IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION,	)	
	)	
Plaintiff	)	
v.	)	C.A. No. _____
	)	
SANDOZ INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Genzyme Corporation ("Genzyme"), by and through its attorneys, and for its Complaint herein against Defendant Sandoz Inc. ("Sandoz"), hereby alleges as follows:

Nature Of The Action

1. This is an action for patent infringement.

Parties

2. Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

3. On information and belief, Sandoz is a corporation organized and existing under the laws of the state of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

Jurisdiction And Venue

4. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, Sandoz manufactures, distributes and sells generic pharmaceutical products throughout the United States, including in the State of

Delaware. This Court has personal jurisdiction over Sandoz because Sandoz has purposefully availed itself of the privilege of doing business in the State of Delaware so as to reasonably allow jurisdiction to be exercised over it. In addition, Sandoz has previously agreed to personal jurisdiction in this Court, and has availed itself of the legal protections of the District of Delaware by filing counterclaims seeking judicial relief from this Court in *Bone Care International LLC et al v. Sandoz Inc.*, Civil Action No. 09-524 (since consolidated under *Bone Care International LLC et al v. Eagle Pharmaceuticals Inc.*, Civil Action No. 09-285). This Court has personal jurisdiction over Sandoz by virtue of, *inter alia*, the above-mentioned facts.

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

Claim For Relief – Patent Infringement

7. Genzyme holds approved New Drug Application ("NDA") No. 021-027 for Hectorol® injectable (2 μg/mL), which product contains the active ingredient doxercalciferol.

8. Doxercalciferol is known chemically as 1α-OH-vitamin D_2, 1-alpha-hydroxyvitamin D_2, 1α-OH-D_2 and 1α-hydroxyergocalciferol.

9. The U.S. Food and Drug Administration ("FDA") approved the Hectorol® injectable product on April 6, 2000, and it is currently indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

10. In April 2008, Genzyme submitted to the FDA (1) an amendment to NDA No. 021-027 seeking approval from the FDA to change the formulation and packaging configuration of its Hectorol® injectable product; and (2) patent information for United States Patent Nos. 5,602,116 ("the '116 patent") and 7,148,211 ("the '211 patent") pursuant to 21 C.F.R. § 314.53.

11. In a letter dated April 7, 2010, Sandoz notified Genzyme that Sandoz submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 200926 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of a generic injectable product containing 2 μg/mL doxercalciferol ("Sandoz's Proposed Generic Product").

Count I – Infringement Of The '116 Patent

12. Genzyme repeats and realleges the allegations of paragraphs 1-11 as though fully set forth herein.

13. On February 11, 1997, the '116 patent, titled "Method For Treating And Preventing Secondary Hyperparathyroidism" was duly and legally issued by the United States Patent and Trademark Office. The '116 patent claims a method for lowering or maintaining lowered serum parathyroid hormone in human patients suffering from hyperparathyroidism secondary to end stage renal disease by administering doxercalciferol. A copy of the '116 patent is attached hereto as Exhibit A.

14. Genzyme is the owner of the '116 patent.

15. On information and belief, Sandoz submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '116 patent.

16. By submitting ANDA No. 200926 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '116 patent, Sandoz has infringed the '116 patent under 35 U.S.C. § 271(e)(2)(A). Further, the

commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Proposed Generic Product, if approved by the FDA, would infringe one or more claims of the '116 patent.

17. On information and belief, Sandoz made, and included in its ANDA, a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which states that, in Sandoz's opinion, the claims of the '116 patent are invalid and unenforceable.

18. The offer for sale and sale of Sandoz's Proposed Generic Product, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, one or more claims of the '116 patent.

19. Sandoz had notice of the '116 patent prior to undertaking its acts of infringement.

20. Genzyme is entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 200926 be a date which is not earlier than the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled, and an award of damages for any commercial sale or use of Sandoz's Proposed Generic Product and any act committed by Sandoz with respect to the subject matter claimed in the '116 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

Count II – Infringement Of The '211 Patent

21. Genzyme repeats and realleges the allegations of paragraphs 1-11 as though fully set forth herein.

22. On December 12, 2006, the '211 patent, titled "Formulation For Lipophilic Agents" was duly and legally issued. The '211 patent claims parenteral formulations of doxercalciferol; a non-ionic solubilizer which is polysorbate 20 and a lipophilic antioxidant which is butylated hydroxytoluene and which are present within a range of concentration; an

optional agent which is ethanol; and an aqueous vehicle. A copy of the '211 patent is attached hereto as Exhibit B.

23. Genzyme is the owner of the '211 patent.

24. On information and belief, Sandoz submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '211 patent.

25. By submitting ANDA No. 200926 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '211 patent, Sandoz has infringed the '211 patent under 35 U.S.C. § 271(e)(2)(A). Further, the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Proposed Generic Product, if approved by the FDA, would infringe one or more claims of the '211 patent.

26. On information and belief, Sandoz made, and included in its ANDA, a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which states that, in Sandoz's opinion, the claims of the '211 patent are invalid and unenforceable.

27. The offer for sale and sale of Sandoz's Proposed Generic Product, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, one or more claims of the '211 patent.

28. Sandoz had notice of the '211 patent prior to undertaking its acts of infringement.

29. Genzyme is entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 200926 be a date which is not earlier than the expiration of the '211 patent, and any other exclusivity to

which Genzyme is or becomes entitled, and an award of damages for any commercial sale or use of Sandoz's Proposed Generic Product and any act committed by Sandoz with respect to the subject matter claimed in the '211 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

Prayer For Relief

WHEREFORE, Genzyme respectfully requests the following relief:

(a) A Judgment declaring that Sandoz has infringed one or more claims of the '116 patent by filing its ANDA No. 200926 relating to Sandoz's Proposed Generic Product;

(b) A Judgment declaring that Sandoz has infringed one or more claims of the '211 patent by filing its ANDA No. 200926 relating to Sandoz's Proposed Generic Product;

(c) An Order that the effective date of any FDA approval of Sandoz's ANDA No. 200926 be no earlier than the date on which the '116 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;

(d) An Order that the effective date of any FDA approval of Sandoz's ANDA No. 200926 be no earlier than the date on which the '211 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;

(e) Preliminary and permanent injunctions enjoining Sandoz, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Sandoz's Proposed Generic Product until after the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled;

(f) Preliminary and permanent injunctions enjoining Sandoz, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation

into the United States of Sandoz's Proposed Generic Product until after the expiration of the '211 patent, and any other exclusivity to which Genzyme is or becomes entitled;

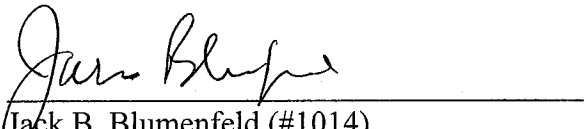
(g) If Sandoz engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled, a Judgment awarding damages to Genzyme resulting from such infringement;

(h) If Sandoz engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Sandoz's Proposed Generic Product prior to the expiration of the '211 patent, and any other exclusivity to which Genzyme is or becomes entitled, a Judgment awarding damages to Genzyme resulting from such infringement;

(i) The costs and reasonable attorney fees of Genzyme in this action; and

(j) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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