IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Plaintiff, v. GLENMARK GENERICS INC., USA, Defendant.	)	Civil Action No. _____

COMPLAINT

Plaintiff SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), for its Complaint against Defendant Glenmark Generics Inc., USA ("Glenmark"), hereby alleges as follows:

Parties

1. Plaintiff GSK is a Pennsylvania corporation having a place of business at One Franklin Plaza, Philadelphia, PA 19102.

2. Upon information and belief, Defendant Glenmark is a Delaware corporation having a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Upon information and belief, Defendant Glenmark manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

Nature Of The Action

3. This is a civil action for the infringement of United States Patent Nos. 6,166,046 ("the '046 Patent"), 6,291,488 ("the '488 Patent"), and 5,998,449 ("the '449 Patent") and for declaratory relief. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction And Venue

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

5. This Court has personal jurisdiction over Defendant Glenmark by virtue of the fact that, *inter alia*, Glenmark is a Delaware corporation.

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

The Patents

7. On December 26, 2000, the '046 Patent, titled "Combination Of Atovaquone With Proguanil For The Treatment Of Protozoal Infections," was duly and legally issued to Glaxo Wellcome Inc. as assignee. Since March 31, 2001, GSK has been, and continues to be, the sole owner of the '046 Patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '046 Patent is attached hereto as Exhibit A.

8. On September 18, 2001, the '488 Patent, titled "Preventing Protozoal Infections," was duly and legally issued to Glaxo Wellcome Inc. as assignee. Since March 31, 2001, GSK has been, and continues to be, the sole owner of the '488 Patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '488 Patent is attached hereto as Exhibit B.

9. On December 7, 1999, the '449 Patent, titled "Combination Of Atovaquone With Proguanil For The Treatment Of Protozoal Infections," was duly and legally issued to Glaxo Wellcome Inc. as assignee. Since March 31, 2001, GSK has been, and continues to be, the sole owner of the '449 Patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '449 Patent is attached hereto as Exhibit C.

Acts Giving Rise To This Action

Count I – Infringement Of The '046 Patent By Defendant Glenmark

10. Upon information and belief, on or after April 3, 2009, Defendant Glenmark submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 91-211 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet for use in the prevention and treatment of malaria ("the Generic Product"). ANDA 91-211 specifically seeks FDA approval to market the Generic Product as an AB-rated generic substitution for GSK's Malarone® brand 250 milligram atovaquone / 100 milligram proguanil hydrochloride tablet product prior to the expiration of the '046 Patent.

11. ANDA 91-211 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '046 Patent are either invalid or not infringed by the manufacture, use or sale of the Generic Product. Upon information and belief, GSK received written notification of ANDA 91-211 and its § 505(j)(2)(A)(vii)(IV) allegation on or about July 9, 2009.

12. Glenmark's submission of ANDA 91-211 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '046 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or induces or contributes to any such conduct during the term of the '046 Patent, it would further infringe the '046 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

13. Glenmark had actual and constructive notice of the '046 Patent prior to filing ANDA 91-211.

14. GSK will be irreparably harmed by Defendant Glenmark's infringing activities unless those activities are enjoined by this Court. GSK does not have an adequate remedy at law. Both the balance of the hardships as between GSK and Glenmark and the public interest further support this Court enjoining Glenmark's infringing activities.

Count II – Infringement Of The '488 Patent By Defendant Glenmark

15. Upon information and belief, on or after April 3, 2009, Defendant Glenmark submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 91-211 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride for use in the prevention and treatment of malaria ("the Generic Product"). ANDA 91-211 specifically seeks FDA approval to market the Generic Product as an AB-rated generic substitution for GSK's Malarone® brand 250 milligram atovaquone / 100 milligram proguanil hydrochloride tablet product prior to the expiration of the '488 Patent.

16. ANDA 91-211 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '488 Patent are either invalid or not infringed by the manufacture, use or sale of the Generic Product. Upon information and belief, GSK received written notification of ANDA 91-211 and its § 505(j)(2)(A)(vii)(IV) allegation on or about July 9, 2009.

17. Glenmark's submission of ANDA 91-211 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '488 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or induces or contributes to any such conduct during the term of the '488 Patent, it would further infringe the '488 Patent under 35 U.S.C. §

271 (a), (b) and/or (c).

18. Glenmark had actual and constructive notice of the '488 Patent prior to filing ANDA 91-211.

19. GSK will be irreparably harmed by Defendant Glenmark's infringing activities unless those activities are enjoined by this Court. GSK does not have an adequate remedy at law. Both the balance of the hardships as between GSK and Glenmark and the public interest further support this Court enjoining Glenmark's infringing activities.

Count III – Infringement Of The '449 Patent By Defendant Glenmark

20. Upon information and belief, on or after April 3, 2009, Defendant Glenmark submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 91-211 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride for use in the prevention and treatment of malaria ("the Generic Product"). ANDA 91-211 specifically seeks FDA approval to market the Generic Product as an AB-rated generic substitution for GSK's Malarone® brand 250 milligram atovaquone / 100 milligram proguanil hydrochloride tablet product prior to the expiration of the '449 Patent.

