IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN, L.P., JANSSEN PHARMACEUTICA N.V., and ORTHO-MCNEIL NEUROLOGICS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
KV PHARMACEUTICAL Company,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen, L.P., Janssen Pharmaceutica N.V., and Ortho-McNeil Neurologics, Inc. (collectively, "Janssen"), by their attorneys, for their complaint against KV Pharmaceutical Company, allege as follows:

The Parties

1. Plaintiff Janssen, L.P., a wholly owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

2. Plaintiff Janssen Pharmaceutica N.V., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

3. Plaintiff Ortho-McNeil Neurologics, Inc., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws

of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Upon information and belief, Defendant KV Pharmaceutical Company ("KV Pharmaceutical") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 2503 South Hanley Road, St. Louis, Missouri 63144.

5. Upon information and belief, KV Pharmaceutical is in the business of manufacturing, distributing, and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

6. KV Pharmaceutical prepared and filed with the FDA, pursuant to 21 U.S.C. 355(j), ANDA No. 78-189 concerning galantamine hydrobromide extended-release capsules and seeks approval of that application from the Food and Drug Administration ("FDA").

7. Upon information and belief, if ANDA No. 78-189 is approved, it is the intention of KV Pharmaceutical to commercially manufacture, use, and sell KV Pharmaceutical's proposed galantamine hydrobromide extended-release capsules in the United States. Upon information and belief, KV Pharmaceutical manufactures, markets, and sells many pharmaceutical products, including numerous generic prescription drug products manufactured and sold pursuant to an approved abbreviated new drug application, that are marketed and sold to customers in the State of Delaware.

Jurisdiction and Venue

8. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 7,160,559 ("the '559 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. KV Pharmaceutical is subject to personal jurisdiction in this judicial district because it is corporation organized and existing under the laws of the State of Delaware and does business in the State of Delaware, and by virtue of, *inter alia*, its being incorporated in the State of Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

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

Regulatory Requirements for Approval of New and Generic Drugs

11. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of a NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

12. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the

ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

13. However, unlike a NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

14. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

15. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

16. Janssen is the holder of an approved new drug application, NDA No. 21-615, for galantamine hydrobromide extended release capsules. That NDA was approved by FDA on April 1, 2005 and covers three strengths of capsule – Eq. 8 mg base, 16 mg base, and 24 mg base. The sole indication or condition of use for which galantamine hydrobromide extended release capsules are approved in NDA No. 21-615 is the treatment of mild to moderate dementia of the Alzheimer's type.

17. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide extended-release capsules for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE ER®. Until 2005, Janssen marketed its galantamine hydrobromide products under the trademark REMINYL®.

18. FDA has listed the '559 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-615.

19. The '559 patent qualifies for listing in the Orange Book in connection with NDA No. 21-615 because it claims an approved use of the drug product that is the subject of that NDA. KV Pharmaceutical has never challenged the listing of the '559 patent in the Orange Book.

KV Pharmaceutical's ANDA

20. KV Pharmaceutical has represented that on or before November 2, 2007, it submitted to FDA an ANDA (ANDA No. 78-189) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and

Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for galantamine hydrobromide extended-release capsules purportedly bioequivalent to Janssen's RAZADYNE ER® products. The purpose of KV Pharmaceutical's ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide extended-release capsules before the expiration of the patents listed in the Orange Book for Janssen's NDA No. 21-615. Hence, KV Pharmaceutical's purpose in submitting ANDA No. 78-189 is to market in the United States the galantamine hydrobromide products described therein before expiration of the '559 patent.

21. On or about November 2, 2007, KV Pharmaceutical sent a letter advising Janssen of KV Pharmaceutical's paragraph IV certification relating to the '559 patent ("KV Pharmaceutical's Notice Letter"). KV Pharmaceutical's Notice Letter included an offer of confidential access that would permit Janssen's outside counsel to review KV Pharmaceutical's ANDA.

22. Upon information and belief, the sole condition of use for which KV Pharmaceutical seeks approval in its ANDA No. 78-189 for its proposed galantamine hydrobromide extended-release capsules is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in Janssen's NDA No. 21-615.

23. Upon information and belief, the sole indication set forth in the proposed labeling submitted by KV Pharmaceutical in its ANDA No. 78-189 for its proposed galantamine hydrobromide extended-release capsules 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 Janssen's RAZADYNE ER® capsules.

