IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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| GENZYME CORPORATION, | ) | |
| Plaintiff, | ) | |
| v. | ) | Civil Action No.: 09-cv-00653-JFM |
| IMPAX LABORATORIES, INC. | ) | |
| Defendant. | ) | |

**PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIMS**

Plaintiff Genzyme Corporation ("Genzyme") for its answer to the counterclaims of Defendant Impax Laboratories, Inc. ("Impax") hereby states as follows:

**PARTIES**

1. Counterclaim-Plaintiff Impax is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

**ANSWER:** On information and belief, Genzyme admits the allegations in paragraph 1.

2. On information and belief, Counterclaim-Defendant Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

**ANSWER:** Genzyme admits the allegations in paragraph 2.

**U.S. Patent No. 6,733,780**

3. On information and belief, on May 11, 2004, U.S. Patent No. 6,733,780 ("the '780 patent"), titled "Direct Compression Polymer Tablet Core," was issued. The face of the

'780 patent lists Genzyme Corporation as assignee. A copy of the '780 patent is attached hereto as Exhibit A.

**ANSWER:** Genzyme admits the allegations in paragraph 3.

4. On information and belief, Genzyme Corporation is the owner of the '780 patent.

**ANSWER:** Genzyme admits the allegation in paragraph 4.

5. On information and belief, the '780 patent is scheduled to expire on October 18, 2020.

**ANSWER:** Genzyme admits the allegation in paragraph 5.

6. On information and belief, Genzyme has the right under the Patent Act to sue for infringement of the '780 patent.

**ANSWER:** Genzyme admits the allegation in paragraph 6.

## BACKGROUND

### A. FDA Approval Of New Brand-Name Drugs.

7. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

**ANSWER:** Genzyme admits the allegations in paragraph 7.

8. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

**ANSWER:** Genzyme admits the allegation in paragraph 8.

9. A NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a

claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2): 21 C.F.R. § 314.53(b), -(c)(2).

**ANSWER:** Genzyme admits the allegations in paragraph 9.

10. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." See 21 U.S.C. § 355(j)(7)(A)(iii).

**ANSWER:** Genzyme admits the allegations in paragraph 10.

**B. Generic Competition - Abbreviated New Drug Applications.**

11. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

**ANSWER:** Genzyme admits that generic drugs are versions of brand-name prescription drugs that contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original. Genzyme denies any remaining allegations in paragraph 11.

12. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

**ANSWER:** Genzyme admits that Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA in

1984 and that to obtain approval for a generic drug under the Hatch-Waxman Amendments, a generic manufacturer submits an ANDA. Genzyme denies all remaining allegations in paragraph 12.

13. To receive FDA approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

**ANSWER:** Genzyme admits the allegation in paragraph 13.

14. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii): 21 C.F.R. § 314.94(a)(12).

**ANSWER:** Genzyme admits the allegation in paragraph 14.

15. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 31494(a)(12).

**ANSWER:** Genzyme admits that a paragraph IV certification asserts that in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. Genzyme denies the remaining allegations in paragraph 15.

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

**ANSWER:** Genzyme admits the allegation in paragraph 16.

17. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Genzyme admits that the patent holder may file an infringement suit against the generic manufacturer upon receiving notice of the paragraph IV certification. Genzyme denies the remaining allegations in paragraph 17.

18. Patent holders have a significant strategic incentive to file suit within 45 days because doing so, regardless of merit, prevents FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Genzyme admits that the approval of an ANDA may be made effective on the last applicable date determined by applying the criteria set out in 21 U.S.C. § 355(j)(5)(B) to each certification to the Orange Book listed patents for the listed reference drug. If a patent holder files an infringement suit against an applicant for an ANDA which contains a paragraph IV certification within 45 days of receipt of the notice of the paragraph IV certification, approval may be made effective upon the expiration of the 30-month period beginning on the date of the receipt of the notice of the paragraph IV certification or such shorter or longer period as the court may order, absent certain exceptions. Genzyme denies the remaining allegations in paragraph 18.

19. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or does not infringe, FDA may approve the ANDA. *Id.*

**ANSWER:** Genzyme admits the allegations in paragraph 19.

## C. Impax's ANDA

20. Impax filed ANDA No. 90-846 seeking generic approval for 400 mg and 800 mg sevelamer hydrochloride tablets ("Impax's ANDA products"). The ANDA shows that Impax's NDA products are bioequivalent to the product that is the subject of NDA No. 21-179, the holder of which FDA lists as Genzyme.

