UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA, N.V., and
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,

Plaintiffs,

v.

APOTEX, INC.,

Defendant.

Civ. Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceutica, N.V. ("Janssen N.V.") and Janssen Pharmaceutica Products, L.P. ("Janssen L.P.") (collectively "plaintiffs" or "Janssen"), by their attorneys, for their complaint against Apotex, Inc. ("Apotex") allege as follows:

The Parties

1. Janssen N.V. 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.

2. Janssen L.P. is a corporation organized and existing under the laws of the State of Pennsylvania and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

3. Upon information and belief, Apotex is a corporation organized and existing under the laws of Canada, having regular and established places of business at 150 Signet Drive, Toronto, Canada M9L 1T9. Upon information and belief, Apotex conducts continuous and systematic business within the state of New Jersey and, alternatively, intends to market and sell the accused drug in New Jersey.

Jurisdiction And Venue

4. This action is based upon the Patent Law of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 4,804,663 ("the '663 patent") and the Federal Declaratory Judgment Act, Title 28 of the United States Code, §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Upon information and belief, Apotex is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its continuous and systematic contacts with New Jersey as evidenced, and its intent to market and sell the accused drug in New Jersey.

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

Count I: Patent Infringement

7. Janssen realleges paragraphs 1 through 6 above as if fully set forth herein.

8. On February 14, 1989, the United States Patent and Trademark Office ("the PTO") issued the '663 patent, entitled "3-Piperidinyl-Substituted 1,2-Benzisoxazoles and 1,2-Benzisothiazoles." A true and correct copy of the '663 patent is attached as Exhibit A.

9. Janssen N.V. holds title to the '663 patent.

10. The United States Food & Drug Administration ("FDA") has approved a New Drug Application ("NDA") filed by Janssen L.P. under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for risperidone, the product covered by the '663 patent and sold by plaintiffs in oral solution form under the trade name RISPERDAL ORAL SOLUTION.

11. Pursuant to 21 U.S.C. § 355(b)(1), the '663 patent is identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), as covering RISPERDAL ORAL SOLUTION.

12. Janssen L.P. filed the NDA for RISPERDAL ORAL SOLUTION and is the exclusive United States distributor of RISPERDAL ORAL SOLUTION.

13. Upon information and belief, on or before September 16, 2005, Apotex submitted Abbreviated New Drug Application ("ANDA") No. 77-719 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), ("Apotex ANDA") seeking FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of risperidone oral solution.

14. Upon information and belief, the Apotex ANDA originally contained a paragraph III certification against the '663 patent.

15. The Apotex ANDA contained a paragraph IV certification with regard to United States Patent Nos. 5,453,425 and 5,616,587.

16. Upon information and belief, on or about January 26, 2006 Apotex changed the Apotex ANDA from a paragraph III certification to a paragraph IV certification.

17. On or about January 27, 2006, Janssen Pharmaceutica Products received a letter dated January 26, 2006 stating that Apotex had amended the Apotex ANDA to include a paragraph IV certification against the '663 patent ("Apotex's ANDA certification letter"). With its paragraph IV certification, Apotex is seeking approval to manufacture, use and sell generic risperidone oral solution before the expiration of the '663 patent. A true and correct copy of Apotex's ANDA certification letter is attached as Exhibit B.

18. Upon information and belief, the Apotex ANDA was filed in the name of Apotex.

19. Apotex's ANDA certification letter states that the Apotex ANDA certifies, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), that the '663 patent is invalid ("paragraph IV certification").

20. Apotex is liable for the infringement of the '663 patent under 35 U.S.C. § 271(e)(2)(A) by filing the Apotex ANDA which, upon information and belief, includes the paragraph IV certification.

21. Apotex had actual and constructive notice of the '663 patent prior to filing the Apotex ANDA.

22. Janssen will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of the '663 patent. Janssen does not have an adequate remedy at law.

Count II: Declaratory Judgement of Patent Infringement

23. Janssen realleges paragraphs 1 through 22 above as if fully set forth herein.

24. Apotex is seeking FDA approval to sell a generic version of Janssen's risperidone oral solution, 1 mg/mL prior to the expiration of the '663 and, upon information and belief, Apotex intends to market the generic product immediately upon FDA approval.

