IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Abbott Laboratories ("Abbott"), for its Complaint against Defendant Hospira, Inc., ("Hospira"), alleges 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") and 6,361,758 ("the '758 patent"). This action arises out of Hospira'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 paricalcitol injectable drug products prior to the expiration of the '799 and '758 patents.

THE PARTIES

2. Abbott is a corporation organized 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. On information and belief, Defendant Hospira is a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 275 Field Drive, Lake Forest, Illinois 60045.

JURISDICTION AND VENUE

4. 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).

5. Hospira 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.

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

FACTS PERTINENT TO ALL COUNTS

7. 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. A copy of the ’799 patent is attached hereto as Exhibit A.

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

9. 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. A copy of the '758 patent is attached hereto as Exhibit B.

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

11. The '799 and '758 patents (collectively, "the patents-in-suit") are listed in the 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®.

12. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of each of the '799 and '758 patents.

13. On information and belief, Hospira prepared and submitted with the FDA NDA No. 201-657 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, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations, prior to the expiration of the patents-in-suit.

14. On or about June 8, 2011, Abbott received a letter ("Paragraph IV Notice") dated June 7, 2011, from Hospira notifying Abbott that Hospira had filed NDA No. 201-657 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 the patents-in-suit are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale or sale of the [paricalcitol injectable] drug product[s] described in Hospira's NDA."

15. Hospira did not provide a factual or legal basis for any challenge to the validity or enforceability of the '799 patent or the '758 patent.

16. On information and belief, Hospira was necessarily aware of the patents-in-suit when it filed NDA No. 201-657 containing the Paragraph IV Certification with the FDA.

17. This action is being commenced by Abbott within forty-five days of the date it received Hospira's Paragraph IV Notice of NDA No. 201-657 containing the Paragraph IV Certification, pursuant to § 505(b)(3)(B) of the FFDCA.

18. Hospira has committed and will commit acts of infringement of the patents-in-suit that create a justiciable case or controversy between Abbott and Hospira. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hospira committed an act of infringement by filing an NDA under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2), with a Paragraph IV Certification that seeks FDA marketing approval for Hospira's paricalcitol injectable drug products prior to expiration of the patents-in-suit. This Court has subject matter jurisdiction with respect to this action to declare Abbott's rights under the patents-in-suit.

COUNT 1
INFRINGEMENT OF THE '799 PATENT

19. Paragraphs 1-18 are incorporated herein by reference.

20. Under 35 U.S.C. § 271(e)(2)(A), Hospira infringed one or more claims of the '799 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 '799 patent, of its paricalcitol injectable drug products, the making, using, selling, offering for sale, or importing of which would infringe one or more claims of the '799 patent.

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

COUNT 2
DECLARATORY JUDGMENT AS TO THE '799 PATENT

22. Paragraphs 1-21 are incorporated herein by reference.

23. Upon information and belief, Hospira has made substantial preparations to sell the paricalcitol injectable drug products described in NDA No. 201-657.

24. Upon further information and belief, Hospira intends to commence sales of such paricalcitol injectable drug products immediately upon receiving approval from the FDA.

25. The manufacture, use, importation, sale, or offer for sale of paricalcitol injectable drug products, once approved by the FDA, would infringe one or more claims of the '799 patent.

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

COUNT 3
INFRINGEMENT OF THE '758 PATENT

27. Paragraphs 1-26 are incorporated herein by reference.

28. Under 35 U.S.C. § 271(e)(2)(A), Hospira infringed one or more claims of the '758 patent by submitting to the FDA an NDA under § 505(b)(2) of the of the FFDCA, 21 U.S.C. 21 U.S.C. § 355(b)(2), seeking approval for the commercial marketing, before the expiration date of the '758 patent, of its paricalcitol injectable drug products, the making, using, selling, offering for sale, or importing of which would one or more claims of the '758 patent.

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

COUNT 4
DECLARATORY JUDGMENT AS TO THE '758 PATENT

30. Paragraphs 1-29 are incorporated herein by reference.

31. Upon information and belief, Hospira has made substantial preparations to sell the paricalcitol injectable drug products described in NDA No. 201-657.

32. Upon further information and belief, Hospira intends to commence sales of such paricalcitol injectable drug products immediately upon receiving approval from the FDA.

33. The manufacture, use, importation, sale, and offer for sale of paricalcitol injectable drug products, once approved by the FDA, would infringe one or more claims of the '758 patent.

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

EXCEPTIONAL CASE

35. Paragraphs 1-34 are incorporated herein by reference.

36. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Abbott demands judgment against Hospira as follows:

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

(b) finding that Hospira has infringed one or more claims of the '799 and '758 patents by filing NDA No. 201-657 under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2);

(c) declaring that Hospira would infringe one or more claims of the '799 and '758 patents by the threatened acts of making, using, importing, 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 Hospira's NDA No. 201-657 relating to paricalcitol injectable products before the expiration of the six-month period of market exclusivity for the '799 and '758 patents granted under 21 U.S.C. § 355A;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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