IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC., Plaintiffs, v. PUREPAC PHARMACEUTICAL CO. and ALPHARMA, INC., Defendants.	C. A. No. 05-382-KAJ **TRIAL BY JURY DEMANDED**

ANSWER AND COUNTERCLAIMS OF DEFENDANTS PUREPAC PHARMACEUTICAL CO. AND ALPHARMA, INC.

Defendants Purepac Pharmaceutical Co. ("Purepac") and Alpharma, Inc. ("Alpharma") (collectively "Defendants") answer the Complaint of Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen") and Synaptech, Inc. (collectively, "Plaintiffs") as follows:

1. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Complaint, and on that basis deny the allegations set forth therein.

2. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and on that basis deny the allegations set forth therein.

3. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and on that basis deny the allegations set forth therein.

4. Defendants admit that Purepac is a corporation incorporated and existing under the laws of the State of Delaware, having a principal place of business at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016. Defendants admit that Purepac is registered to do business and does business in the State of Delaware.

5. Defendants admit that Purepac is a wholly owned subsidiary of Alpharma, which is a corporation organized and existing under the laws of Delaware with a principal place of business at One Executive Drive, Fort Lee, New Jersey 07024. Defendants admit that Alpharma is registered to do business and does business in the State of Delaware.

6. Defendants admit that Purepac filed an abbreviated new drug application ("ANDA") No. 77-585 for galantamine hydrobromide tablets. Defendants further admit that portions of Purepac's ANDA No. 77-585 are derived from information provided to it by Alpharma. Defendants further admit that, in the event that the United States Food and Drug Administration ("FDA") approves Purepac's ANDA, Purepac intends to market and sell such galantamine hydrobromide tablets. Defendants further admit that they market and sell pharmaceutical products in Delaware and other states, including generic prescription drug products manufactured and sold pursuant to approved ANDAs. Defendants deny the remaining allegations set forth in Paragraph 6 of the Complaint.

7. Defendants admit that Plaintiffs filed a civil action asserting patent infringement arising under Title 35 of the United States Code, for alleged infringement of United States Patent No. 4,663,318 ("the '318 patent"). Defendants deny that Plaintiffs' claims are valid or have merit. Defendants further admit that, with respect to the claims against them, this Court has jurisdiction over the subject matter of Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Defendants admit that this Court has personal jurisdiction over Purepac for the purposes of this action. Defendants deny the remaining allegations set forth in Paragraph 8 of the Complaint.

9. Defendants admit that this Court has personal jurisdiction over Alpharma for the purposes of this action. Defendants deny the remaining allegations set forth in Paragraph 9 of the Complaint.

10. Defendants admit that venue is proper in this district with respect to them pursuant to 28 U.S.C. §§ 1391(b) and 1400(b). Defendants deny the remaining allegations set forth in Paragraph 10 of the Complaint.

11. Defendants admit that to introduce a drug that has not previously been approved by the FDA into interstate commerce, a new drug application ("NDA") must be submitted to the FDA, including information required under 21 U.S.C. § 355(b). Defendants otherwise deny the allegations set forth in Paragraph 11 of the Complaint to the extent they are inconsistent with the law. Defendants further deny the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Defendants admit that an abbreviated application process is available for approval to market a generic version of a listed drug, and that an abbreviated new drug application ("ANDA") must include information required under 21 U.S.C. § 355(j). Defendants further admit that whether the FDA will consider a drug to be bioequivalent to a listed drug is at least partially governed by 21 U.S.C. § 355(j). Defendants otherwise deny the allegations set forth in Paragraph 12 of the Complaint to the extent they are inconsistent with the law.

13. Defendants admit that 21 U.S.C. § 355(j) does not require that an ANDA contain all of the same information required in an NDA. Defendants further admit that 21 U.S.C.

§ 355(j) at least partially governs what information must be included in an ANDA. Defendants otherwise deny the allegations set forth in Paragraph 13 of the Complaint to the extent they are inconsistent with the law. Defendants further deny the remaining allegations set forth in Paragraph 13 of the Complaint.

