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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Plaintiffs, v. ASTRAZENECA AB, ASTRAZENECA LP, AKTIEBOLAGET HÄSSLE and ZENECA INC. Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), by and through undersigned counsel, hereby bring their Complaint for Declaratory Judgment against Defendants AstraZeneca AB, AstraZeneca LP, Aktiebolaget Hässle and Zeneca Inc. (collectively, "Defendants" or "AstraZeneca") and alleges as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 6,428,810 ("the '810 patent") to enable DRL to bring its proposed over-the-counter ("OTC") esomeprazole magnesium delayed release oral tablets, eq. 20 mg base, as described in DRL's Abbreviated New Drug Application ("ANDA") No. 211571 ("DRL's ANDA Product") to market at the earliest possible date under the applicable statutory and regulatory provisions and to allow the public to benefit from increased generic availability for this product.

THE PARTIES

2. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

3. Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

4. Upon information and belief, Defendant AstraZeneca AB is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden. Upon information and belief, Astra Aktiebolaget, a predecessor company of AstraZeneca AB, has assigned all of its rights to the '810 patent to AstraZeneca AB.

5. Upon information and belief, Defendant AstraZeneca LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Upon information and belief, AstraZeneca LP is authorized to do business in New Jersey, with a registered agent for service of process located at The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

6. Upon information and belief, AstraZeneca LP holds an approved New Drug Application for esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base, that is sold under the name NEXIUM® 24HR.

7. Upon information and belief, Aktiebolaget Hässle is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

8. Upon information and belief, defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation having a principal place of business at Wilmington Delaware, and has rights in the United States to market and sell products covered by the '810 patent.

JURISDICTION AND VENUE

9. This Complaint for a declaratory judgment arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.,* the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, (as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355)), and by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) ("the MMA") (collectively herein the "Hatch-Waxman Act"), based upon an actual controversy between the parties for a final judgment declaring that DRL is free, upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, use, market, sell, offer to sell, and/or import DRL's ANDA Product as described in DRL's ANDA No. 211571.

10. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Personal jurisdiction as to Defendants is proper in this district because they have consented to personal jurisdiction by filing numerous cases in this district, including *AstraZeneca AB et al. v. Cipla Ltd., et al*. Civil Action No. 1:16-cv-09583; *AstraZeneca AB et al. v. Perrigo Co, et al*. Civil Action No. 3:15-cv-01057; *AstraZeneca AB et al. v. Lupin Ltd, et a1*., 3:15-cv-06902; *AstraZeneca AB et a1. v. Zydus Pharmaceuticals (USA) Inc. et al*., 3:14-cv-04782; and *AstraZeneca AB et al. v. HEC Pharm Co., Ltd. et al.,* 3:15-cv-06025, each of which involve defendants in the cases filing declaratory judgment counterclaims on, *inter alia*, the '810 patent.

12. Upon information and belief the Court also has personal jurisdiction over the Defendants due to them availing themselves of the rights and privileges of this forum, because Defendants conduct substantial business in, and have regular systematic contact with, this District including through marketing and sales of their NEXIUM® 24HR product and other pharmaceutical products, deriving substantial revenue from sale of their products in this district.

13. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

The '810 Patent

14. On its face, the '810 patent, entitled "Pharmaceutical Formulation Comprising Omeprazole," indicates it was issued by the United States Patent and Trademark Office on August 6, 2002. A copy of the '810 patent is attached hereto as **Exhibit A.**

15. According to the records at the United States Patent and Trademark Office, the '810 patent has been assigned to Defendant AstraZeneca AB through Astra Aktiebolag.

16. Upon information and belief, Zeneca is a licensee of the '810 patent with respect to commercializing pharmaceutical products esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base, in the United States.

Legal Framework and Factual Background

Hatch-Waxman Act Overview

17. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 2l U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

18. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

19. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted. *See* 2l U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

20. Once the FDA approves an NDA, the FDA lists the patent information submitted by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). *See* 21 U.S.C. §355(b)(1).

21. With respect to generic drug products, the Hatch-Waxman Act authorizes the submission of an ANDA to seek approval of a generic version of any Reference Listed Drug ("RLD") in the Orange Book. The Hatch-Waxman Act further authorizes the inclusion within an ANDA of a so-called "Paragraph IV" certification, in which the applicant certifies to the FDA

that the proposed ANDA product will not infringe any valid and enforceable claim of one or more patents in the Orange Book for the RLD. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

22. With respect to any such Paragraph IV certification, the ANDA applicant must provide notice of the certification to the patent holder and the holder of the New Drug Application ("NDA") for the RLD ("the NDA holder"), along with a statement of the factual and legal basis for its certification ("Notice Letter"). The filing of an ANDA with a Paragraph IV certification creates jurisdiction so that the patent and NDA holder may commence a patent infringement action within 45 days of receiving that notice ("the 45-day statutory period"). *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa) and 35 U.S.C. § 271(e)(2).