25. The manufacture, use, sale, or offer for sale in the United States of the importation into the United States of a generic version of risperidone oral solution, 1 mg/mL during the term of the '663 patent will constitute patent infringement under 35 U.S.C. § 271(a), (b) and/or (c).

26. Apotex has admitted that its generic product will contain risperidone, a compound covered by the claims of the '663 patent.

27. There is an actual controversy and continuing controversy between Janssen and Apotex as to Apotex's infringement of the '663 patent. Apotex's manufacture and sales in the United States and importation into the United States will result in infringement of the '663 patent and will result in substantial economic harm to Janssen. Apotex has created a reasonable apprehension in Janssen of imminent harm and loss resulting from Apotex's threatened actions. This threatened harm will be redressed by the Court's declaration of the parties' rights and liabilities.

Prayer For Relief

WHEREFORE, Janssen respectfully requests:

A. A judgment providing that the effective date of any FDA approval for the making, using, selling, offering for sale, or importing of risperidone oral solutions as described in ANDA No. 77-719 by Apotex be no earlier than the date on which the '663 patent expires (including the patent term extension granted to the '663 patent);

B. A judgment declaring that the making, using, selling, offering to sell in the United States, or importing into the United States of the risperidone oral solution described in ANDA No. 77-719 would constitute infringement of the '663 patent, or inducing or contributing to such conduct, by Apotex pursuant to 35 U.S.C. § 271(a), (b) and (c);

C. A judgment permanently enjoining Apotex and each of its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the risperidone oral solution described in ANDA No. 77-719 or any product that infringes or induces or contributes to the infringement of the '663 patent;

D. A declaration that this case is exceptional;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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

Dated: March 3, 2006

LOWENSTEIN SANDLER PC

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that plaintiffs Janssen Pharmaceutica, N.V. and Janssen Pharmaceutica Products, L.P. have filed five patent infringement actions, which are pending in the United States District Court for the District of New Jersey.

The first such action is titled *Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. v. Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 03-6185 (JCL) (MF) (Newark vicinage) ("the *DRL I* action"). The complaint in the *DRL I* action alleges in part that defendants Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc. infringed United States Patent No. 4,804,663 ("the '663 patent") by filing Abbreviated New Drug Application ("ANDA") No. 76-879, seeking approval to engage in the commercial manufacture, use, offer for sale and sale of generic risperidone oral solution tablets, 1 mg/mL before the '006 patent expires. The second such action is titled *Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. v. Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 05-884 (JCL) (MF) (Newark vicinage) ("the *DRL II* action"). The complaint in the *DRL II* action alleges in part that defendants Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc. infringed the '663 patent by filing ANDA No. 77-328.

The third such action is titled *Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. v. Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc.*, Civil Action No. 05-5362 (JCL) (MF) (Newark vicinage) ("the *DRL III* action"). The complaint in the *DRL III* action alleges that defendants Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc. infringed the '663 patent and United States Patent No. 5,648,093 ("the '093 patent"), which are identified in the Orange Book as covering risperidone orally disintegrating tablets, by filing ANDA No. 77-328. The fourth such action is titled *Janssen*

Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. v. Mylan Pharmaceuticals Inc., Civil Action No. 03-6220 (JCL) (MF) (Newark vicinage) ("the *Mylan* action"). The complaint in the *Mylan* action alleges that defendant Mylan Pharmaceuticals Inc. infringed the '663 patent by filing ANDA No. 76-288. The fifth such action is entitled *Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. v. Barr Laboratories, Inc.*, Civil Action No. 05-4897 (JCL) (MF) (Newark vicinage) ("the *Barr* action"). The complaint in the *Barr* action alleges that defendant Mylan Pharmaceuticals Inc. infringed the '663 patent by filing ANDA No. 77-617, which gave rise to the foregoing Complaint for Patent Infringement.

The *DRL I* action, the *DRL II* action, the *DRL III* action, the *Mylan* action, *Barr* action, and the present action all involve the validity, enforceability, and infringement of the '663 patent.

By: _____
Douglas S. Eakeley

Dated: March 3, 2006