14. Defendants admit that according to 21 U.S.C. § 355(j), an ANDA must contain information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug. Defendants otherwise deny the allegations set forth in Paragraph 14 of the Complaint to the extent they are inconsistent with the law.

15. Defendants admit that according to 21 U.S.C. § 355(a), no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to such drug. Defendants otherwise deny the allegations set forth in Paragraph 15 of the Complaint to the extent they are inconsistent with the law.

16. Defendants admit that Janssen Pharma is identified by the FDA as the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base. Defendants further admit that February 28, 2001 is the date identified by the FDA as the date on which NDA No. 21-169 was approved. Defendants further admit that the sole indication of use for which galantamine hydrobromide tablets are approved by the FDA in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type. Defendants deny the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Defendants admit that a commercial formulation of galantamine

hydrobromide approved by the FDA for the treatment of mild to moderate dementia of the Alzheimer's type is sold under the trademarks RAZADYNE® and/or REMINYL®. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 17 of the Complaint, and on that basis deny the allegations set forth therein.

18. Defendants admit that the '318 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with NDA No. 21-169.

19. Defendants admit that they have not previously challenged the listing of the '318 patent in the Orange Book. Defendants deny that the '318 patent has any valid claims for an approved use of the drug product that is the subject of NDA No. 21-169 such that it qualifies for listing in the Orange Book. Defendants further deny the remaining allegations set forth in Paragraph 19 of the Complaint.

20. Defendants admit that Purepac has represented that on or before April 29, 2005, Purepac submitted to the FDA ANDA No. 77-585 and paragraph IV certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) for galantamine hydrobromide tablets bioequivalent to the commercial formulation of galantamine hydrobromide marketed under the trademark REMINYL®. Defendants further admit that Purepac filed the ANDA and paragraph IV certifications to obtain approval under 21 U.S.C. § 505(j) to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for NDA No. 21-169. Defendants further admit that if Purepac obtains such approval from the FDA for ANDA No. 77-585 Purepac intends to market in the United States the galantamine hydrobromide products described in the ANDA, and that

such marketing may occur before the expiration of the '318 patent. Defendants deny the remaining allegations set forth in Paragraph 20 of the Complaint.

21. Defendants admit that the condition of use for which Purepac seeks approval in its ANDA No. 77-585 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in NDA No. 21-169. Defendants deny the remaining allegations set forth in Paragraph 21 of the Complaint.

22. Defendants admit that the indication set forth in the proposed labeling submitted by Purepac in its ANDA No. 77-585 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for the commercial formulation of galantamine hydrobromide which is marketed under the trademarks RAZADYNE® and/or REMINYL®. Defendants deny the remaining allegations set forth in Paragraph 22 of the Complaint.

23. Defendants reallege their responses to the allegations contained in Paragraphs 1 – 22 above as if fully set forth herein.

24. Defendants admit that United States Patent No. 4,663,318 (the '318 patent) is entitled "Method of Treating Alzheimer's Disease" and states on its face that it was issued May 5, 1987. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 24 of the Complaint, and on that basis deny the remaining allegations.

25. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 25 of the Complaint, and

on that basis deny the allegation set forth therein.

26. Defendants admit that a commercial formulation of galantamine hydrobromide is marketed under the trademarks RAZADYNE® and/or REMINYL®. Defendants deny that the conditions of use for which the commercial formulation of galantamine hydrobromide is approved fall within one or more valid claims of the '318 patent. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 26 of the Complaint, and on that basis deny the remaining allegations set forth therein.

27. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint, and on that basis deny the allegations set forth therein.

28. Defendants deny the allegations set forth in paragraph 28 of the Complaint.

29. Defendants deny the allegations set forth in paragraph 29 of the Complaint.

30. Defendants deny the allegations set forth in paragraph 30 of the Complaint.

31. Defendants deny the allegations set forth in paragraph 31 of the Complaint.

32. Defendants admit that they had knowledge of the '318 patent prior to Purepac filing ANDA No. 77-585. Defendants deny that this knowledge can or does form the basis for a finding of willful infringement and as such deny the remaining allegations set forth in Paragraph 32 of the Complaint.

