IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), allege as follows:

THE PARTIES

1. BIAL - PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 455 Trofa, Portugal.

2. BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 365 Trofa, Portugal.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is

marketed and sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

4. Sunovion Pharmaceuticals Inc. ("Sunovion") 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.

5. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034 India.

6. On information and belief, Dr. Reddy's Laboratories, Ltd. 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 Delaware.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

8. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

9. On information and belief, Dr. Reddy's Laboratories, Inc. 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 Delaware, in concert with Dr. Reddy's Laboratories, Ltd.

10. On information and belief, the acts of Dr. Reddy's Laboratories, Ltd. complained of herein were done with the cooperation, participation, and assistance of Dr. Reddy's Laboratories, Inc.

11. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 211238, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211238 ("DRL's Generic Product") throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent No. 10,912,781 ("the '781 patent" or "the patent-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to ANDA No. 211238, which DRL filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patent-in-suit.

13. DRL has infringed one or more claims of the '781 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 211238 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of DRL's Generic Product prior to the expiration of the '781 patent, or any extensions thereof. DRL will infringe one or more claims of the '781 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of DRL's Generic Product prior to the expiration of the '781 patent, or any extensions thereof.

14. Plaintiffs previously filed a separate action in this Court against DRL for patent infringement, which included counts for infringement of U.S. Patent Nos. 9,750,747 ("the '747

patent"), 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), and 9,763,954 ("the '954 patent"). *Bial - Portela & CA S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* C.A. No. 18-341-CFC (the "First Suit") was filed on March 2, 2018. The First Suit was filed in response to a letter from DRL dated January 17, 2018 ("DRL's First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 211238 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent. The First Suit included counts for infringement of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent.

15. Plaintiffs previously filed a separate action in this Court against DRL for patent infringement, which included counts for infringement of U.S. Patent Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 patent"). *Bial - Portela & CA S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* C.A. No. 20-784-CFC (the "Second Suit") was filed on June 9, 2020, and an amended complaint was filed on July 7, 2020. Plaintiffs received a letter from DRL dated August 21, 2020 ("DRL's Second Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 211238 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '287, patent, the '354 patent, and the '536 patent. The Second Suit included counts for infringement of the '287 patent, the '354 patent, and the '536 patent.

16. The First Suit and the Second Suit did not include counts for infringement of U.S. Patent No. 5,753,646 ("the '646 patent"), which will expire on June 27, 2021, because DRL's First Notice Letter and DRL's Second Notice Letter did not assert noninfringement or invalidity

of the '646 patent. Based on information and belief, DRL is maintaining its certification as to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '954 patent, the '287 patent, the '354 patent, and the '536 patent set out in DRL's First Notice Letter and DRL's Second Notice Letter. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit and the Second Suit.

JURISDICTION AND VENUE

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

18. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

19. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Dr. Reddy's Laboratories, Ltd. is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

21. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd., *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Dr. Reddy's Laboratories, Ltd. is organized under the laws of India.

22. This Court also has personal jurisdiction over DRL because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, DRL satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4)

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