

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

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GLAXO GROUP LIMITED and )  
SMITHKLINE BEECHAM )  
CORPORATION d/b/a )  
GLAXOSMITHKLINE, )  
1 Franklin Plaza )  
Philadelphia, Pennsylvania 19102, )  
) )  
Plaintiffs, )  
) )  
v. )  
) )  
NOVARTIS CORPORATION, )  
One Health Plaza )  
East Hanover, New Jersey 07936, )  
) )  
Defendant. )

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CIVIL ACTION

No. \_\_\_\_\_

**COMPLAINT UNDER 35 U.S.C. § 146**

Plaintiffs Glaxo Group Limited and SmithKline Beecham Corporation d/b/a GlaxoSmithKline (collectively "GSK"), for their Complaint against Defendant Novartis Corporation ("Novartis"), hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action under 35 U.S.C. § 146 to review and remedy factually and legally incorrect decisions of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office (the "PTO"). This action seeks review and remedy of the Board's decisions in Patent Interference No. 105,482 ("the '482 Interference"), including the Decision on Motions (Paper 83), dated July 16, 2008, and the Judgment (Paper 85), also dated July 16, 2008. This action also seeks review and remedy of the Board's decisions in related Patent Interference Nos. 105,624 ("the '624 Interference"), 105,625 ("the '625 Interference"), and

105,626 ("the '626 Interference"), including the July 16, 2008 Decisions on Motions and Judgments issued in those three interferences.

2. Pursuant to 35 U.S.C. § 146 and 37 C.F.R. § 1.304(a)(1), the time period for filing a civil action for remedy regarding these erroneous Board decisions ends on September 14, 2008. This complaint, therefore, is timely filed.

### **THE PARTIES**

3. Plaintiff Glaxo Group Limited is a company organized and existing under the laws of England having an office and place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB60NN, United Kingdom.

4. Plaintiff SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a Pennsylvania corporation having a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102.

5. On information and belief, Defendant Novartis Corporation is a New Jersey corporation having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

### **JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 146. This Court has personal jurisdiction over Defendant pursuant to, *inter alia*, 35 U.S.C. § 146.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 35 U.S.C. § 146.

### **FACTS GIVING RISE TO THE COMPLAINT**

8. Plaintiff SmithKline Beecham Corporation is the assignee and owner of the entire right, title, and interest in and to the patent at issue in the '482 Interference, U.S. Patent No. 6,511,652 ("the Ashurst '652 Patent"), titled "Metered Dose Inhaler for Beclomethasone

Dipropionate." This patent duly and legally issued on January 28, 2003 from an application filed on February 18, 2000, based on a prior application filed on April 11, 1996. The named inventors are Ian C. Ashurst, Ignatius Loy Britto, Craig Steven Herman, Li Li-Bovet, and Michael Thomas Riebe.

9. Plaintiff SmithKline Beecham Corporation is also the assignee and owner of the entire right, title, and interest in and to the patent at issue in the '624 Interference, U.S. Patent No. 6,511,653 ("the Ashurst '653 Patent"), titled "Metered Dose Inhaler for Beclomethasone Dipropionate." This patent duly and legally issued on January 28, 2003 from an application filed on February 8, 2000, based on a prior application filed on April 11, 1996. The named inventors are Ian C. Ashurst, Ignatius Loy Britto, Craig Steven Herman, Li Li-Bovet, and Michael Thomas Riebe.

10. Plaintiff SmithKline Beecham Corporation is also the assignee and owner of the entire right, title, and interest in and to the patent at issue in the '625 Interference, U.S. Patent No. 6,532,955 ("the Ashurst '955 Patent"), titled "Metered Dose Inhaler for Albuterol." This patent duly and legally issued on March 18, 2003 from an application filed on May 15, 2000, based on a prior application filed on April 14, 1995. The named inventors are Ian C. Ashurst, Ignatius Loy Britto, Craig Steven Herman, Li Li-Bovet, and Michael Thomas Riebe.