23. The Hatch-Waxman Act expressly authorizes the bringing of a declaratory judgment action under 28 U.S.C. § 2201 where the following conditions are met: (1) the 45-day period for the patent and NDA holder to bring suits has passed, without either entity having brought suit, and (2) the ANDA applicant included with its Paragraph IV certification notice a statutory offer of confidential access to review the ANDA to the patent and NDA holders. *See* 21 U.S.C. § 355(j)(5)(C)(i).

24. In order to encourage generic market entry, the first ANDA applicant to file a substantially complete ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period.

25. In order to prevent a First Filer from unduly delaying generic market competition, the MMA also added provisions whereby the First Filer will forfeit the 180-day exclusivity period. 21 U.S.C. §355 (j)(5)(D). One such forfeiture provision provides that the First Filer forfeits the 180-day exclusivity period if it does not market its product within 75 days after "a

court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent [which entitled the first applicant to exclusivity] is invalid or not infringed." Once the exclusivity period has run or been forfeited, the FDA may grant final approval to subsequently filed ANDAs.

26. Thus, removal of a blocking exclusivity period may be obtained by a final judgment that all patents which are the subject of the Paragraph IV certification giving rise to exclusivity are not infringed or are invalid. *See* 21 U.S.C. *§* 355(j)(5)(D)(i)(I). The Hatch-Waxman Act expressly provides that such a final judgment may come from a declaratory judgment action brought by a generic challenger. *Id.* Upon such a forfeiture, the FDA may grant final approval to the generic challenger's ANDA.

AstraZeneca's NDA and Its Listing of Patents in the Orange Book

27. Upon information and belief, AstraZeneca LP holds approved NDA No. 207920 for esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base, under the brand name NEXIUM® 24HR.

28. Upon information and belief, AstraZeneca LP caused the '810 patent to be listed in the Orange Book with respect to the RLD NEXIUM® 24HR shortly after the '810 patent's issuance on August 6, 2002. The Orange Book lists the patent expiration date for the '810 patent to be November 3, 2019 and lists a six-month pediatric exclusivity for this patent which prevents DRL from obtaining final FDA approval until on or about May 3, 2020.

29. By listing the '810 patent in the Orange Book, AstraZeneca LP represented to the FDA that such patent is that to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1).

30. As a consequence of listing the ’810 patent in the Orange Book, AstraZeneca LP maintains, and has affirmatively represented to the FDA and the public, that the ’810 patent claims the product approved in NDA No. 207920, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant, including DRL, seeking FDA approval to market a generic version of the drug prior to the expiration of the ’810 patent.

First Filer Status of an Unknown Party and the Need to Provoke Forfeiture

31. Although not known to DRL at this time, according to the FDA website, another unidentified ANDA applicant filed the first substantially complete ANDA that included a paragraph IV certification and, thus, holds eligibility for the 180-day market exclusivity.

32. Specifically, according to the FDA website another party submitted an ANDA on September 9, 2016. The FDA is treating the September 9, 2016 filing as the “First Applicant” for determining eligibility for 180-day exclusivity.

33. Upon information and belief, AstraZeneca to date has not filed a lawsuit against this other, unidentified ANDA applicant (the “First Filer”).

34. DRL does not know who the blocking ANDA applicant is or when (or if) the ANDA applicant will ever get FDA approval for or will market generic esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base.

35. Upon information and belief, the unknown First Filer on NEXIUM® 24HR failed to secure a final court decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the ’810 patent is invalid or not infringed.

36. Upon information and belief, the unknown First Filer has failed to market the drug after receiving final approval from the FDA and no other generic has triggered the

forfeiture provisions by securing a final court decision, thus effectively blocking DRL from getting to the market, unless through a declaratory judgment as DRL seeks to do in this action.

DRL's ANDA No. 211571 for esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base

37. On or about February 28, 2018, DRL submitted ANDA No. 211571 to the FDA for proposed esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base.

38. DRL's ANDA No. 211571 included a Paragraph IV Certification for the '810 patent.

39. As noted above, the FDA website indicates that the First Filer's ANDA was submitted on September 9, 2016. DRL's ANDA is deemed by the FDA to have been filed subsequent to that other, unnamed filer.

40. As a result, DRL is blocked by the First Filer's 180-day exclusivity.

41. Because, as noted above, the '085 and '070 patent are expired and their pediatric exclusivity period is set to expire on November 25, 2018, DRL needs a final decision finding the '810 patent as either not infringed or invalid to trigger forfeiture of the First Filer's exclusivity and to clear the blocking injury it is suffering in order to bring DRL's ANDA Product to market as soon after November 25, 2018 as possible.

42. DRL's paragraph IV certification in its ANDA certified that the '810 patent will not be infringed by the manufacture, use or sale of DRL's ANDA Product described therein.

43. DRL served a Notice Letter dated March 30, 2018 on AstraZeneca AB, AstraZeneca LP and Pfizer Consumer Healthcare ("Pfizer") informing them of DRL's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of DRL's esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base,

before the expiration of the ’810 patent. DRL’s Notice Letter complied fully with 35 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95.

44. The ’810 patent states that it relates to an omeprazole containing formulation comprising a core material that comprises the active ingredient containing omeprazole “and optionally an alkaline reacting compound, the active ingredient in admixture with a pharmaceutically acceptable excipient, such as for instance a binding agent, and on said core material a separating layer and an enteric coating letter. A hydroxypropyl cellulose (HPC) with a specific cloud point is used in the manufacture of the claimed pharmaceutical formulations.” *Abstract*.

