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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 FOR PATENT INFRINGEMENT** **(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® brand drug prior to the expiration of United States Patent No. 7,230,012 ("the '012 patent").

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. ("Barr") is a corporation having its 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 '012 Patent

12. On June 12, 2007, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '012 patent, entitled "Pharmaceutical Compositions And Dosage Forms of Thalidomide" to Celgene as assignee of the inventors Paul D'Angio and John McCarty. A copy of the '012 patent is attached hereto as Exhibit A.

The THALOMID® Drug Product

13. 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 as THALOMID® brand drug. The claims of the '012 patent cover pharmaceutical compositions containing the drug thalidomide.

14. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '012 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to THALOMID® brand drug.

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15. Pursuant to Section 505 of the FFDCA, Barr filed ANDA No. 78-505 for thalidomide capsules. That ANDA seeks approval to engage in the commercial use,

manufacture, sale, offer for sale or importation into the United States of thalidomide capsules 50 mg, 100 mg, and 200 mg ("Barr's Proposed Products"), before the '012 patent expires.

16. In connection with the filing of ANDA No. 78-505, Barr provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleged that the claims of several U.S. Patents owned by Celgene are invalid, unenforceable, and/or not infringed by the activities described in Barr's ANDA. Those patents are 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").

17. No earlier than December 6, 2006, Barr sent written notice of its initial ANDA filing to Celgene ("Barr's Initial Notice Letter"). Barr's Initial Notice Letter alleged that the claims of the '501, '720, '976, '977, '784, '399, and '018 patents are invalid, unenforceable, and/or will not be infringed by Barr. Barr's notice also informed Celgene that Barr seeks approval to market Barr's Proposed Products before those patents expire.

18. In response to Barr's Initial Notice Letter, Celgene filed suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Celgene's receipt of Barr's notice. *See Celgene Corp. v. Barr Labs., Inc, et al.*, No. 07-0286 (SDW) (D.N.J.).

Acts Giving Rise to this Suit

19. After the '012 patent issued and Celgene listed it in the Orange Book with respect to Thalomid® brand drug, Barr amended its ANDA to certify against the '012 patent and was thus required to send Celgene a supplemental notification pursuant to 21 U.S.C. § 505(j)(2)(B)(ii).

20. In connection with the filing and amendment of its ANDA as described in the proceeding paragraphs, Barr has provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '012 patent are invalid.

21. No earlier than July 11, 2007, Barr sent written notice of its ANDA amendment to Celgene ("Barr's Supplemental Notice Letter"). Barr's Supplemental Notice Letter alleged that the claims of the '012 patent are invalid. Barr's Supplemental Notice letter also informed Celgene that Barr seeks approval to market Barr's Proposed Products before the '012 patent expires.

22. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Celgene's receipt of Barr's Supplemental Notice Letter.

Count I: Barr's Filing of the ANDA Infringes the '012 Patent

23. Plaintiffs repeat and reallege the allegations of paragraphs 1-22 as though fully set forth herein.

24. Barr's submission and amendment of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules, prior to the expiration of the '012 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

25. There is a justiciable controversy between the parties hereto as to infringement of the '012 patent.

26. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '012 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

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