11. Plaintiff SmithKline Beecham Corporation is also the assignee and owner of the entire right, title, and interest in and to the patent at issue in the '626 Interference, U.S. Patent No. 6,546,928 ("the Ashurst '928 Patent"), titled "Metered Dose Inhaler for Fluticasone Propionate." This patent duly and legally issued on April 15, 2003 from an application filed on May 15, 2000, based on a prior application filed on April 14, 1995. The named inventors are Ian C. Ashurst, Ignatius Loy Britto, Craig Steven Herman, Li Li-Bovet, and Michael Thomas Riebe.

12. The four patents described in Paragraphs 8 through 11 (collectively "GSK Patents") are attached, respectively, as Exhibits A, B, C, and D to this Complaint.

13. On information and belief, Novartis is the assignee and owner of the entire right, title, and interest in and to U.S. Patent Application No. 10/424,633 ("the Brugger '633

Application"), filed on April 28, 2003, titled "An aerosol container and a method for storage and administration of a predetermined amount of a pharmaceutically active aerosol." The named inventors of this application are Francois Brugger and Angelika Stampf.

14. On September 28, 2006, the Board declared and instituted the '482 Interference between the GSK Patents and the Brugger '633 Application, based on subject matter defined by a single count, Count 1, which the Board later replaced with Count B. (Paper 83)

15. The Board redeclared the scope of the '482 Interference, and removed the GSK Patents other than the Ashurst '652 Patent from the '482 Interference, prior to its Decision and Judgment, and declared three new interference proceedings for these three removed patents. The '624 Interference was declared with respect to the Ashurst '653 Patent, the '625 Interference was declared with respect to the Ashurst '955 Patent, and the '626 Interference was declared with respect to the Ashurst '928 Patent. (Paper 80)

16. Count B of the '482 Interference, as substituted by the Board, was the sole count that served as the basis for the Board's decisions in the '482 Interference. Count B states as follows: "A metered dose inhaler having part or all of its internal surfaces coated with only one or more fluorocarbon polymers for dispersing an inhalation drug formulation, comprising a particulate drug and a fluorocarbon propellant." (Paper 83)

17. Plaintiffs filed a motion in the '482 Interference for judgment that claim 23 of the Ashurst '652 Patent does not correspond to the interference count because claim 23 is a patentably distinct invention involving a blend coating with a nonfluorocarbon polymer.

18. Plaintiffs' motion also sought judgment that certain claims in Plaintiffs' three other patents (the Ashurst '653 Patent, the Ashurst '955 Patent, and the Ashurst '928 Patent) are similarly patentably distinct from the invention of the Brugger '633 Application, and likewise do not correspond to the interference count. In its decision in the '482 Interference, the Board denied this portion of Plaintiffs' motion as moot, as the Board removed these patents from the '482 Interference and declared the new '624, '625, and '626 Interferences.

19. On July 16, 2008, the Board issued its "Decision on Motions" in the '482

Interference (Exhibit E to this Complaint), which erroneously denied certain motions brought by Ashurst and Plaintiff GSK and erroneously granted certain motions brought by Brugger and Defendant Novartis.

20. For example, the Board erroneously determined that: (a) claim 23 of the Ashurst '652 Patent corresponded with Count B of the '482 interference; and (b) claim 23 of the Ashurst '652 Patent was unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art.

21. The Board also issued, on the same day, an erroneous Decision on Motions and erroneous Judgment in each of the related '624, '625, and '626 Interferences that cancelled claims of the Ashurst '653 Patent, the Ashurst '955 Patent, and the Ashurst '928 Patent. (Respectively, Exhibits F, G, and H to this Complaint). The Board erroneously determined in these interferences that: (a) certain patent claims corresponded with Count B of the '482 Interference; and (b) certain patent claims were unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art. The Board's erroneous decisions in these related interferences were based on, and incorporated, its erroneous Decision on Motions and Judgment in the '482 Interference.

