IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and WISCONSIN ALUMNI RESEARCH FOUNDATION, Plaintiffs, v. DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES INC., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs AbbVie Inc. ("AbbVie") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") (collectively "DRL" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 6,136,799 ("the '799 patent"), 6,361,758 ("the '758 patent"), and 5,597,815 ("the '815 patent"). This action arises out of DRL's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of AbbVie's highly successful Zemplar® injectable products, in 2 µg/ml and 5 µg/ml formulations, prior to the expiration of the patents owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. AbbVie is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 1 N. Waukegan Road, North Chicago, Illinois 60064.

3. WARF is a nonprofit Wisconsin corporation, having its principal place of business at 614 Walnut Street, Madison, Wisconsin 53726. WARF is the designated technology transfer organization for the University of Wisconsin-Madison ("University"). WARF's mission is to support research at the University, to transfer technology, and to ensure that the inventions and discoveries of the University benefit humankind. WARF carries out this mission by patenting and licensing University inventions and by returning a portion of the proceeds of that licensing to fund additional research at the University. To date, WARF's contributions to the University have included funds to support research, build facilities, purchase land and equipment, and support many faculty and graduate student fellowships.

4. On information and belief, Defendant Dr. Reddy's Ltd. is a corporation operating and existing under the laws of India having its principal place of business at No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India. On information and belief, Dr. Reddy's Ltd. manufactures generic drug products for sale and use throughout the United States, including in this judicial district, itself and through its subsidiary and exclusive United States agent, Dr. Reddy's Inc. Dr. Reddy's Ltd. has been a named party in lawsuits filed in the United States District Court for the District of Delaware where it has not contested jurisdiction.

5. On information and belief, Defendant Dr. Reddy's Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 200 Somerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, New Jersey 08807-2862.

On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd., and is the United States agent for Dr. Reddy's Ltd. On information and belief, Dr. Reddy's Inc. is engaged in the manufacture and sale of generic pharmaceutical products for distribution throughout the United States, including the State of Delaware. Dr. Reddy's Inc. has been a named party in lawsuits filed in the United States District Court for the District of Delaware where it has not contested jurisdiction.

JURISDICTION AND VENUE

6. 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*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Defendants are each subject to personal jurisdiction in this district because, *inter alia*, they committed or aided, abetted, contributed to, and/or participated in the commission of an act of patent infringement against AbbVie, a Delaware corporation. This Court also has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware. For example, Defendants regularly and continuously transact business within the State of Delaware, including, but not limited to, the regular sale of drug products within the State of Delaware.

8. DRL did not challenge personal jurisdiction in this District in at least the following actions: *Pfizer Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 09-00943; *Janssen Pharmaceutica N.V. et al. v. Dr. Reddy's Laboratories, Inc.*, No. 05-00380; and *Bayer AG et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 04-00179.

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

FACTS PERTINENT TO ALL COUNTS

10. The ’799 patent, entitled “Cosolvent Formulations,” issued on October 24, 2000, and a copy is attached hereto as Exhibit A. Named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier assigned the ’799 patent to Abbott Laboratories (“Abbott”), and Abbott subsequently assigned the ’799 patent to AbbVie.

11. The ’799 patent expires on April 8, 2018.

12. The ’758 patent, entitled “Cosolvent Formulations,” issued on March 26, 2002, and a copy is attached hereto as Exhibit B. Named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier assigned the ’758 patent to Abbott, and Abbott subsequently assigned the ’758 patent to AbbVie.

13. The ’758 patent expires on April 8, 2018.

14. The ’815 patent, entitled “Prevention of Hyperphosphatemia in Kidney Disorder Patients,” issued on January 28, 1997, and a copy is attached hereto as Exhibit C. Named inventors Hector F. Deluca and Eduardo Slatopolsky assigned the ’815 patent to WARF and Washington University, respectively, and Washington University transferred all substantial rights in the ’815 patent to WARF. AbbVie is the exclusive licensee of the ’815 patent.

15. The ’815 patent expires on July 13, 2015.

16. The ’799, ’758, and ’815 patents (collectively, the “patents-in-suit”) are listed in the United States Food and Drug Administration (“FDA”) publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) as covering paricalcitol, which is marketed by AbbVie under the brand name Zemplar®. The ’815 patent claims an approved use of paricalcitol as set forth in the Orange Book, Patent Use Code

U-1195, which recites the use of paricalcitol for "[p]revention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5, which may result in renal osteodystrophy, while avoiding hyperphosphatemia."

17. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of the '799, '758, and '815 patents.

