IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and WISCONSIN ALUMNI RESEARCH FOUNDATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AGILA SPECIALTIES PRIVATE LIMITED, STRIDES ARCOLAB LIMITED, and STRIDES INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendants Agila Specialties Private Limited ("Agila"), Strides Arcolab Limited ("Strides Arcolab"), and Strides Inc. (collectively "Defendants" or "Strides") 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 Agila's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott'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. Abbott is a corporation organized and existing under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, 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 Agila is an Indian corporation having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore - 560076, India. On information and belief, Agila is a wholly owned subsidiary of Strides Arcolab and is the specialties unit of Strides Arcolab. On information and belief, Strides Inc. is the U.S. agent for Agila. On information and belief, Agila is engaged in the manufacture, marketing, and sale of generic pharmaceutical products for distribution throughout the United States, including into the State of Delaware.

5. On information and belief, Defendant Strides Arcolab is an Indian corporation having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore - 560076, India. On information and belief, Strides Arcolab, itself and through its wholly owned subsidiary and agent Strides Inc. and its wholly owned subsidiary Agila, is in

the business of, among other things, manufacturing, marketing, and selling generic pharmaceutical products for distribution throughout the United States, including into the State of Delaware.

6. On information and belief, Defendant Strides Inc. is a corporation organized and existing under the laws of New Jersey and maintains offices at 201 S. Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Inc. is a wholly owned subsidiary and agent of Strides Arcolab. On information and belief, Strides Inc. is also the U.S. agent for Agila. On information and belief, Strides Inc., on behalf of Strides Arcolab and Agila, manufactures, markets, and sells generic pharmaceutical products for distribution throughout the United States, including into the State of Delaware.

7. On information and belief, Defendants Agila and Strides Inc. are wholly owned subsidiaries of Strides Arcolab that act in concert with respect to collaborating in the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical products pursuant to Abbreviated New Drug Applications.

JURISDICTION AND VENUE

8. 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).

9. Agila, Strides Inc., and Strides Arcolab are subject to personal jurisdiction in this District because, on information and belief, they regularly and continuously transact business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

10. Strides Inc. did not challenge personal jurisdiction in this District in *Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC v. Strides Inc. and Onco Therapies, Ltd.*, No. 11-1121.

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

FACTS PERTINENT TO ALL COUNTS

12. On October 24, 2000, the PTO issued the '799 patent, entitled "Cosolvent Formulations," to Plaintiff Abbott, the assignee of the named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier. Abbott remains the current assignee and owner of the '799 patent. A copy of the '799 patent is attached hereto as Exhibit A.

13. The '799 patent expires on April 8, 2018.

14. On March 26, 2002, the PTO issued the '758 patent, entitled "Cosolvent Formulations," to Plaintiff Abbott, the assignee of the named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier. Abbott remains the current assignee and owner of the '758 patent. A copy of the '758 patent is attached hereto as Exhibit B.

15. The '758 patent expires on April 8, 2018.

16. On January 28, 1997, the PTO issued the '815 patent, entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients," to Plaintiff WARF, the assignee of the named inventors Hector F. Deluca and Eduardo Slatopolsky. Abbott is the exclusive licensee of the '815 patent. A copy of the '815 patent is attached hereto as Exhibit C.

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

18. 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 Abbott 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.”

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

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

21. On information and belief, Strides actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

22. On information and belief, Strides prepared and submitted to the FDA ANDA No. 203897, 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.

23. On or about March 12, 2012, Plaintiffs received a letter dated March 8, 2012, from Strides Inc. notifying Plaintiffs that Agila had filed ANDA No. 203897 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”), and stating

that, in Agila'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. 203897.

24. Strides was necessarily aware of the patents-in-suit when it filed ANDA No. 203897 containing the Paragraph IV Certification with the FDA.

25. 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 Agila's paricalcitol injection ANDA No. 203897.

26. Upon information and belief, Strides 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. Upon information and belief, Agila'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 Agila'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.

32. 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." ('815 patent, 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 Agila with respect to its ANDA products and included with every vial of Strides's proposed paricalcitol injection products.

33. 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.

34. Upon information and belief, Strides has knowledge of the claims and disclosures of the ’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. 203897, if approved and marketed in the United States, would result in Strides knowingly and intentionally encouraging, promoting, and inducing infringement of the ’815 patent.

35. 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. 203897 constitute a material part of the claimed method, are knowingly and especially made and adapted for use in that method, and, if approved and marketed in the United States, will unavoidably contribute to the infringement of the ’815 patent.

36. Plaintiffs are commencing this action within forty-five days of the date they received Strides Inc. and Agila’s Paragraph IV Notice of ANDA No. 203897 containing the Paragraph IV Certification.

37. Strides has committed and will commit acts of infringement of the patents-in-suit that create a justiciable case or controversy between Plaintiffs and Strides. Pursuant to 35 U.S.C. § 271(e)(2)(A), Strides committed an act of infringement by filing an ANDA with a Paragraph IV Certification that seeks FDA-marketing approval for Strides’s generic versions of Abbott’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

38. Paragraphs 1-37 are incorporated herein by reference.

39. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the '799 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the '799 patent, 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.

40. Abbott will be substantially and irreparably damaged and harmed if Strides's infringement is not enjoined. Abbott does not have an adequate remedy at law.

COUNT 2
DECLARATORY JUDGMENT AS TO THE '799 PATENT

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

42. Upon information and belief, Strides 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 Abbott.

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

44. The manufacture, importation, use, 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.

45. Strides'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.

46. Abbott will be substantially and irreparably damaged and harmed if Strides's threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

COUNT 3
INFRINGEMENT OF THE '758 PATENT

47. Paragraphs 1-46 are incorporated herein by reference.

48. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the '758 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the '758 patent, 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.

49. Abbott will be substantially and irreparably damaged and harmed if Strides's infringement is not enjoined. Abbott does not have an adequate remedy at law.

COUNT 4
DECLARATORY JUDGMENT AS TO THE '758 PATENT

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

51. Upon information and belief, Strides 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 Abbott.

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

53. The manufacture, importation, use, 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.

54. Strides’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.

55. Abbott will be substantially and irreparably damaged and harmed if Strides’s threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

COUNT 5
INFRINGEMENT OF THE ’815 PATENT

56. Paragraphs 1-55 are incorporated herein by reference.

57. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the ’815 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the ’815 patent, 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.

58. Upon information and belief, Strides 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. 203897 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.

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

COUNT 6
DECLARATORY JUDGMENT AS TO THE ’815 PATENT

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

61. Upon information and belief, Strides 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 Abbott.

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

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

64. Strides’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.

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

EXCEPTIONAL CASE

66. Paragraphs 1-65 are incorporated herein by reference.

67. This is an exceptional case warranting imposition of attorneys' fees against Defendants under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Strides as follows:

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

(b) finding that Strides has infringed one or more claims of the '799, '758, and '815 patents by filing ANDA No. 203897 under 21 U.S.C. § 355(j)(2);

(c) finding that Strides 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 injection products prior to the expiration of said patents;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Agila's ANDA No. 203897 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 Strides from commercially making, importing, using, offering to sell, or selling its generic paricalcitol injection products, in accordance with 35 U.S.C. § 271(e)(4)(B);

(f) finding this to be an exceptional case and awarding Plaintiffs attorneys' 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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