IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and WISCONSIN ALUMNI RESEARCH FOUNDATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
HIKMA PHARMACEUTICAL CO., LTD., WEST-WARD PHARMACEUTICALS CORP. and EXELA PHARMA SCIENCES LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs AbbVie Inc. ("AbbVie") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendants Hikma Pharmaceutical Co., Ltd., ("Hikma"), West-Ward Pharmaceuticals Corp. ("West-Ward"), and Exela Pharma Sciences, LLC ("Exela Pharma") (collectively "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 5,597,815 ("the '815 patent"). This action arises out of Hikma's filing of a New Drug Application ("NDA") under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), with the U.S. Food and Drug Administration ("FDA") for approval to manufacture and sell a generic copy of AbbVie's highly successful Zemplar® paricalcitol injectable drug products prior to the expiration of the '815 patent.

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. Upon information and belief, Defendant Hikma is a Jordanian company, having its registered address at Bayader Wadi El-Seer, Industrial Area, P.O. Box 182400, Amman, Jordan, 11118. Hikma is a worldwide pharmaceutical company in the business of developing and manufacturing branded and generic drugs. Accordingly to Hikma's website, Hikma's generics business in the United States "operates as West-Ward Pharmaceuticals, a domestic marketer and manufacturer of generic pharmaceutical products." Upon information and belief, Hikma entered into a partnership with Exela Pharma to develop and manufacture innovative and generic injectable products. Hikma's website states, "Increasingly, we are also working with companies that can help us to develop our product pipeline. Through arrangements like the one with Exela, a North Carolina-based company that develops and manufactures innovative and

generic injectable products, we hope to bring more differentiated products to market. A great example of this is our NDA approval for our formulation of Argatroban, received in January 2012." Upon information and belief, Hikma is a subsidiary of Hikma Investment Company and Hikma Pharmaceuticals PLC.

5. Upon information and belief, Defendant West-Ward is a company organized and existing under the laws of the State of Delaware, having a place of business at 401 Industrial Way West, Eatontown, NJ 07724. Upon information and belief, West-Ward acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States of entities affiliated with Hikma. West-Ward's website states the following: "West-Ward Pharmaceuticals is one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC." West-Ward's website indicates that it has a sales representative for the State of Delaware. Upon information and belief, West-Ward has active pharmacy wholesaler and controlled substance distributor and manufacturer licenses in Delaware. Upon information and belief, West-Ward is a wholly-owned subsidiary of Eurohealth (U.S.A.) Inc., a holding company, and its parent Hikma Pharmaceuticals PLC.

6. Upon information and belief, Defendant Exela Pharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1325 William White Place, Lenoir, North Carolina 28645. Upon information and belief, Exela Pharma is in the business of developing and manufacturing pharmaceutical products, including injectable products for sale and use in the United States. Upon information and belief, Exela Pharma has entered into a partnership with Hikma to develop and manufacture generic

paricalcitol injectable drug products. Upon information and belief, Exela Pharma is a wholly-owned subsidiary of Exela PharmaSci, Inc. and its parent Exela Holdings, Inc.

JURISDICTION AND VENUE

7. 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).

8. Hikma is subject to personal jurisdiction in this district because, *inter alia*, together with West-Ward and Exela Pharma, Hikma has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against AbbVie, a Delaware corporation.

9. This Court also has personal jurisdiction over Hikma because, *inter alia*, together with West-Ward (a Delaware corporation) and Exela Pharma (a Delaware corporation), Hikma has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Hikma regularly and continuously transacts business within the State of Delaware, including, but not limited to, shipping pharmaceuticals to West-Ward from locations outside the United States for distribution by West-Ward within the United States generally, and within this district specifically.

10. In the alternative, this Court has personal jurisdiction over Hikma under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law and, upon information and belief, Hikma is not subject to the jurisdiction of the courts of general jurisdiction of any state and the

exercise of personal jurisdiction over Hikma is consistent with the Constitution and the laws of the United States.

11. West-Ward is subject to personal jurisdiction in this district because it is a Delaware corporation and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

12. Exela Pharma is subject to personal jurisdiction in this district because it is a Delaware corporation and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the development and manufacturing of pharmaceutical products for sale within the United States generally, and within this district specifically. Exela Pharma has previously consented to the jurisdiction of this Court in *Cornerstone Therapeutics Inc., et al. v. Exela Pharma Sciences, LLC et al.*, C.A No. 13-1275 and *Cadence Pharmaceuticals Inc., et al. v. Exela Pharma Sciences, LLC*, C.A. No. 11-733.