**ANSWER:** Genzyme admits that it is the holder of NDA No. 21-179 for Renagel® tablets, 400 mg and 800mg, which products contain the active ingredient sevelamer hydrochloride. Genzyme further admits that by a letter dated January 27, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) ("Impax's Notice Letter"), Impax informed Genzyme that it had submitted to the FDA ANDA No. 90-846 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 Impax's ANDA products. Genzyme denies the remaining allegations in paragraph 20.

21. Genzyme lists U.S. Patent Nos. 5,667,775 ("the '775 patent") and 6,733,780 ("the '780 patent"), among others, in the Orange Book in connection with NDA No. 21-179.

**ANSWER:** Genzyme admits the allegations in paragraph 21.

22. Because Impax seeks FDA approval to market its ANDA product before expiration of the '775 and '780 patents, Impax's ANDA includes paragraph IV certifications to those patents.

**ANSWER:** Genzyme admits that Impax's Notice Letter informed Genzyme that, as part of ANDA No. 90-846, Impax had filed paragraph IV certifications in respect of the '775 patent and '780 patent. Genzyme is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 22 and therefore denies the same.

23. On January 27, 2009, Impax sent to Genzyme a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the '775 and '780 patents are invalid, unenforceable, and/or not infringed by Impax's ANDA products.

**ANSWER:** Genzyme admits that Impax's Notice Letter dated January 27, 2009 purported to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) and informed Genzyme of Impax's paragraph IV certifications. Genzyme denies all remaining allegations in paragraph 23.

24. On March 23, 2009, Genzyme filed its patent infringement lawsuit against Impax, alleging that Impax's ANDA products would infringe the '775 patent, which Impax has denied herein.

**ANSWER:** Genzyme admits the allegations in paragraph 24.

25. Although a case or controversy exists between the parties on the '780 patent, Genzyme did not bring a lawsuit that Impax's ANDA products would infringe the '780 patent.

**ANSWER:** Genzyme admits that it did not bring a suit alleging that Impax's ANDA products would infringe the '780 patent. Genzyme contests this Court's subject matter jurisdiction with respect to the '780 patent and has moved to dismiss Impax's counterclaims for declaratory judgment of invalidity and/or non-infringement of the '780 patent. Genzyme denies any remaining allegations in paragraph 25.

26. Impax, on its notice letter and as required under 21 U.S.C. § 355(j)(5)(C), extended to Genzyme an Offer of Confidential Access to Application to access certain information in Impax's ANDA for generic sevelamer hydrochloride tablets.

**ANSWER:** Genzyme admits that Impax provided access to some information in its ANDA pursuant to an Offer of Confidential Access to Application. Genzyme denies all remaining allegations in paragraph 26.

27. By providing this Offer of Confidential Access to Application, and because Genzyme did not sue Impax on the '780 patent within 45 days of receipt of Impax's notice of paragraph IV certification, Impax is statutorily entitled to file and maintain a declaratory judgment action against Genzyme under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

**ANSWER:** Genzyme admits that it did not sue Impax on the '780 patent within 45 days of receipt of Impax's Notice Letter. Genzyme contests this Court's subject matter jurisdiction with respect to the '780 patent and has moved to dismiss Impax's counterclaims for declaratory judgment of invalidity and/or non-infringement of the '780 patent. Genzyme denies all remaining allegations in paragraph 27.

**D. Impax's Need to Obtain Court Judgment on the '780 Patent**

28. Impax is not only entitled to file these counterclaims, but Impax requires the decision of this Court to avoid indefinite delays in its approval of ANDA No. 90-846.

**ANSWER:** Genzyme contests this Court's subject matter jurisdiction with respect to the '780 patent and has moved to dismiss Impax's counterclaims for declaratory judgment of non-infringement and/or invalidity of the '780 patent. Genzyme denies all remaining allegations in paragraph 28.

