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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH & LOMB, INC.; BAUSCH & LOMB IRELAND LIMITED; and EYE THERAPIES, LLC, Plaintiffs, v. SLAYBACK PHARMA LLC; SLAYBACK PHARMA INDIA LLP; DR. REDDY'S LABORATORIES S.A.; and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 23-22906 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") by way of Complaint against Defendants Slayback Pharma LLC, Slayback Pharma India LLP, Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratories, Inc. (collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 11,833,245 ("the '245 patent"), arising under the United States patent laws, Title 35, United States Code § 100 et seq.,

including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Defendants' 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 Brimonidine Tartrate Ophthalmic Solution, 0.025% ("Defendants' generic brimonidine ophthalmic solution") prior to the expiration of the '245 patent.

THE PARTIES

2. Plaintiff Bausch & Lomb, Inc. ("Bausch") is a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609. Bausch is the registered holder of approved New Drug Application ("NDA") No. 208144, which covers Lumify® ophthalmic solution/drops (brimonidine tartrate, 0.025%).

3. Plaintiff Bausch & Lomb Ireland Limited ("Bausch Ireland") is a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland. Bausch Ireland exclusively licenses the '245 patent.

4. Plaintiff Eye Therapies, LLC ("Eye Therapies") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 26933 Camino De Estrella, 2nd Fl., Dana Point, California 92624. Eye Therapies is the owner of the '245 patent.

5. Upon information and belief, Slayback Pharma, LLC ("Slayback") is a Delaware limited liability company having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, NJ 08540, within this judicial district.

6. Upon information and belief, Slayback Pharma India LLP ("Slayback India") is a limited liability partnership organized under the laws of India, having a principal place of business

at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU - Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana 500072, India.

7. Upon information and belief, Slayback is the parent corporation of Slayback India, and the acts of Slayback complained of herein were done with the cooperation, participation and assistance of Slayback India.

8. Upon information and belief, Dr. Reddy's Laboratories S.A., ("DRL SA") is a corporation organized and existing under the laws of Switzerland, having a place of business at Elisabethenanlage 11, CH-4051 Basel, Switzerland.

9. Upon information and belief, Dr. Reddy's Laboratories, Inc. ("DRL Inc." and together with DRL SA, "DRL") is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540.

10. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL SA and is controlled by DRL SA, and the acts of DRL Inc. complained herein were done with the cooperation, participation and assistance of DRL SA.

11. Upon information and belief, Slayback has transferred to DRL the ownership of Defendants' ANDA seeking approval to market Defendants' generic brimonidine ophthalmic solution and intends to market the product upon approval.

THE PATENTS IN SUIT

12. The U.S. Patent and Trademark Office ("PTO") issued the '245 patent on December 5, 2023. The '245 patent claims, *inter alia*, methods of reducing eye redness consisting of topically administering 0.025% brimonidine as the sole active ingredient into ocular tissue. Plaintiffs hold all substantial rights in the '245 patent and have the right to sue for infringement thereof. A copy of the '245 patent is attached hereto as Exhibit 1.

13. In the prosecution that led to the issuance of the '245 patent, on May 31, 2023, Eye Therapies submitted to the USPTO the Final Written Decision by Patent Trial and Appeal Board in IPR2022-00142 ("the FWD"), which held that the claims of a different patent, U.S. Patent No. 8,293,742, unpatentable. Eye Therapies cited the FWD on page 1 of an Information Disclosure Statement and, on the same day, submitted claim amendments that were further explained in the submitted Remarks. *See* Exhibit 2 at 52.

14. Subsequent to this disclosure and claim amendments, on June 12, 2023, the Examiner issued correspondence, where he certified that he considered the FWD and issued a Final Rejection, raising only issues under 35 U.S.C. § 112. *See* Exhibit 2 at 24-31.

