter, Umedica offered confidential access to portions of its ANDA No. 219640 on terms and conditions set forth in the Eliquis Notice Letter (“the Umedica Offer”). Umedica requested that Plaintiffs accept the Umedica Offer before receiving access to Umedica’s ANDA No. 219640. The Umedica Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For

example, the Umedica Offer does not extend to any in-house counsel, and for outside counsel, it contains broad bars on patent prosecution and regulatory approval of apixaban. The Umedica Offer also unreasonably restricted the ability of counsel to seek the opinions of outside experts without written notice to Umedica. The restrictions Umedica has placed on access to ANDA No. 219640 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information*” (emphasis added).

19. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Eliquis Notice Letter.

COUNT I

(INFRINGEMENT OF THE '945 PATENT)

20. Each of the preceding paragraphs 1 to 19 is incorporated as if fully set forth herein.

21. Umedica’s submission of ANDA No. 219640 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Umedica ANDA product prior to the expiration of the ’945 patent constituted a technical act of infringement of at least one of the claims of the ’945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. § 271(e)(2)(A).

22. Umedica’s commercial manufacture, use, offer to sell, sale, or importation of the Umedica ANDA product prior to the expiration of the ’945 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the ’945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. §§ 271(a), (b) and/or (c).

23. Upon FDA approval of Umedica's ANDA No. 219640, Umedica will infringe one or more claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, by making, using, offering to sell, and selling the Umedica ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '945 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

24. For example, in the Eliquis Notice Letter, Umedica described the Umedica ANDA product as an "oral tablet" containing 2.5 mg or 5 mg of apixaban. Upon information and belief, the Umedica ANDA product is a "[a] solid pharmaceutical composition" containing a "therapeutically effective amount of crystalline apixaban" and "a pharmaceutically acceptable diluent or carrier" as required by claim 1 of the '945 patent. Upon information and belief, the Umedica ANDA product contains crystalline apixaban particles that "have a D90 equal to or less than about 89 μm " and "wherein at least 77 wt % of apixaban dissolves with 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate" as required by claim 1 of the '945 patent. In the Eliquis Notice Letter, Umedica did not substantively contest infringement of any claim of the '945 patent.

25. If Umedica's marketing and sale of the Umedica ANDA product prior to expiration of the '945 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the patent-in-suit are not invalid, are not unenforceable, and are infringed by Umedica's submission of ANDA No. 219640, either literally

or under the doctrine of equivalents, and that Umedica's making, using, offering to sell, or selling in the United States, or importing into the United States the Umedica ANDA product will infringe the claims of the patents-in-suit, either literally or under the doctrine of equivalents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 219640 shall be a date which is not earlier than the expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Umedica, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Umedica ANDA product until after the expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Umedica engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Umedica ANDA product prior to the expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: September 30, 2024

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Respectfully submitted,

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