18. On information and belief, DRL manufactures, markets, and sells pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within the United States generally, and into the State of Delaware specifically.

19. On information and belief, DRL actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

20. On information and belief, DRL prepared and submitted with the FDA ANDA No. 204910, seeking approval to engage in the commercial manufacture, use, and sale of paricalcitol injection products, in 2 µg/ml and 5 µg/ml formulations, prior to the expiration of the patents-in-suit.

21. On or about April 22, 2013, Abbott[1] received a letter dated April 19, 2013, from DRL notifying Abbott that DRL had filed ANDA No. 204910 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), and stating that, in DRL's opinion, the patents-in-suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol injection products described in ANDA No. 204910. Plaintiff WARF did not receive any such Paragraph IV Certification from DRL at that time.

[1] The April 19, 2013 letter addressed Abbott rather than Plaintiff AbbVie.

22. On or about May 20, 2013, AbbVie and WARF received letters dated May 17, 2013, from DRL notifying Plaintiffs that DRL had filed ANDA No. 204910 containing a Paragraph IV Certification, and stating that, in DRL's opinion, the patents-in-suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol injection products described in ANDA No. 204910.

23. DRL was necessarily aware of the patents-in-suit when it filed ANDA No. 204910 containing the Paragraph IV Certification with the FDA.

24. Upon information and belief, Plaintiffs allege that at least claim 4 of the '815 patent directed to "[a] method of treating a patient having renal osteodystrophy while avoiding hyperphosphatemia comprising administering to said patient a vitamin D compound that has minimal effect on blood serum phosphorus of said patient, said vitamin D compound selected from a 19-nor-vitamin D_2 compound [wherein the vitamin D compound is paricalcitol] . . . ." reads on the proposed label of DRL's paricalcitol injection ANDA No. 204910.

25. Upon information and belief, DRL seeks FDA-marketing approval under 21 U.S.C. § 355(j) *et seq.* of paricalcitol injection drug products for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5. This use is the only FDA-authorized use of paricalcitol injection, and, if approved, would induce infringement of at least claim 4 of the '815 patent prior to its expiration.

26. Secondary hyperparathyroidism, characterized by parathyroid hyperplasia, persistently elevated parathyroid ("PTH") levels in the blood, and systemic mineral and bone abnormalities, is a common consequence of reduced kidney function in patients with chronic kidney disease. Paricalcitol is a vitamin D analog proven effective, at appropriate dosage

strengths, in suppressing elevated levels of blood PTH, the defining characteristic of secondary hyperparathyroidism found in patients suffering from chronic kidney disease and its corresponding abnormalities in bone metabolism. PTH is a major regulator of bone turnover and skeletal cellular activity.

27. Clinical studies of renal osteodystrophy have generally utilized the levels of PTH as a marker for bone turnover. Obtaining direct evidence of bone effects requires highly invasive techniques, for example bone biopsy, which are intrusive for patients as well as difficult and expensive for investigators. Thus, newer vitamin D analogs, including paricalcitol, have largely obtained FDA approval for use in the control of intact PTH and do not contain bone biopsy data to document their direct effect on bone histology. However, limited data does exist to show that features of hyperparathyroid bone disease are improved by vitamin D treatment, such as paricalcitol. Moreover, physicians and medical professionals understand that because intact PTH levels correlate with bone turnover, avoidance of very high intact PTH levels prevents renal osteodystrophy.

28. Paricalcitol at appropriate dosage strengths suppresses PTH levels with minor effects on calcium and phosphate metabolism, which is critical to maintaining mineral homeostasis and proper parathyroid functioning. (Exhibit D, Approved Labeling of Zemplar®, "Clinical Studies".) By suppressing elevated PTH levels and encouraging proper phosphorus metabolism, paricalcitol has been shown to have positive impact on serum markers associated with renal osteodystrophy.

29. Numerous studies have shown that renal osteodystrophy is associated with high serum levels of intact PTH. The approved labeling of Zemplar® recommends paricalcitol

in CKD patients (Stage 5) who have elevated plasma levels of intact PTH to reduce PTH levels, which, left untreated results in a greater chance of brittle bones due to high bone turnover.

30. Upon information and belief, DRL's proposed drug label contains descriptions indicating that secondary hyperparathyroidism is characterized by elevated levels of PTH, and further indicates that elevated PTH levels often precede abnormalities in serum calcium and phosphorus levels, and affect bone turnover and may result in renal osteodystrophy. (*See, e.g.*, Exhibit D, Approved Labeling of Zemplar®, "Clinical Pharmacology".) Accordingly, a treating physician or healthcare professional following DRL's proposed labeled indication would intend that the use of paricalcitol injection to treat secondary hyperparathyroidism in patients with late stage renal failure would necessarily also treat bone abnormalities associated with elevated PTH; that is, would thus also treat renal osteodystrophy as described and claimed in the '815 patent.