13. On information and belief, West-Ward is the agent, affiliate, representative, and/or alter ego of and/or acts in concert with Hikma for purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

14. On information and belief, Exela Pharma is the agent, affiliate, representative, and/or alter ego of and/or acts in concert with Hikma, for purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

15. On information and belief, West-Ward and Exela Pharma each act as agents of Hikma with respect to the acts complained of herein.

16. On information and belief, the acts of Hikma complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and/or assistance of, and, in part, for the benefit of West-Ward and Exela Pharma.

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

FACTS PERTINENT TO ALL COUNTS

18. The '815 patent, entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients," issued on January 28, 1997, and a copy is attached hereto as Exhibit A. Named inventors Hector 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.

19. The '815 patent expires on July 13, 2015.

20. The '815 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering the use of 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 FDA's Orange Book, Patent Use Code U-1195, which recites the use of paricalcitol for "Prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5, which may result in renal osteodystrophy, while avoiding hyperphosphatemia."

21. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of the '815 patent.

22. On information and belief, Hikma, West-Ward, and Exela Pharma, collaborate in the development, manufacture, marketing, and sale of many pharmaceutical products (including

generic drug products manufactured and sold pursuant to approved 505(b)(2) applications) within the United States generally, and the State of Delaware specifically.

23. On information and belief, Hikma actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

24. On information and belief, Hikma, West-Ward, and Exela Pharma collaborated in the research, development, preparation, and filing of NDA No. 205917 for generic paricalcitol injection products.

25. Upon information and belief, Hikma submitted to the FDA NDA No. 205917 under § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), (also known as a 505(b)(2) application), seeking approval to engage in the commercial manufacture, use, and sale of paricalcitol injectable drug products in 2 mcg/ml and 5 mcg/ml formulations, prior to the expiration of the '815 patent.

26. On or about July 31, 2013, AbbVie and WARF received letters dated July 30, 2013, from Hikma notifying Plaintiffs that Hikma had filed NDA No. 205917 containing a certification under § 505(b)(2)(A)(iv) of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv), ("Paragraph IV Certification"), and stating that, in Hikma's opinion, none of the claims of the '815 patent "will be infringed by Hikma's commercial manufacture, use or sale of its paricalcitol injectable formulations that are the subject of the NDA, and/or that those claims are invalid or unenforceable."

27. On information and belief, Hikma, West-Ward, and Exela Pharma collaborated and acted in concert in the decision to file and the filing of NDA No. 205917 containing the Paragraph IV Certification.

28. On information and belief, Hikma, West-Ward, and Exela Pharma were necessarily aware of the ’815 patent when they filed NDA No. 205917 containing the Paragraph IV Certification with the FDA.

29. 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 [where the vitamin D compound is paricalcitol] . . . .” reads on the proposed label of Defendants’ paricalcitol injection NDA No. 205917.

30. Upon information and belief, Defendants seeks FDA marketing approval under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2) 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.

31. 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.

32. 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.

33. 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 B, 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.

34. 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.

35. Upon information and belief, Defendants' 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 B, Approved Labeling of Zemplar®, "Clinical Pharmacology".) Accordingly, a treating physician or healthcare professional following Defendants' 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.

36. At the time the '815 patent was filed, renal osteodystrophy was understood as a broad term that encompasses secondary hyperparathyroidism such that treatment of secondary hyperparathyroidism was understood to be treatment of renal osteodystrophy. For example, a 1988 publication by Dr. DeLuca, described how the discovery of the active form of vitamin D led to "an immediate application" to renal osteodystrophy in that oral treatment with a synthetic form of the drug resulted in, inter alia, "a suppression of secondary hyperparathyroidism." (H. DeLuca, The Vitamin D Story, 2 FASEB J 224 (1988).) The same article noted that injection of synthetic active vitamin D was "extremely effective in suppressing secondary hyperparathyroidism found in renal osteodystrophy." (*Id.* at 226.) A 1991 treatise chapter co-authored by Dr. Slatopolsky described the treatment of secondary hyperparathyroidism as an objective under the general heading of "Prevention and Management of Renal Osteodystrophy." These publications reflect the understanding of skilled artisans in the field that treatment of renal osteodystrophy would encompass treatment of secondary hyperparathyroidism such that the '815 patent claims would cover the approved indication for Zemplar and Defendants' generic paricalcitol products.

