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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION and CHILDREN'S MEDICAL CENTER CORPORATION, **Plaintiffs,** **v.** **BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Celgene Corporation ("Celgene") and Children's Medical Center Corporation ("CMCC"), by their undersigned attorneys, bring this action against defendants, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., for patent infringement and allege 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 CMCC and exclusively licensed to Celgene that cover that product's use, *i.e.*, United States Patent Nos. 5,629,327 (the "'327 patent") and 6,235,756 (the "'756 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. Plaintiff CMCC is a Massachusetts not-for-profit corporation, having a principal place of business at 55 Shattuck Street, Boston, Massachusetts 02115. CMCC is the sole member of Children's Hospital Boston, also a Massachusetts not-for-profit corporation and the primary pediatric teaching hospital of Harvard Medical School.

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

5. 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, New Jersey 07677.

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

7. 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.

8. 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.

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

Jurisdiction and Venue

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

11. 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.

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

The Patents in Suit

13. On May 13, 1997, the USPTO duly and lawfully issued the '327 patent, entitled "Methods and Compositions for Inhibition of Angiogenesis" to CMCC as assignee of the inventor Robert D'Amato. A copy of the '327 patent is attached hereto as Exhibit A.

14. On May 22, 2001, the USPTO duly and lawfully issued the '756 patent, entitled "Methods and Compositions for Inhibition of Angiogenesis by Thalidomide" to CMCC as assignee of the inventor Robert D'Amato. A copy of the '756 patent is attached hereto as Exhibit B.

15. Celgene is an exclusive licensee under the '327 and '756 patents.

The THALOMID® Drug Product

16. 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 '327 and '756 patents cover methods of treatment by administering compositions containing thalidomide.

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '327 and '756 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

18. Pursuant to Section 505 of the FFDCA, Barr filed ANDA No. 78-505 and amendments thereto 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, 150 mg, and 200 mg ("Barr's Proposed Products"), before the patents-in-suit expire.

19. In connection with the filing of its ANDA as described in the preceding paragraph, Barr has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the '327 and '756 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Barr's ANDA.

20. On May 21, 2008, Barr amended its ANDA to seek approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of Barr's Proposed Products before the '327 and '756 patents expire. The '327 and '756 patents were listed in the Orange Book prior to Barr's filing of its ANDA. After amending its ANDA, Barr was required to send Celgene and CMCC notification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

21. No earlier than May 22, 2008, Barr sent written notice of its ANDA amendment to Celgene and CMCC ("Barr's Supplemental Notice Letter"). Barr's Supplemental Notice Letter alleged that the claims of the '327 and '756 patents are invalid, unenforceable, and/or will

not be infringed by the activities described in Barr's ANDA. Barr's Supplemental Notice letter also informed Celgene and CMCC that Barr seeks approval to market Barr's Proposed Products before the '327 and '756 patents expire.

22. In response, Celgene and CMCC filed this Complaint pursuant to 21 U.S.C. § 355(i)(5)(B)(ii).

Count I: Barr's Filing of the ANDA Infringes the '327 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 '327 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 the infringement of the '327 patent.

26. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '327 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

27. Celgene and CMCC will be substantially and irreparably damaged and harmed if Barr's infringement of the '327 patent is not enjoined.

28. Celgene and CMCC do not have an adequate remedy at law.

29. This case is an exceptional one, and Celgene and CMCC are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Barr's Filing of the ANDA Infringes the '756 Patent

30. Plaintiffs repeat and reallege the allegations of paragraphs 1-29 as though fully set forth herein.

31. 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 '756 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

32. There is a justiciable controversy between the parties hereto as to the infringement of the '756 patent.

33. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '756 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

34. Celgene and CMCC will be substantially and irreparably damaged and harmed if Barr's infringement of the '756 patent is not enjoined.

35. Celgene and CMCC do not have an adequate remedy at law.

36. This case is an exceptional one, and Celgene and CMCC are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Inducing Infringement

37. Plaintiffs repeat and reallege the allegations of paragraphs 1-36 as though fully set forth herein.

38. Upon information and belief, Barr Pharmaceuticals, Inc. has infringed the '327 and '756 patents under 35 U.S.C. § 271(b) by actively inducing Barr Laboratories, Inc. to infringe the '327 and '756 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Celgene and CMCC respectfully request the following relief:

(A) A Judgment be entered that Defendants have infringed the '327 and '756 patents by submitting the aforementioned ANDA and amendments thereto;

(B) A Judgment be entered that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Barr's Proposed Products will infringe one or more claims of the '327 and '756 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 78-505 be a date which is not earlier than the later of the expiration of the '327 and '756 patents or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Barr's Proposed Products until after the expiration of the '327 and/or '756 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods or compositions as claimed in the '327 and/or '756 patents, or from actively inducing or contributing to the infringement of the '327 and/or '756 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Barr's Proposed Products will directly infringe or induce and/or

contribute to infringement of the '327 and/or '756 patents or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(G) To the extent that Defendants have committed any acts with respect to the methods or compositions claimed in the '327 and '756 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiffs be awarded damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Barr's Proposed Products prior to the expiration of the '327 and/or '756 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: July 3, 2008

By: s/ Charles M. Lizza

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter captioned, *Celgene Corporation v. Barr Laboratories, Inc.*, Civil Action No. 07-286 (SDW)(MCA), is related to the matter in controversy because the matter in controversy involves the same plaintiffs, the same defendants and the same Abbreviated New Drug Application ("ANDA"), and in both cases, the defendants are seeking FDA approval to market a generic version of the same thalidomide drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 3, 2008

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