29. On information and belief, Impax is not the first ANDA filer with respect to the '780 patent.

**ANSWER:** On information and belief, Genzyme admits the allegation in paragraph 29.

30. On information and belief, another company is the first ANDA filer with respect to the '780 patent, and, thus, arguably is entitled to a 180-day period of exclusivity on the '780 patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

**ANSWER:** On information and belief, Genzyme admits the allegations in paragraph 30.

31. If this is proven true, generic competition for sevelamer hydrochloride tablets may be delayed until 180 days after the expiration of the '780 patent in 2020, unless the first filer begins commercial marketing of its generic sevelamer hydrochloride tablets prior to the '780 patent's expiration date. Genzyme's refusal to litigate the validity and/or noninfringement of the '780 patent is purposefully preventing a court decision of invalidity, unenforceability and/or noninfringement on the '780 patent, which would trigger the first filer's 180-day exclusivity period for the '780 patent and thereby allow generic competition to the benefit of both Impax and the American public.

**ANSWER:** Genzyme denies the allegations in paragraph 31.

32. Moreover, until and unless Impax obtains a court decision of noninfringement and/or invalidity on the '780 patent, it faces potentially enormous infringement liability if it commences marketing before the '780 patent expires and the marketed product is deemed to infringe a valid claim of the '780 patent. I mpax can alleviate this harm and obtain patent certainty only through a declaratory judgment from this Court on the '780 patent.

**ANSWER:** Genzyme denies the allegations in paragraph 32. Genzyme has granted Impax a covenant not to sue on the '780 patent based upon either the submission of ANDA No. 90-846 to the FDA, or upon the importation, manufacture, use, sale or offer for sale of the products that are the subject of and described in ANDA No. 90-846. The covenant not to sue removes any possibility that Impax faces infringement liability, based on the '780 patent, if it commences marketing before its expiration.

## JURISDICTION AND VENUE

33. Impax realleges and incorporates by reference the allegations of paragraphs 1-32.

**ANSWER:** Genzyme repeats and realleges its answers in paragraphs 1-32 above as if fully set forth herein.

34. Substantial, present, genuine, and justiciable controversies exist between Genzyme and Impax regarding the '775 and '780 patents.

**ANSWER:** Genzyme states that whether controversies exists between Genzyme and Impax regarding the '775 and '780 patents are legal conclusions to which no response is required. To the extent that a further response is required, Genzyme admits that there is a controversy between Genzyme and Impax regarding the '775 patent. Genzyme contests this Court's subject matter jurisdiction with respect to the '780 patent and has moved to dismiss Impax's counterclaims for declaratory judgment of invalidity and/or non-infringement of the '780 patent. Genzyme denies any remaining allegations in paragraph 34.

35. This Court has subject matter jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

**ANSWER:** Genzyme does not contest this Court's subject matter jurisdiction with respect to the '775 patent but does contest this Court's subject matter jurisdiction with respect to the '780 patent. Genzyme denies any remaining allegations in paragraph 35.

36. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

**ANSWER:** Genzyme admits the allegation in paragraph 36.

## COUNTERCLAIM I
## Declaration of Invalidity of the '775 Patent

37. Impax realleges and incorporates by reference the allegations of paragraphs 1-36.

**ANSWER:** Genzyme repeats and realleges its answers in paragraphs 1-36 above as if fully set forth herein.

38. This counterclaim arises under the Patent Laws of the United States, 35 US.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '775 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or under the doctrine of non-statutory double patenting.

**ANSWER:** Genzyme admits that Impax purports to set out a claim under the Patent Laws of the United States, 35 US.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '775 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or under the doctrine of non-statutory double patenting, but denies that Impax is entitled to such relief.

39. A present, genuine, and justiciable controversy exists between Genzyme and Impax regarding, *inter alia*, the validity of claims of the '775 patent.

**ANSWER:** Genzyme states that whether a controversy exists between Genzyme and Impax regarding the validity of claims of the '775 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme admits that there is a controversy between Genzyme and Impax regarding the validity of the claims of the '775 patent. Genzyme denies any remaining allegations in paragraph 39.

40. Claims of the '775 patent are invalid under one or more provisions of 35 U.S.C.§§ 101, 102, 103, and/or 112, and/or under the doctrine of non-statutory double patenting.

**ANSWER:** Genzyme denies the allegations in paragraph 40.

41. Impax is entitled to a declaration that claims of the '775 patent are invalid.

**ANSWER:** Genzyme denies that Impax is entitled to the relief in paragraph 41.

## COUNTERCLAIM II
## Declaration of Non-Infringement of the '775 Patent

42. Impax realleges and incorporates by reference the allegations of paragraphs 1-41.

**ANSWER:** Genzyme repeats and realleges its answers in paragraphs 1-41 above as if fully set forth herein.

43. This counterclaim arises 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, and seeks a declaration that one or more claims of the '775 patent will not be infringed by the manufacture, use, or sale of the products described in Impax's ANDA No. 90-846.