15. On June 30, 2023, Eye Therapies further amended its claims and submitted remarks responsive to the Examiner's Final Rejection. *See* Exhibit 2 at 17-23. Then, on July 24, 2023, the Examiner allowed the case. *See* Exhibit 2 at 12. The issue fee was promptly paid on July 25, 2023, and the '245 patent finally issued on December 5, 2023. *See* Exhibit 2 at 1-2, 11.

16. Bausch is the holder of NDA No. 208144 for Lumify®, which the FDA approved on December 22, 2017. In conjunction with NDA No. 208144, the '245 patent will be submitted for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

17. Brimonidine tartrate ophthalmic solution, 0.025%, is sold in the United States under the trademark Lumify®.

DEFENDANTS' INFRINGING ANDA SUBMISSION

18. Upon information and belief, Defendants filed or caused to be filed with the FDA ANDA No. 216361, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

19. Upon information and belief, Defendants' ANDA No. 216361 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Defendants' generic brimonidine ophthalmic solution, intended to be a generic version of Lumify®.

20. On or about August 16, 2021, Plaintiffs received a letter from Slayback dated August 13, 2021, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 216361 ("Slayback's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95. Slayback's Notice Letter was addressed to Bausch and Eye Therapies.

21. Slayback's Notice Letter alleges that ANDA No. 216361 was submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of generic brimonidine ophthalmic solution, intended to be generic versions of Lumify®.

22. Slayback's Notice Letter states that ANDA No. 216361 contains the "required bioavailability or bioequivalence data or information with respect to brimonidine tartrate ophthalmic solution, 0.025%," for generic brimonidine ophthalmic solution.

23. Upon information and belief, Slayback's actions related to ANDA No. 216361 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Slayback India.

24. On or about August 9, 2023, Plaintiffs received a letter from DRL dated August 3, 2023, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 216361 ("DRL's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95. DRL's Notice Letter was addressed to Bausch and Eye Therapies.

25. DRL's Notice Letter alleges that ANDA No. 216361 was submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of generic brimonidine ophthalmic solution, intended to be generic versions of Lumify®.

26. DRL's Notice Letter states that ANDA No. 216361 contains the "required bioavailability and/or bioequivalence data or information" for generic brimonidine ophthalmic solution.

27. Upon information and belief, DRL's actions related to ANDA No. 216361 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of DRL SA.

28. Upon information and belief, ANDA No. 216361 seeks approval of Defendants' generic brimonidine ophthalmic solution that is the same, or substantially the same, as Lumify®.

29. As a result of Slayback's Notice Letter and DRL's Notice Letter, Plaintiffs filed related Complaints against Slayback and DRL in this District. *See Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 21-16766; *Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 23-2454, consolidated into *In re Lumify*, Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED).

30. Plaintiffs, DRL, and Slayback consented to DRL joining to Civil Action No. 21-16766, which was Ordered by this Court on December 2, 2022. *See* Civil Action No. 21-16766, ECF No. 61.

31. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding ANDA No. 216361 for the '245 patent ("'245 Patent Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95.

32. Despite that Defendants have not yet sent a '245 Patent Notice Letter, Defendants' prior Notice Letters and the information contained therein, coupled with regulatory requirements, demonstrate Defendants' infringement of the '245 patent.

JURISDICTION AND VENUE

33. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. *See also Cephalon Inc. v. Sandoz Inc.*, Civil Action No. 11-821, 2012 U.S. Dist. LEXIS 26494, at *15 (D. Del. Mar. 1, 2012) (finding that court had subject matter jurisdiction pursuant to 35 U.S.C. § 271(e)(2) and/or 25 U.S.C. § 1338(a) regardless of receipt of a later Paragraph IV certification, where the defendant had sent an original Paragraph IV certification putting the plaintiffs on notice of the infringing ANDA).

34. Upon information and belief, this court has jurisdiction over Slayback. Upon information and belief, Slayback is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback 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 Defendants' generic brimonidine ophthalmic solution. Upon information and belief, Slayback purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Slayback has its principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540. Upon information and belief, Slayback has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

35. Upon information and belief, Slayback 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, the State of New Jersey and elsewhere. Slayback's ANDA filings constitute formal acts that reliably indicate plans

to engage in marketing of the proposed generic drugs. Upon information and belief, Slayback intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Slayback will engage in marketing of Defendants' generic brimonidine ophthalmic solution in New Jersey upon approval of Defendants' ANDA.