33. Defendants deny the allegations set forth in paragraph 33 of the Complaint.

First Defense

34. The manufacture, use, offering for sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-585 will not infringe directly or indirectly any valid claim of the '318 patent.

35. Purepac's filing of its ANDA No. 77-585 did not infringe any valid claim of the '318 patent.

Second Defense

36. Each claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

Third Defense

At least one of the Plaintiffs lacks standing to assert infringement of the '318 patent by Defendants.

COUNTERCLAIMS

Jurisdiction and Venue

1. These counterclaims seek declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202.

2. This Court has jurisdiction over these counterclaims pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 1331 and 1338(a).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

4. A justiciable controversy exists between the parties hereto with respect to validity, scope, and infringement of certain claims of U.S. Patent No. 4,663,318 ("the '318 patent").

Acts Giving Rise To This Action

5. On information and belief Janssen Pharma is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base.

6. On information and belief Janssen Pharma caused the '318 patent to be listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as a patent which claims the drug for which Janssen Pharma submitted NDA No. 21-169 or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, or in the method of using the drug. On information and belief, Synaptech, Inc. is the record owner of the '318 patent and Janssen Pharma is the exclusive licensee.

7. Purepac submitted its ANDA No. 77-585 to obtain FDA approval to engage in the commercial manufacture, use and sale of Eq. 4 mg base, 8 mg base, and 12 mg base galantamine hydrobromide tablets, prior to the expiration of the '318 patent.

8. Purepac sent letters dated April 29, 2005 ("Notification Letters") to Janssen Pharmaceutical, Inc. and Synaptech, Inc., notifying each that Purepac's ANDA No. 77-585 was received by the FDA, and that Purepac's ANDA contained a "paragraph IV certification" that the '318 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Purepac's ANDA.

9. On June 10, 2005, Plaintiffs filed the instant suit asserting infringement of the '318 patent.

10. Plaintiffs' filing of the Complaint has created a reasonable apprehension on the part of Purepac and Alpharma that Janssen Pharmaceutica N.V., Janssen, L.P., and/or Synaptech will assert that Purepac's making, using, selling, offering to sell, or importing of the product described in Purepac's ANDA No. 77-585 infringes or will infringe the '318 patent.

First Counterclaim

11. Purepac and Alpharma reallege the allegations contained in the preceding paragraphs as if fully set forth herein.

12. The manufacture, use, offer to sell, sale, and/or importation into the United States of the galantamine hydrobromide tablets that are the subject of Purepac's ANDA No. 77-585 will not infringe directly or indirectly any valid claim of the '318 patent. Nor did the filing of Purepac's ANDA infringe any valid claim of the '318 patent.

Second Counterclaim

13. Purepac and Alpharma reallege the allegations contained in the preceding paragraphs as if fully set forth herein.

14. The '318 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

DEMAND FOR JURY TRIAL

Defendants/counterclaimants Purepac Pharmaceutical Co. and Alpharma, Inc. hereby demand trial by jury of all claims and counterclaims triable of right by jury.

PRAYER FOR RELIEF

WHEREFORE, defendants Purepac Pharmaceutical Co. and Alpharma, Inc. respectfully request that:

a) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed with prejudice;

b) The filing of Purepac's ANDA No. 77-585 be declared not to infringe any valid claims of the '318 patent;

c) The manufacture, use, offer to sell, sale, and/or importation into the United States of Purepac's galantamine hydrobromide tablets that are the subject of Purepac's ANDA No. 77-585 be declared not to infringe any valid claims of the '318 patent.

d) The '318 patent be declared invalid.

e) Purepac and Alpharma be awarded their costs in this action.

f) Purepac and Alpharma be awarded their attorneys' fees pursuant to 35 U.S.C. § 285; and

g) Purepac and Alpharma be awarded such other and further relief as this Court may deem just and proper.

June 30, 2005

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on June 30, 2005, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that copies of the foregoing document were sent by email and by hand to the above counsel and by email and first class mail to the following non-registered participants:

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