Count 1: Patent Infringement

24. Janssen realleges paragraphs 1 through 23 above as if fully set forth herein.

25. On January 9, 2007, the United States Patent and Trademark Office duly and legally issued the '559 patent, entitled "Controlled Release Galantamine Formulation." The term of the '559 patent runs through December 20, 2019. A true and correct copy of the '559 patent is attached hereto as Exhibit A.

26. Janssen is the owner of the '559 patent.

27. Janssen currently markets galantamine hydrobromide extended-release capsules in the United States under the trademark RAZADYNE ER® and previously marketed its galantamine hydrobromide products in the United States under the trademark REMINYL®. The product RAZADYNE ER® and the conditions of use for which RAZADYNE ER® is approved fall within one or more of the claims of the '559 patent.

28. KV Pharmaceutical is liable for infringement of the '559 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 78-189 with a paragraph IV certification seeking FDA approval of ANDA No. 78-189 prior to expiration of the '559 patent.

29. The product for which KV Pharmaceutical seeks approval in its ANDA No. 78-189 falls within one or more of the claims of the '559 patent. If approved,

the manufacture, use, offer for sale, and sale in the United States, and importation into the United States of KV Pharmaceutical's proposed galantamine hydrobromide product would infringe one or more of the claims of the '559 patent.

30. Upon information and belief, if ANDA No. 78-189 is approved, KV Pharmaceutical intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the galantamine hydrobromide product for which approval is sought in KV Pharmaceutical's ANDA No. 78-189.

31. The manufacture, use, offer for sale and sale in the United States, and importation into the United States of KV Pharmaceutical's proposed galantamine hydrobromide product would infringe one or more claims of the '559 patent, and KV Pharmaceutical would be liable for direct infringement under 35 U.S.C. § 271(a).

32. Upon information and belief, the conditions of use for which KV Pharmaceutical seeks approval in its ANDA No. 78-189 fall within one or more of the claims of the '559 patent. Upon information and belief, if approved, use of KV Pharmaceutical's proposed galantamine hydrobromide product in accordance with the proposed labeling submitted in ANDA No. 78-189 would infringe one or more of the claims of the '559 patent.

33. Upon information and belief, if approved, KV Pharmaceutical's galantamine hydrobromide products for which approval is sought in KV Pharmaceutical ANDA No. 78-189 will be administered to human patients in a therapeutically effective amount for treatment of dementia of the Alzheimer's type, which administration would constitute direct infringement of one or more claims of the '559 patent. Upon information and belief, this infringement will occur at KV Pharmaceutical's behest, with

its intent, knowledge, and encouragement, and KV Pharmaceutical will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Janssen's rights under the '559 patent.

34. KV Pharmaceutical's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '559 patent, of the galantamine hydrobromide product for which approval is sought in ANDA No. 78-189, would actively induce and contribute to infringement of the '559 patent, and KV Pharmaceutical would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

35. KV Pharmaceutical's infringement of the '559 patent has been, and continues to be, willful.

36. Janssen will be irreparably harmed if KV Pharmaceutical is not enjoined from infringing or actively inducing or contributing to infringement of the '559 patent. Janssen does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that KV Pharmaceutical has infringed the '559 patent under 35 U.S.C. § 271(e)(2)(A), and that such infringement is willful.

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of the KV Pharmaceutical ANDA No. 78-189 for galantamine hydrobromide extended-release Eq. 8 mg base, 16 mg base, and 24 mg base capsules be not earlier than the expiration date of the '559 patent;

C. A judgment declaring that KV Pharmaceutical's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the galantamine hydrobromide products for which approval is sought in ANDA No. 78-189 would constitute infringement of the '559 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

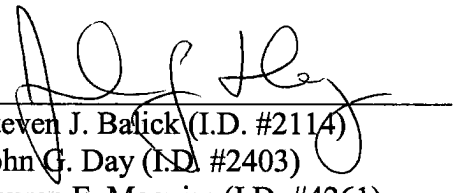
D. A permanent injunction enjoining KV Pharmaceutical and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the galantamine hydrobromide extended-release capsules for which approval is sought in ANDA No. 78-189, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '559 patent, until expiration of that patent;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES



Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Plaintiffs Janssen, L.P., Janssen Pharmaceutica N.V., and Ortho-McNeil Neurologics, Inc.

Of Counsel:

George F. Pappas
Christopher N. Sipes
Kurt G. Calia
Steven P. Berman
Sarah J. Chickos
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-6000

DATED: December 18, 2007

186714.1