#### **DISSATISFACTION WITH THE BOARD'S DECISIONS**

22. Plaintiffs are dissatisfied with the Board's decisions and judgment in the '482 Interference. For example, numerous rulings in the Board's July 16, 2008 Decision on Motions in the '482 Interference (Paper 83), and as a result in its Second Redeclaration in the '482 Interference (Paper 84) and Judgment (Paper 85), were erroneous. The Board's July 16, 2008 decisions and rulings in the '624, '625, and '626 Interferences were based on, and incorporated, its faulty Decision on Motions in the '482 Interference (Paper 83), and were likewise erroneous. The Board also erroneously precluded Plaintiffs from seeking certain discovery during the interference proceedings. (Paper 44)

23. Plaintiffs seek a judgment correcting the erroneous decisions and judgments of the Board, based on the record before the Board and based on any additional evidence that Plaintiffs may introduce in this action.

24. The Board's decisions were erroneous both in fact and law, including:
- a. the Board denied Plaintiffs' requests for additional discovery (*e.g.*, Ashurst's Miscellaneous Motion for Discovery), and based its decisions, including its Decision on Motions and Judgment in the '482 Interference, as well as in the '624, '625, and '626 Interferences, on an incomplete factual record;
  - b. the Board erroneously determined, in the '482 Interference, that claim 23 of the Ashurst '652 Patent corresponds with Count B of the '482 Interference and/or otherwise interferes with the Brugger '633 Application;
  - c. the Board erroneously determined, in the '482 Interference, that claim 23 of the Ashurst '652 Patent was unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art;
  - d. the Board erroneously determined, in the '624 Interference, that claims 1-24 of the Ashurst '653 Patent correspond with Count B of the '482 Interference and/or otherwise interfere with the Brugger '633 Application;
  - e. the Board erroneously determined, in the '624 Interference, that claims 1-24 of the Ashurst '653 Patent were unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art;
  - f. the Board erroneously determined, in the '625 Interference, that certain claims of the Ashurst '955 Patent, including claims 19 and 22, correspond with Count B of the '482 Interference and/or otherwise interfere with the Brugger '633 Application;
  - g. the Board erroneously determined, in the '625 Interference, that certain claims of the Ashurst '955 Patent, including claims 19 and 22, were unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art;
  - h. the Board erroneously determined, in the '626 Interference, that certain

claims of the Ashurst '928 Patent, including claims 19 and 22, correspond with Count B of the '482 Interference and/or otherwise interfere with the Brugger '633 Application; and

- i. the Board erroneously determined, in the '626 Interference, that certain claims of the Ashurst '928 Patent, including claims 19 and 22, were unpatentable under 35 U.S.C. § 102(g) and/or § 103 based on prior art.

25. Plaintiffs have been harmed by the Board's erroneous decisions and therefore request that the Court set aside the Board's decisions pursuant to 5 U.S.C. § 706. Specifically, the Board's decisions are unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law.

26. Plaintiffs seek that the Court hold that claim 23 of the Ashurst '652 Patent is a patentably distinct invention from the subject matter of Count B of the '482 Interference, and is patentably distinct from, and does not interfere with, the Brugger '633 Application. Plaintiffs further seek that the Court hold that claim 23 of the Ashurst '652 Patent is valid and patentable under 35 U.S.C. §§ 102 and 103 and that Plaintiffs are entitled to the Ashurst '652 Patent. Plaintiffs request that the Court reverse and vacate the Board's Decision on Motions and Judgment in the '482 Interference on these issues, and all other issues wrongly decided by the Board. Plaintiffs seek the same relief with respect to the Board's erroneous decisions in the '624, '625, and '626 Interferences regarding claims involving a blend coating with a nonfluorocarbon polymer, including claims 1-24 of the Ashurst '653 Patent, claims 19 and 22 of the Ashurst '955 Patent, and claims 19 and 22 of the Ashurst '928 Patent, respectively.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for relief as follows:

- A. A judgment that claim 23 of U.S. Patent No. 6,511,652 is valid and patentable under 35 U.S.C. §§ 102 and 103;

B. A judgment that claims 1-24 of U.S. Patent No. 6,511,653 are valid and patentable under 35 U.S.C. §§ 102 and 103;

C. A judgment that certain claims of U.S. Patent No. 6,532,955, including claims 19 and 22, are valid and patentable under 35 U.S.C. §§ 102 and 103;

D. A judgment that certain claims of U.S. Patent No. 6,546,928, including claims 19 and 22, are valid and patentable under 35 U.S.C. §§ 102 and 103;

