IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation,	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
SANDOZ INC., a Colorado corporation,	)	
Defendant.	)	

COMPLAINT

Plaintiff Abbott Laboratories ("Abbott"), for its complaint against defendant Sandoz Inc. ("Sandoz"), alleges as follows:

THE PARTIES

1. 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.

2. On information and belief, Sandoz is a corporation organized under the laws of the State of Colorado. Sandoz's corporate headquarters are located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

3. 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. Specifically, this action arises under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Sandoz is subject to personal jurisdiction in this District because, upon information and belief, Sandoz regularly and continuously transacts business in the District of Delaware, by making and shipping into this Judicial District, or by using, offering to sell or selling, or by causing others to use, offer to sell or sell in this Judicial District, pharmaceutical products. Upon information and belief, Sandoz derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Delaware and this Judicial District. By filing its Abbreviated New Drug Application ("ANDA"), Sandoz has committed and, unless enjoined, will continue to commit a tortious act within the State of Delaware, which Sandoz expects or reasonably should expect to have consequences in the State of Delaware.

5. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b).

FACTUAL BACKGROUND

A. The ′510 Patent

6. Abbott sells a prescription drug product under the brand name Nimbex® (cisatracurium besylate). Nimbex® (cisatracurium besylate) is an intravenous non-depolarizing neuromuscular blocker, also known as a skeletal muscle relaxant. Nimbex® (cisatracurium besylate) is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or to aide in mechanical ventilation of patients in Intensive Care Units. The active ingredient in Nimbex® is cisatracurium besylate.

7. On December 15, 1995, the United States Food and Drug Administration ("FDA") approved New Drug Application No. 020551 to market Nimbex® (cisatracurium besylate) in three dosages: (i) 2 mg/mL (sold by Abbott in a 10 mL vial); (ii) 10 mg/mL preservative free (sold by Abbott in a 20 mL vial); and (iii) 2 mg/mL preservative free (sold by

Abbott in a 5 mL vial). As a result, Nimbex® (cisatracurium besylate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs listed in the Orange Book may be used as the basis of a later applicant's ANDA to obtain approval of the applicant's generic drug product under the provisions of 21 U.S.C. § 355(j).

8. Abbott is the owner of and has the right to enforce United States Patent No. 5,453,510 ("the ′510 patent"), entitled "Neuromuscular Blocking Agents." (A copy of the ′510 patent is attached as Exhibit A and is incorporated by reference.) The ′510 patent issued on September 26, 1995, and expires on September 26, 2012.

9. The ′510 patent is listed in the FDA's Orange Book in association with the 2 mg/mL, 10 mg/mL preservative free, and 2 mg/mL preservative free dosage strengths of Nimbex® (cisatracurium besylate).

B. Sandoz Notifies Abbott Regarding the Filing of ANDA Nos. 200154 and 200159

10. Abbott received a letter from Sandoz dated November 6, 2009, stating that (i) Sandoz submitted ANDA No. 200154 to the FDA, requesting approval to market a generic version of Nimbex® (cisatracurium besylate)—called "Cisatracurium Besylate Injection"—in 2 mg/mL, 5 mL vial and 10 mg/mL, 20 mL vial, Preservative Free dosage strengths; (ii) the active ingredient in Sandoz's proposed product is cisatracurium besylate; (iii) the ANDA included a Paragraph IV Certification (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) directed to the ′510 patent; and (iv) Sandoz sought FDA approval to market Sandoz's proposed generic product before the ′510 patent expires.

11. Abbott received a second letter from Sandoz, also dated November 6, 2009, stating that (i) Sandoz submitted ANDA No. 200159 to the FDA, requesting approval to market a generic version of Nimbex® (cisatracurium besylate)—called "Cisatracurium Besylate

Injection"—in a 2 mg/mL, 10 mL vial dosage strength; (ii) the active ingredient in Sandoz's proposed product is cisatracurium besylate; (iii) the ANDA included a Paragraph IV Certification (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) directed to the ′510 patent; and (iv) Sandoz sought FDA approval to market Sandoz's proposed generic product before the ′510 patent expires.

12. Sandoz attached to both letters a purportedly "Detailed Statement of Factual and Legal Bases" for its Paragraph IV Certification with regards to the ′510 patent. *See* 21 U.S.C. § 355(j)(2)(B)(iv); *see also* 21 C.F.R. §§ 314.95(c)(6)(i)-(ii). In that document, Sandoz only contested the validity and enforceability of the ′510 patent. 21 C.F.R. § 314.95(c)(6)(ii). Sandoz did not otherwise contest that its proposed Cisatracurium Besylate Injections would, if allowed on the market, infringe the ′510 patent. Applicable regulations require an ANDA applicant to set forth in its Paragraph IV Certification notice "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." 21 C.F.R. § 314.95(c)(6). If the applicant contends that the patent will not be infringed by its proposed generic product, its notice must include "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed." 21 C.F.R. § 314.95(c)(6)(i). Sandoz's provision of Paragraph IV Certification notices with no non-infringement contentions is therefore an admission that the proposed generic cisatracurium besylate products described in ANDA Nos. 200154 and 200159, if allowed on the market, will infringe the claims of the ′510 patent.