45. The sole independent claim, claim l, and thereby all claims of the patent (as the remainder of the claims ultimately depend on claim 1), require a separating layer which “comprises a hydroxypropyl cellulose (HPC) with a cloud point of at least 38ºC”.

46. DRL set forth in the detailed statement of the notice letter the reasons why DRL’s ANDA Product does not infringe upon any valid claim of the ’810 Patent.

47. DRL’s ANDA Product does not comprise the required elements of claim 1 of the ’810 Patent and, therefore, it does not infringe that claim. As the sole independent claim, that is, claim 1, from which all other claims depend directly or indirectly, is not infringed, all other dependent claims are also not infringed.

48. DRL’s Notice Letter included an offer of access to confidential information within the meaning of 271 U.S.C. § 355(j)(5)(C)(i)(III).

49. AstraZeneca AB, AstraZeneca LP, or Pfizer failed to bring an action for infringement of the ’810 patent against DRL within the 45-day statutory period.

50. Accordingly, both requirements are met for the declaratory judgment action

expressly authorized by the Hatch-Waxman Act: (1) the 45-day period has passed without either AstraZeneca AB, AstraZeneca LP, or Pfizer bringing an action for infringement, and (2) DRL made the statutory offer of confidential access in connection with the '810 patent. *See* 21 U.S.C. § 355(j)(5)(C)(i).

51. Under the framework of the Hatch-Waxman Amendments, DRL is restrained from selling a non-infringing product because Defendants' action of listing the '810 patent in the Orange Book delays FDA final approval of DRL's ANDA Product and excludes DRL from the market.

52. As detailed above, it is uncertain when, or even if, the First Filer's exclusivity period will begin. Accordingly, DRL may be blocked indefinitely from competing with Defendants.

53. To prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides DRL the right to attempt to trigger a forfeiture of the first filer's exclusivity period by obtaining a judgment that the '810 patent is not infringed or is invalid. *See* 21 U.S.C. § 355G)(5)(D)(i)(l).

54. A final judgment of non-infringement of the '810 patent in favor of DRL is thus necessary to trigger the forfeiture of the blocking first filer's 180-day exclusivity period, and will thus allow DRL to obtain FDA approval to market DRL's ANDA Product.

55. A real, actual and justiciable controversy exists between DRL and Defendants regarding DRL's non-infringement of the '810 patent, constituting a case of actual controversy to ensure that DRL's ANDA Product can freely enter the market earlier than it would absent a final and non-appealable order relating to the '810 patent. This controversy regarding patent certainty is defined in 21 U.S.C. §355(j)(5)(C)(i)(II) and is within the jurisdiction of this Court under the

Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

56. But for AstraZeneca LP's decision to list the '810 patent in the Orange Book, FDA approval of DRL's ANDA would not have been independently delayed by that patent. DRL is being injured by AstraZeneca LP's actions of requesting the FDA to list the '810 patent in the FDA Orange Book and continuing said listing in the FDA Orange Book.

57. DRL's injury can be redressed by the requested relief: a declaratory judgment of non-infringement of DRL's ANDA Product would trigger the first applicant's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of DRL's ANDA Product. If DRL is blocked by the First Filer's exclusivity, DRL will be monetarily harmed, as it will lose sales of its ANDA product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete with others in the market for esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '810 PATENT

58. DRL re-alleges and incorporates by reference each of the allegations of paragraphs 1-57, as if fully set forth herein.

59. A present, genuine and justiciable controversy exists between DRL and the Defendants concerning, *inter alia*, the issue of whether DRL's manufacture, use, offer for sale, or sale of the proposed esomeprazole magnesium delayed release oral tablets (OTC), eq. 20 mg base, as described in DRL's ANDA No. 211571, would infringe any valid and enforceable claim of the '810 patent.

60. DRL is entitled to a declaratory judgment that the manufacture, use, offer for sale, or sale of DRL's proposed esomeprazole magnesium delayed release oral tablets (OTC), eq. 20

mg base, as described in DRL's ANDA No. 211571, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the '810 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests the Court enter judgment as follows:

a. Declaring that the claims of the '810 patent have not been infringed by the filing of DRL's ANDA No. 211571;

b. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of DRL' s ANDA No. 211571 have not infringed, do not infringe, and would not, *if* marketed, infringe, or induce or contribute to the infringement by others of, any claims of the '810 patent;

c. Declaring that the United States Food & Drug Administration may immediately approve DRL's ANDA Product of ANDA No. 211571 when that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the '810 patent is not infringed pursuant to 21 U.S.C. § 355G)(5)(B)(iii)(I)(aa); and any other marketing exclusivity periods to which Defendants might otherwise be entitled (including any pediatric exclusivity) with respect to the '810 patent is shortened to expire upon the date of entry of judgment in this case;

d. Awarding DRL such other and further relief that the Court deems just and proper under the circumstances.

DATED: November 12, 2018

Respectfully submitted,

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