E. A judgment that claim 23 of U.S. Patent No. 6,511,652 is patentably distinct from Count B of the '482 Interference and does not otherwise interfere with the Brugger '633 Application;

F. A judgment that claims 1-24 of U.S. Patent No. 6,511,653 are patentably distinct from Count B of the '482 Interference and do not otherwise interfere with the Brugger '633 Application;

G. A judgment that certain claims of U.S. Patent No. 6,532,955, including claims 19 and 22, are patentably distinct from Count B of the '482 Interference and do not otherwise interfere with the Brugger '633 Application;

H. A judgment that certain claims of U.S. Patent No. 6,546,928, including claims 19 and 22, are patentably distinct from Count B of the '482 Interference and do not otherwise interfere with the Brugger '633 Application;

I. A judgment that the Board's decision that claim 23 of U.S. Patent No. 6,511,652 is unpatentable under 35 U.S.C. §§ 102 and 103 in the '482 Interference is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

J. A judgment that the Board's decision that claims 1-24 of U.S. Patent No. 6,511,653 are unpatentable under 35 U.S.C. §§ 102 and 103 in Interference No. 105,624 is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

K. A judgment that the Board's decision that certain claims of U.S. Patent No. 6,532,955, including claims 19 and 22, are unpatentable under 35 U.S.C. §§ 102 and 103 in Interference No. 105,625 is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

L. A judgment that the Board's decision that certain claims of U.S. Patent No. 6,546,928, including claims 19 and 22, are unpatentable under 35 U.S.C. §§ 102 and 103 in Interference No. 105,626 is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

M. A judgment that the Board's decision that claim 23 of U.S. Patent No. 6,511,652 corresponds with Count B of the '482 Interference or otherwise interferes with the Brugger '633 Application is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

N. A judgment that the Board's decision that claims 1-24 of U.S. Patent No. 6,511,653 correspond with Count B of the '482 Interference or otherwise interfere with the Brugger '633 Application is unwarranted by the facts, unsupported by substantial evidence,

and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

O. A judgment that the Board's decision that certain claims of U.S. Patent No. 6,532,955, including claims 19 and 22, correspond with Count B of the '482 Interference or otherwise interfere with the Brugger '633 Application is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

P. A judgment that the Board's decision that certain claims of U.S. Patent No. 6,546,928, including claims 19 and 22, correspond with Count B of the '482 Interference or otherwise interfere with the Brugger '633 Application is unwarranted by the facts, unsupported by substantial evidence, and/or not in accordance with the law, and reversing and vacating the Board's decision and judgment on these grounds pursuant to 5 U.S.C. § 706;

Q. A judgment that Plaintiffs are entitled to U.S. Patent No. 6,511,652, and ordering and authorizing the PTO to reinstate, reissue, or otherwise take steps necessary to reverse the cancellation of claim 23 of the Ashurst '652 Patent;

R. A judgment that Plaintiffs are entitled to U.S. Patent No. 6,511,653, and ordering and authorizing the PTO to reinstate, reissue, or otherwise take steps necessary to reverse the cancellation of claims 1-24 of that patent;

S. A judgment that Plaintiffs are entitled to U.S. Patent No. 6,532,955, and ordering and authorizing the PTO to reinstate, reissue, or otherwise take steps necessary to reverse the cancellation of certain claims, including claims 19 and 22, of that patent;

T. A judgment that Plaintiffs are entitled to U.S. Patent No. 6,546,928, and ordering and authorizing the PTO to reinstate, reissue, or otherwise take steps necessary to reverse the cancellation of certain claims, including claims 19 and 22, of that patent;

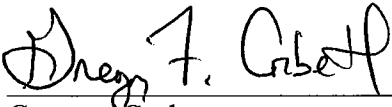
U. A judgment terminating the '482 Interference and Interference Nos. 105,624, 105,625, and 105,626 after entry of the above relief;

V. An order that costs and attorney fees be awarded in favor of Plaintiffs against Defendants; and

W. Such other and further relief as the Court deems just and proper.

Dated: September 12, 2008

Respectfully submitted,

By:   
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