**ANSWER:** Genzyme admits that Impax purports to set out a claim under the Patent Laws of the United States, 35 US.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '775 patent will not be infringed by the manufacture, use, or sale of the products described in Impax's ANDA No. 90-846, but denies that Impax is entitled to such relief.

44. A present, genuine, and justiciable controversy exists between Genzyme and Impax regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Impax's proposed ANDA products would infringe claims of the '775 patent.

**ANSWER:** Genzyme states that whether a controversy exists between Genzyme and Impax regarding the issue of whether the manufacture, use, or sale of Impax's proposed ANDA products would infringe claims of the '775 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme admits that there is a controversy between Genzyme and Impax regarding infringement of the '775 patent by Impax's proposed ANDA products. Genzyme denies any remaining allegations in paragraph 44.

45. The manufacture, use, or sale of Impax's ANDA products would not infringe claims of the '775 patent.

**ANSWER:** Genzyme denies the allegation in paragraph 45.

46. Impax is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '775 patent.

**ANSWER:** Genzyme denies that Impax is entitled to the relief in paragraph 46.

**COUNTERCLAIM III**
**Declaration of Invalidity of the '780 Patent**

47. Impax realleges and incorporates by reference the allegations of paragraphs 1-46.

**ANSWER:** Genzyme has moved to dismiss counterclaim III and, therefore, no response to the allegations in paragraph 47 is required at this time.

48. This counterclaim arises 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, and seeks a declaration that one or more of the claims of the '780 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

**ANSWER:** Genzyme has moved to dismiss counterclaim III and, therefore, no response to the allegations in paragraph 48 is required at this time.

49. A present, genuine, and justiciable controversy exists between Genzyme and Impax regarding, *inter alia*, the validity of claims of the '780 patent.

**ANSWER:** Genzyme has moved to dismiss counterclaim III and, therefore, no response to the allegations in paragraph 49 is required at this time.

50. Claims of the '780 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

**ANSWER:** Genzyme has moved to dismiss counterclaim III and, therefore, no response to the allegations in paragraph 50 is required at this time.

51. Impax is entitled to a declaration that claims of the '780 patent are invalid.

**ANSWER:** Genzyme has moved to dismiss counterclaim III and, therefore, no response to the allegations in paragraph 51 is required at this time.

**COUNTERCLAIM IV**
**Declaration of Non-Infringement of the '780 Patent**

52. Impax realleges and incorporates by reference the allegations of paragraphs 1-51.

**ANSWER:** Genzyme has moved to dismiss counterclaim IV and, therefore, no response to the allegations in paragraph 52 is required at this time.

53. This counterclaim arises 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, and seeks a declaration that one or more claims of the '780 patent will not be infringed by the manufacture, use, or sale of the products described in Impax's ANDA No. 90-846.

**ANSWER:** Genzyme has moved to dismiss counterclaim IV and, therefore, no response to the allegations in paragraph 53 is required at this time.

54. A present, genuine, and justiciable controversy exists between Genzyme and Impax regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Impax's proposed ANDA products would infringe claims of the '780 patent.

**ANSWER:** Genzyme has moved to dismiss counterclaim IV and, therefore, no response to the allegations in paragraph 54 is required at this time.

55. The manufacture, use, or sale of Impax's ANDA products would not infringe claims of the '780 patent.

**ANSWER:** Genzyme has moved to dismiss counterclaim IV and, therefore, no response to the allegations in paragraph 55 is required at this time.

56. Impax is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '780 patent

**ANSWER:** Genzyme has moved to dismiss counterclaim IV and, therefore, no response to the allegations in paragraph 56 is required at this time.

## AFFIRMATIVE DEFENSE

57. This Court lacks subject matter jurisdiction with respect to the '780 patent.

## PRAYER FOR RELIEF

Genzyme denies that Impax is entitled to any relief, either as prayed for in its counterclaims or otherwise.

Genzyme further denies each allegation contained in Impax's counterclaims that was not specifically admitted, denied or otherwise responded to in this Answer .

/s/ George E. Brown
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21st day of August, 2009, a copy of the foregoing Answer to Counterclaims was sent by ECF filing to:

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/s/ George E. Brown