36. Upon information and belief, this court has jurisdiction over Slayback India. Upon information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback India 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 Defendants' generic brimonidine ophthalmic solution. Upon information and belief, Slayback India purposefully has conducted and continues to conduct business in this judicial district in concert with Slayback.

37. Upon information and belief, Slayback and Slayback India operate as interrelated corporate entities. Upon information and belief, Slayback is the parent corporation of Slayback India. Upon information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

38. Upon information and belief, this court has jurisdiction over DRL Inc. Upon information and belief, DRL Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL 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 Defendants' generic brimonidine ophthalmic solution. Upon information and belief, DRL Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, DRL Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

39. Upon information and belief, this court has jurisdiction over DRL SA. Upon information and belief, DRL SA is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL SA 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 Defendants' generic brimonidine ophthalmic solution. Upon information and belief, DRL SA purposefully has conducted and continues to conduct business in this judicial district in concert with DRL Inc. and Slayback.

40. Upon information and belief, DRL operates as interrelated corporate entities. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL SA and is controlled by DRL SA. Upon information and belief, DRL SA and DRL Inc. each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

41. Upon information and belief, DRL has taken the costly, significant step of seeking FDA approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. DRL's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, DRL intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, DRL will engage in marketing of Defendants' generic brimonidine ophthalmic solution in New Jersey upon approval of Defendants' ANDA.

42. In a related matter, DRL agreed that it would not contest personal jurisdiction or venue in that action. *Bausch & Lomb, Inc. et al. v. Slayback Pharma LLC et al.*, Civil Action No. 21-16766, ECF No. 61.

43. Defendants know or should know that Lumify® is manufactured for Bausch, at least because that information is included in the label for Lumify® and is publicly available and because Defendants have been sued in *Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 21-16766.

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

45. Venue is proper against Slayback Pharma, LLC, which maintains a regular and established place of business in this judicial district.

46. Venue is proper against Slayback India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

47. Venue is proper against DRL Inc., which maintains a regular and established place of business in this judicial district.

48. Venue is proper against DRL SA, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '245 Patent Under § 271(e)(2)

49. Paragraphs 1-48 are incorporated herein as set forth above.

50. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '245 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216361 seeking approval for the commercial marketing of Defendants' generic brimonidine ophthalmic solution before the expiration date of the '245 patent.

51. Upon information and belief, Defendants' generic brimonidine ophthalmic solution will, if approved and marketed, infringe at least one claim of the '245 patent.

52. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic brimonidine ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '245 patent.

53. If Defendants' marketing and sale of Defendants' generic brimonidine ophthalmic solution prior to the expiration of the '245 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

Declaratory Judgment of Infringement of the '245 Patent

54. Paragraphs 1-53 are incorporated herein as set forth above.

55. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

57. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic brimonidine ophthalmic solution before the expiration date of the '245 patent, including the filing of ANDA No. 216361.

58. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic brimonidine ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '245 patent.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic brimonidine ophthalmic solution will constitute infringement of at least one claim of the '245 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants 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), Defendants have infringed at least one claim of the '245 patent by submitting or causing to be submitted ANDA No. 216361 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic brimonidine ophthalmic solution before the expiration of the '245 patent;

2. Order that the effective date of any approval by the FDA of Defendants' generic brimonidine ophthalmic solution be a date that is not earlier than the expiration of the '245 patent, or such later date as the Court may determine;

3. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of Defendants' generic brimonidine ophthalmic solution until expiration of the '245 patent, or such later date as the Court may determine;

4. Enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendants' ANDA No. 216361 until expiration of the '245 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: December 5, 2023
Newark, New Jersey

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: December 5, 2023
Newark, New Jersey

s/ William P. Deni, Jr.
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