21. Upon information and belief, ANDA 91-211 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '449 Patent are either invalid or not infringed by the manufacture, use or sale of the Generic Product. Upon information and belief, GSK received written notification of ANDA 91-211 and its § 505(j)(2)(A)(vii)(IV) allegation against the '449 Patent on or about August 10, 2009.

22. Glenmark's submission of ANDA 91-211 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '449 Patent under 35 U.S.C.

§ 271(e)(2)(A). Moreover, if Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or induces or contributes to any such conduct during the term of the '449 Patent, it would further infringe the '449 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

23. Glenmark had actual and constructive notice of the '449 Patent prior to filing its § 505(j)(2)(A)(vii)(IV) allegation against the '449 Patent in ANDA 91-211, and at least constructive notice of the '449 Patent prior to that time.

24. GSK will be irreparably harmed by Defendant Glenmark's infringing activities unless those activities are enjoined by this Court. GSK does not have an adequate remedy at law. Both the balance of the hardships as between GSK and Glenmark and the public interest further support this Court enjoining Glenmark's infringing activities.

Count IV – Declaratory Judgment Of
Infringement Of The '449 Patent By Defendant Glenmark

25. GSK incorporates the allegations of Paragraphs 1-24 above as if fully set forth herein.

26. Upon information and belief, on or after April 3, 2009, Defendant Glenmark submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 91-211 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride for use in the prevention and treatment of malaria ("the Generic Product"). ANDA 91-211 specifically seeks FDA approval to market the Generic Product as an AB-rated generic substitution for GSK's Malarone® brand 250 milligram atovaquone / 100 milligram proguanil hydrochloride tablet product prior to the expiration of the '046, '488, and '449 Patents.

27. Glenmark's submission of ANDA 91-211 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation against the '449 Patent, constitutes infringement of the '449 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or induces or contributes to any such conduct during the term of the '449 Patent, it would further infringe the '449 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

28. By its actions, Glenmark has infringed the '449 Patent and taken significant, concrete steps to conduct additional infringing activity through its submission of ANDA 91-211 to the FDA.

29. An actual and justiciable case or controversy exists between GSK and Glenmark regarding Glenmark's infringement of the '449 Patent. A declaration of Glenmark's infringement of the '449 Patent is necessary and appropriate to resolve this controversy.

30. Glenmark had actual and constructive notice of the '449 Patent prior to filing its § 505(j)(2)(A)(vii)(IV) allegation against the '449 Patent in ANDA 91-211, and at least constructive notice of the '449 Patent prior to that time.

31. GSK will be irreparably harmed by Defendant Glenmark's infringing activities unless those activities are enjoined by this Court. GSK does not have an adequate remedy at law. Both the balance of the hardships as between GSK and Glenmark and the public interest further support this Court enjoining Glenmark's infringing activities.

Prayer For Relief

WHEREFORE, GSK prays for judgment as follows:

A. That Defendant Glenmark has infringed the '046 Patent, the '488 Patent, and the '449 Patent;

B. Declaring that Glenmark has infringed, and if it commercially

manufactures, uses, offers for sale or sells the Generic Product within the United States, or induces or contributes to any such conduct during the term of the '449 Patent will further infringe, the '449 Patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 91-211 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '046 Patent, the '488 Patent, and the '449 Patent, including any extensions;

D. That Defendant Glenmark, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Generic Product and any other product that infringes or induces or contributes to the infringement of the '046 Patent, prior to the expiration of the '046 Patent, including any extensions;

E. That Defendant Glenmark, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Generic Product and any other product that infringes or induces or contributes to the infringement of the '488 Patent, prior to the expiration of the '488 Patent, including any extensions;

F. That Defendant Glenmark, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Generic Product and any other product that infringes or induces or contributes

to the infringement of the '449 Patent, prior to the expiration of the '449 Patent, including any extensions;

G. That GSK be awarded monetary relief if Defendant Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product, or any other product that infringes or induces or contributes to the infringement of the '046 Patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to GSK with prejudgment interest;

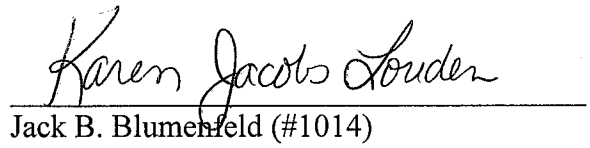
H. That GSK be awarded monetary relief if Defendant Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product, or any other product that infringes or induces or contributes to the infringement of the '488 Patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to GSK with prejudgment interest;

I. That GSK be awarded monetary relief if Defendant Glenmark commercially manufactures, uses, offers for sale or sells the Generic Product, or any other product that infringes or induces or contributes to the infringement of the '449 Patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to GSK with prejudgment interest;

J. That this is an exceptional case under 35 U.S.C. § 285 and that GSK be awarded the attorney fees, costs and expenses that it incurs prosecuting this action; and

K. That GSK be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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August 14, 2009
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