31. The specification of the '815 patent discloses that secondary hyperparathyroidism is a "universal complication" in patients with chronic renal failure ('815 patent, col. 1, ll. 26-27), and that paricalcitol is an "ideal tool" for the treatment of secondary hyperparathyroidism and renal osteodystrophy because it suppresses PTH with "minimal effect on calcium and phosphorus," (*id.*, col. 9, ll. 63-66.) This use and effect is reflected in the approved dosage and use of paricalcitol injection described in the Zemplar® label, which, on information and belief, will be copied by DRL with respect to its ANDA products and included with every vial of DRL's proposed paricalcitol injection products.

32. Based on the Zemplar® label, physicians and healthcare professionals prescribing and administering paricalcitol injection understand and intend that treating secondary hyperparathyroidism by suppressing PTH will treat renal osteodystrophy while avoiding

hyperphosphatemia. Indeed, some of the advantages in treating patients with paricalcitol over other vitamin D analogs are reduced calcemic and phosphatemic activities of paricalcitol treatment, which can be attributed to lower potency in stimulating intestinal calcium and phosphate absorption.

33. Upon information and belief, DRL has knowledge of the claims and disclosures of '815 patent, and has knowledge that its proposed label directs physicians and healthcare professionals to prescribe paricalcitol injection for the prevention and treatment of secondary hyperparathyroidism in patients with chronic kidney disease Stage 5 with the effect of treating renal osteodystrophy while avoiding hyperphosphatemia. Therefore, the proposed products and labeling in ANDA No. 204910, if approved and marketed in the United States, would result in DRL knowingly and intentionally encouraging, promoting, and inducing infringement of the '815 patent.

34. Moreover, there is no substantial non-infringing use of paricalcitol injection that is authorized in the United States. The proposed products and labeling in ANDA No. 204910, if approved and marketed in the United States, will unavoidably contribute to the infringement of the '815 patent.

35. Plaintiffs are commencing this action within forty-five days of the date that Abbott received DRL's April 19, 2013 Paragraph IV Notice of ANDA No. 204910.

36. DRL purported to include an "Offer of Confidential Access" to Plaintiffs to ANDA No. 204910 along with its Paragraph IV Notice. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(III), restrictions to an Offer of Confidential Access must serve the purpose of protecting trade secrets and other confidential business information. Restrictions may not be made based on counsel's status as in-house. *U.S. Steel Corp. v. U.S.*,

730 F.2d 1465, 1468 (Fed. Cir. 1984); see also *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 936 (N.D. Ill. 2010) (applying *U.S. Steel* to an Offer of Confidential Access).

37. DRL's Offer of Confidential Access restricted disclosure to outside counsel and required that the outside counsel (a) not be involved in patent prosecution matters for the Plaintiffs and (b) not be involved in any FDA counseling, litigation or other work before or involving FDA, relating to paricalcitol injection products. DRL's Offer of Confidential Access also restricted disclosure to unspecified sections of ANDA No. 204910 that DRL in its sole discretion has decided is necessary for Plaintiffs to determine whether or not to file an action within 45 days.

38. The proposed terms of DRL's Offer of Confidential Access to Plaintiffs did not allow any of Plaintiffs' in-house litigation team members, who are crucial decision makers in the process of filing any infringement action, access to the necessary information with which to decide whether DRL's proposed generic copy of AbbVie's paricalcitol injection products likely infringed Plaintiffs' patents. The restrictions to other work performed by those having access to the ANDA were not directed to the purpose of protecting trade secrets and other confidential business information. Furthermore, under the proposed terms of DRL's Offer of Confidential Access, DRL could have technically complied by making very minimal disclosures to Plaintiffs.

39. While DRL and Plaintiffs' outside counsel have had a series of discussions attempting to reach agreement on the terms and conditions of the Offer of Confidential Access, the parties did not reach agreement. For the reasons explained above, Plaintiffs cannot agree to all of the restrictions DRL continues to place on its Offer of

Confidential Access, and, therefore, are necessarily filing this Complaint without having had any access to any portion of DRL's ANDA.

40. DRL has committed and will commit acts of infringement of the patents-in-suit that create a justiciable case or controversy between Plaintiffs and DRL. Pursuant to 35 U.S.C. § 271(e)(2)(A), DRL committed an act of infringement by filing an ANDA with a Paragraph IV Certification that seeks FDA-marketing approval for DRL generic versions of AbbVie's paricalcitol injection products prior to expiration of the patents-in-suit. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the patents-in-suit.

