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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____ **COMPLAINT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, brings this action against defendants, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., for patent infringement and alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 United States Code, arising from Barr Laboratories, Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's THALOMID® prior to the expiration of certain patents owned by Celgene that cover that product's use, i.e.,

United States Patent Nos. 6,045,501 (the '501 patent"), 6,315,720 ("the '720 patent"), 6,561,976 ("the '976 patent"), 6,561,977 ("the '977 patent"), 6,755,784 ("the '784 patent"), 6,869,399 ("the '399 patent"), and 7,141,018 ("the '018 patent") (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, defendant Barr Laboratories, Inc. is a corporation having a principal place of business at 223 Quaker Road, Pomona, New York 10970.

4. On information and belief, defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

5. On information and belief, defendant Barr Laboratories, Inc. is a subsidiary of defendant Barr Pharmaceuticals, Inc.

6. On information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are registered to do business in New Jersey. Further, on information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. maintain executive offices and a manufacturing facility and otherwise transact business within this District.

7. On information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Barr Pharmaceuticals, Inc.

8. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are referred to hereinafter, collectively, as "Barr."

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 2201 and 2202.

10. This Court has personal jurisdiction over Barr by virtue of the fact that Barr has availed itself of the laws of New Jersey and conducts business in New Jersey.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents in Suit

12. On April 4, 2000, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '501 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '501 patent is attached hereto as Exhibit A.

13. On November 13, 2001, the USPTO duly and lawfully issued the '720 patent, entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '720 patent is attached hereto as Exhibit B.

14. On May 13, 2003, the USPTO duly and lawfully issued the '976 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other

Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '976 patent is attached hereto as Exhibit C.

15. On May 13, 2003, the USPTO duly and lawfully issued the '977 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '977 patent is attached hereto as Exhibit D.

16. On June 29, 2004, the USPTO duly and lawfully issued the '784 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On May 3, 2005, a certificate of correction was granted by the USPTO to correct a typographical error in claim 29 of the '784 patent. A copy of the '784 patent and its certificate of correction is attached hereto as Exhibit E.

17. On March 22, 2005, the USPTO duly and lawfully issued the '399 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On March 7, 2006, a certificate of correction was granted by the USPTO to correct typographical errors in claim 19 of the '399 patent. A copy of the '399 patent and its certificate of correction is attached hereto as Exhibit F.

18. On November 28, 2006, the USPTO duly and lawfully issued the '018 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '018 patent is attached hereto as Exhibit G.

The THALOMID® Drug Product

19. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for thalidomide capsules (NDA No. 20-785), which it sells under the trade name THALOMID®. The claims of the '501, '720, '976, '977, '784, '399 and '018 patents cover, *inter alia*, methods of use and delivery of pharmaceutical compositions containing the drug thalidomide.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '501, '720, '976, '977, '784, '399 and '018 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to THALOMID®.

Acts Giving Rise to this Suit

21. Pursuant to Section 505 of the FFDCA, Barr filed an ANDA for thalidomide capsules, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules 50 mg, 100 mg and 200 mg ("Barr's Proposed Products"), before the patents-in-suit expire. The Barr ANDA number is 78-505.

22. In connection with the filing of its ANDA as described in the preceding paragraph, Barr has provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '501, '720, '976, '977, '784, '399 and '018 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Barr's ANDA.

23. No earlier than December 6, 2006, Barr sent written notice of its ANDA filing to Celgene. The notice alleged that the claims of the '501, '720, '976, '977, '784, '399, and '018

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