13. Sandoz did not include in its Paragraph IV Certifications or accompanying letters to Abbott dated November 6, 2009, an Offer of Confidential Access to its ANDA

Nos. 200154 and 200159 likely to bear on the composition of Sandoz's proposed generic cisatracurium besylate products.

14. On information and belief, Sandoz seeks FDA approval of its proposed generic cisatracurium besylate products as an adjunct to general anesthesia, to be used by healthcare providers as a material component of treatment to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or to aide in mechanical ventilation of patients in Intensive Care Units. On information and belief, Sandoz understands and intends that its proposed generic cisatracurium besylate products, if approved, will be utilized by providers for these purposes in their treatment of patients.

15. On information and belief, Sandoz's proposed generic cisatracurium besylate products will include labeling indicating that it has been approved by the FDA to facilitate tracheal intubation and provide skeletal muscle relaxation during surgery or to aide in mechanical ventilation of patients in Intensive Care Units. On information and belief, that label will also include information regarding the administration of Sandoz's proposed cisatracurium besylate products in a manner and concentration identical to one of those that have been approved by the FDA under Abbott's New Drug Application for Nimbex® (cisatracurium besylate): (i) 2 mg/mL (sold by Abbott in a 10 mL vial); (ii) 10 mg/mL preservative free (sold by Abbott in a 20 mL vial); and (iii) 2 mg/mL preservative free (sold by Abbott in a 5 mL vial).

COUNT I: INFRINGEMENT OF THE '510 PATENT

16. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-15 as if fully set forth herein.

17. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in

a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent.

18. On information and belief, Sandoz submitted ANDA Nos. 200154 and 200159 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use and/or sale of its generic cisatracurium besylate products before the expiration of the ′510 patent.

19. Sandoz's submission of ANDA No. 200154 for approval to sell Cisatracurium Besylate Injections in 2 mg/mL, 5 mL vial preservative free and 10 mg/mL, 20 mL vial preservative free dosage strengths before the expiration of the ′510 patent constitutes an act of infringement of the ′510 patent pursuant to 35 U.S.C. § 271(e)(2).

20. Sandoz's submission of ANDA No. 200159 for approval to sell Cisatracurium Besylate Injections in a 2 mg/mL, 10 mL vial dosage strength before the expiration of the ′510 patent constitutes an act of infringement of the ′510 patent pursuant to 35 U.S.C. § 271(e)(2).

21. Sandoz's proposed generic version of Nimbex® (cisatracurium besylate), as described in ANDA No. 200154, utilizes a composition, formulation and method that infringes the ′510 patent.

22. Sandoz's proposed generic version of Nimbex® (cisatracurium besylate), as described in ANDA No. 200159, utilizes a composition, formulation and method that infringes the ′510 patent.

23. On information and belief, when Sandoz filed ANDA Nos. 200154 and 200159, it was aware of the ′510 patent and that the filing of its ANDA seeking approval from the FDA prior to expiration of the ′510 patent was an act of infringement of the ′510 patent.

24. Abbott commenced this action within forty-five days of the date it received Sandoz's Paragraph IV Certification notices of ANDA Nos. 200154 and 200159 containing the Paragraph IV Certifications.

25. On information and belief, the use of Sandoz's proposed generic cisatracurium besylate products to be distributed and/or sold by Sandoz would infringe one or more claims of the ′510 patent under 35 U.S.C. § 271.

26. On information and belief, this infringing use of Sandoz's proposed generic cisatracurium besylate products will occur at Sandoz's behest, and with its intent, knowledge and encouragement, and Sandoz will actively induce, encourage, contribute to, aid and abet this administration with knowledge that it is in contravention of the ′510 patent.

27. As a result, Sandoz is and will be indirectly liable for inducing and/or contributing to infringement of the ′510 patent under 35 U.S.C. §§ 271(e)(2), (b) or (c).

28. Sandoz is liable for direct infringement of the ′510 patent.

29. Sandoz is liable for inducing the infringement and contributing to the infringement of the ′510 patent.

30. Abbott has no adequate remedy at law to redress Sandoz's infringement.

31. By reason of the foregoing, there is a substantial and ongoing actual controversy between Abbott and Sandoz. Declaration of rights is both necessary and appropriate to establish that Sandoz directly infringes, induces, and contributes to the infringement of the ′510 patent.

32. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Abbott's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

a. a judgment declaring that the ′510 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA Nos. 200154 and 200159;

b. an order declaring that the effective date of any FDA approval of ANDA Nos. 200154 and 200159 or Sandoz's generic cisatracurium besylate products shall be no earlier than the expiration date of Abbott's ′510 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

c. an injunction prohibiting Sandoz and any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a cisatracurium besylate product covered by the ′510 patent, or otherwise infringing one or more claims of the ′510 patent during the life of the patent;

d. judgment declaring that Sandoz's generic cisatracurium besylate products, if approved by the FDA, would infringe one or more claims of the ′510 patent;

e. judgment declaring that Sandoz's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic cisatracurium besylate products would constitute infringement of one or more claims of the ′510 patent;

f. an injunction prohibiting Sandoz and any of its officers, agents, attorneys and employees and those acting in privity or concert with it, from engaging in further acts of direct infringement, inducement of infringement, and contributory infringement of the ′510 patent;

g. an award of Abbott's costs and attorneys' fees pursuant to 35 U.S.C. § 271(e)(4) and § 285; and

h. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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