COUNT 1
INFRINGEMENT OF THE '799 PATENT

41. Paragraphs 1-40 are incorporated herein by reference.

42. Under 35 U.S.C. § 271(e)(2)(A), DRL infringed one or more claims of the '799 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '799 patent, of generic paricalcitol injection products labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce direct infringement of one or more claims of the '799 patent by ultimate purchasers.

43. AbbVie will be substantially and irreparably damaged and harmed if infringement by DRL is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 2
DECLARATORY JUDGMENT AS TO THE '799 PATENT

44. Paragraphs 1-43 are incorporated herein by reference.

45. Upon information and belief, DRL has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by AbbVie.

46. Upon further information and belief, DRL intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

47. The manufacture, importation, sale, and offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the ’799 patent.

48. DRL’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce infringement of one or more claims of the ’799 patent.

49. AbbVie will be substantially and irreparably damaged and harmed if DRL’s threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 3
INFRINGEMENT OF THE ’758 PATENT

50. Paragraphs 1-49 are incorporated herein by reference.

51. Under 35 U.S.C. § 271(e)(2)(A), DRL infringed one or more claims of the ’758 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the ’758 patent, of generic paricalcitol injection products labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce direct infringement of one or more claims of the ’758 patent by ultimate purchasers.

52. AbbVie will be substantially and irreparably damaged and harmed if infringement by DRL is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 4
DECLARATORY JUDGMENT AS TO THE '758 PATENT

53. Paragraphs 1-52 are incorporated herein by reference.

54. Upon information and belief, DRL has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by AbbVie.

55. Upon further information and belief, DRL intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

56. The manufacture, importation, sale, and offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the '758 patent.

57. DRL's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce direct infringement of one or more claims of the '758 patent.

58. AbbVie will be substantially and irreparably damaged and harmed if DRL's threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 5
INFRINGEMENT OF THE '815 PATENT

59. Paragraphs 1-58 are incorporated herein by reference.

60. Under 35 U.S.C. § 271(e)(2)(A), DRL infringed one or more claims of the '815 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '815 patent, of generic paricalcitol injection products

labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce direct infringement of one or more claims of the '815 patent by ultimate purchasers.

61. Upon information and belief, DRL has infringed, induced or contributed to and will infringe, induce or contribute to infringement of at least claim 4 of the '815 patent by (1) filing ANDA No. 204910 seeking approval to introduce into interstate commerce generic paricalcitol injection products in 2 µg/ml and 5 µg/ml formulations; (2) preparing to sell generic paricalcitol injection products pursuant to its ANDA; and (3) intending to sell such generic paricalcitol injection products, upon FDA approval, together with instructions and labeling which will result in direct infringement of at least claim 4 of the '815 patent by ultimate purchasers and users.

62. Plaintiffs will be substantially and irreparably damaged and harmed if infringement by DRL is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT 6
DECLARATORY JUDGMENT AS TO THE '815 PATENT

63. Paragraphs 1-62 are incorporated herein by reference.

64. Upon information and belief, DRL has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by AbbVie.

65. Upon further information and belief, DRL intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

66. The manufacture, importation, use, sale, or offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the ’815 patent.

67. DRL’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce direct infringement of one or more claims of the ’815 patent.

68. Plaintiffs will be substantially and irreparably damaged and harmed if DRL’s threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against DRL as follows:

(a) declaring the ’799, ’758, and ’815 patents valid and enforceable;

(b) finding that DRL has infringed one or more claims of the ’799, ’758, and ’815 patents by filing ANDA No. 204910 under 21 U.S.C. § 355(j)(2);

(c) finding that DRL has infringed one or more claims of the ’799, ’758, and ’815 patents by the threatened acts of making, importing, using, offering to sell, or selling its generic paricalcitol injectable products prior to the expiration of said patents;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of DRL’s ANDA No. 204910 relating to generic paricalcitol injection products before the expiration of the six-month period of market exclusivity for the ’799, ’758, and ’815 patents granted under 21 U.S.C. § 355A;

(e) enjoining DRL from commercially making, importing, using, offering to sell, or selling its generic paricalcitol injectable products, in accordance with 35 U.S.C. § 271(e)(4)(B);

(f) finding this to be an exceptional case and awarding Plaintiffs attorney fees under 35 U.S.C. §§ 285 and 271(e)(4)(C); and

(g) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

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