37. 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, upon information and belief, will be copied by Defendants with respect to its NDA products and included with every vial of Defendants’ proposed paricalcitol injectable drug products.

38. 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.

39. Upon information and belief, Defendants have knowledge of the claims and disclosures of ’815 patent, and have knowledge that their 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 NDA No. 205917, if approved and marketed in the United States, would result in Defendants knowingly and intentionally encouraging, promoting, and inducing infringement of the ’815 patent.

40. Moreover, there is no substantial non-infringing use of paricalcitol injection that is authorized in the United States. The proposed products and labeling in NDA No. 205917, if approved and marketed in the United States, will unavoidably contribute to the infringement of the ’815 patent.

41. Plaintiffs are commencing this action within forty-five days of the date that Plaintiffs received Hikma’s July 30, 2013 Paragraph IV Notice of NDA No. 205917.

42. Hikma has committed and will commit acts of infringement of the ’815 patent that create a justiciable case or controversy between Plaintiffs and Defendants. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hikma committed an act of infringement by filing a 505(b)(2) application with a Paragraph IV certification that seeks FDA marketing approval for Hikma’s generic copy of AbbVie’s paricalcitol injection prior to the expiration of the ’815 patent. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs’ rights under the ’815 patent.

43. Upon information and belief, Hikma, West-Ward, and Exela Pharma continue to collaborate to seeking approval of NDA No. 205917 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of a generic paricalcitol injection (including commercial marketing and sale of such products in the State of Delaware) in the event that the FDA approves NDA No. 205917.

COUNT 1
INFRINGEMENT OF THE ’815 PATENT

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

45. Under 35 U.S.C. § 271(e)(2)(A), Hikma infringed one or more claims of the ’815 patent by submitting to the FDA an NDA under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval for the commercial marketing, before the expiration date of the

'815 patent, of its paricalcitol injectable drug products labeled for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5, products the use of sale of which would infringe and contribute to and induce direct infringement of one or more claims of the '815 patent by ultimate purchasers.

46. Upon information and belief, West-Ward and Exela Pharma have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of at least claim 4 of the '815 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Hikma (1) to file NDA No. 205917 seeking approval to introduce into interstate commerce paricalcitol injectable drug products in 2 mcg/ml and 5 mcg/ml formulations; (2) to prepare to sell paricalcitol injectable drug products pursuant to the NDA 205917; and (3) to intend to sell such paricalcitol injectable drug 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.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT 2
DECLARATORY JUDGMENT AS TO THE '815 PATENT

48. Paragraphs 1–47 are incorporated herein by reference.

49. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell generic paricalcitol injection products labeled for the same indication and the same dosage and method of use as the Zemplar® products sold by AbbVie.

50. Upon further information and belief, Defendants intend to commence sales of such generic paricalcitol injectable drug products immediately upon receiving approval from the FDA.

51. The manufacture, importation, use, sale, or offer for sale of such generic paricalcitol injectable drug products, once approved by the FDA, will infringe one or more claims of the ’815 patent.

52. Defendants’ 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(a) declaring the ’815 patent valid and enforceable;

(b) finding that Hikma has infringed one or more claims of the ’815 patent by filing NDA No. 205917 under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2);

(c) declaring that Defendants would infringe one or more claims of the ’815 patent by the threatened acts of making, importing, using, offering to sell, or selling its paricalcitol injectable products prior to the expiration of said patent;

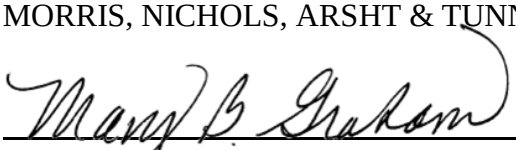
(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Hikma’s NDA No. 205917 relating to paricalcitol injectable drug products before the expiration of the six-month period of market exclusivity for the ’815 patent granted under 21 U.S.C. § 355A;

(e) enjoining Defendants from commercially making, importing, using, offering to sell, or selling their paricalcitol injectable drug 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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