

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC.,

Plaintiff,

v.

**BAXTER INTERNATIONAL INC., and
BAXTER HEALTHCARE CORPORATION,**

Defendants.

C.A. No. 05 _____

COMPLAINT

Talecris Biotherapeutics, Inc. (referred to as “Talecris”) by its attorneys, for its complaint against Baxter International Inc. and Baxter Healthcare Corporation (collectively referred to as “Baxter”), alleges as follows:

Nature of the Action

1. This is an action by Talecris against Baxter for:
 - (a) a declaratory judgment of infringement of one or more claims of United States Letters Patent No. 6,686,191 under 35 U.S.C. § 271(g);
 - (b) a declaratory judgment of infringement of one or more claims of United States Letters Patent No. 6,686,191 under 35 U.S.C. § 271(a);
 - (c) a declaratory judgment of infringement of one or more claims of United States Letters Patent No. 6,686,191 under 35 U.S.C. § 271(b).

The Parties

2. Plaintiff Talecris Biotherapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware and maintains a place of business at 4101 Research Commons, 79 TW Alexander Drive, Research Triangle Park, North Carolina 27709.

3. Defendant Baxter International Inc. is a corporation organized and existing under the laws of the State of Delaware, maintains a place of business at One Baxter Parkway, Deerfield, Illinois 60015-4633, and maintains an agent and address for service of process at Corporation Trust Center, 1209 Orange Street, Wilmington Delaware 19801.

4. Defendant Baxter Healthcare Corporation is a corporation organized and existing under the laws of the State of Delaware, maintains a place of business at One Baxter Way, Westlake Village, California 91362, and maintains an agent and address for service of process at Corporation Trust Center, 1209 Orange Street, Wilmington Delaware 19801.

5. Upon information and belief, Baxter Healthcare Corporation is a wholly-owned subsidiary, and is the principal United States operating subsidiary, of Baxter International Inc.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction of this action, pursuant to 28 U.S.C. §§ 1331 and 1338, in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1, *et seq.*

7. The defendants are subject to personal jurisdiction in this district.

8. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391 (c), (d) and 1400 (b).

The '191 Patent

9. On February 3, 2004, the United States Patent and Trademark Office issued United States Letters Patent No. 6,686,191 (“the ‘191 patent”), entitled “Preparation of Virally Inactivated Intravenously Injectable Immune Serum Globulin,” upon an application filed by William R. Alonso. The ‘191 patent is assigned to Bayer HealthCare LLC. A copy of the ‘191 patent is attached hereto as “Exhibit A”.

10. The ‘191 patent expires on or about July 29, 2020.

11. Representative claims of the ‘191 patent include:

Claim 1:

A method of treating a solution of antibodies which may have virus activity, the method comprising
a) contacting the solution with a trialkylphosphate and a detergent under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity; and
b) then incubating the solution of step a) under conditions of controlled time, pH, temperature, and ionic strength, such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for intravenous administration.

Claim 23:

An intravenously injectable immune serum globulin preparation produced by the method of claim 1 and substantially free of lipid enveloped viruses, wherein the preparation has an ionic strength less than about 0.001, a pH between about 3.5 and about 5.0, an antibody concentration of about 10% wt./wt., and a glycine concentration of about 0.2 M.

12. Talecris is the exclusive licensee of the ‘191 patent with the right to enforce the patent.

Factual Allegations

13. On or about April 27, 2005, Baxter obtained approval for a biologics license application (“BLA”) from the United States Food and Drug Administration (the “FDA”) for the commercial manufacture, use, and sale of a product identified as “Immune Globulin Intravenous (Human),

10% Solution” to be sold under the trade name “GAMMAGARD LIQUID” (hereinafter “GAMMAGARD LIQUID”). A copy of the letter approving Baxter’s BLA is attached to this Complaint as Exhibit B.

14. The BLA identifies the manufacturer of GAMMAGARD LIQUID as defendant Baxter HealthCare Corporation. Baxter’s BLA approves the manufacture of GAMMAGARD LIQUID at Baxter’s facility in Lessines, Belgium.

15. Baxter has publicly announced its intention to begin sales of its GAMMAGARD LIQUID product within the United States during or before the fourth quarter of 2005 and has taken immediate and active steps to commence sale in the United States of its GAMMAGARD LIQUID product. See Exhibit “C” attached and incorporated by reference as if fully set forth herein.

16. Upon information and belief, Baxter has begun or shortly intends to begin importing into the United States and stockpiling GAMMAGARD LIQUID product in anticipation of its intended launch of GAMMAGARD LIQUID sales in the United States.

17. The labeling information for GAMMAGARD LIQUID approved by the FDA (the “approved label”) lists three steps of the manufacturing process. The approved label describes, *inter alia*, the steps of manufacturing GAMMAGARD LIQUID as “solvent/detergent (S/D) treatment,” “35 nm nanofiltration,” and “a low pH incubation at elevated temperature.”

18. Upon information and belief, the steps and conditions listed by Baxter in the approved label as part of its manufacturing process for GAMMAGARD LIQUID, if practiced in the United States, infringes literally or under the doctrine of equivalents, or will infringe literally or under the doctrine of equivalents, one or more claims of the ‘191 patent.

19. Upon information and belief, the importation into the United States, and/or offer for sale, sale, or use within the United States, of Baxter's GAMMAGARD LIQUID infringes literally or under the doctrine of equivalents, or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. §§ 271(a), (b) and (g).

FIRST CLAIM FOR RELIEF;
DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '191 PATENT UNDER 35 U.S.C. § 271 (g)

20. Talecris realleges paragraphs 1 through 19 above as if fully set forth herein.

21. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

22. Upon information and belief, Baxter's GAMMAGARD LIQUID product is made, and is intended to be made, by a process which, if practiced in the United States, infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent.

23. Upon information and belief, Baxter International Inc.'s importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(g).

24. Alternatively, upon information and belief, Baxter Healthcare Corporation's importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of

equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(g).

25. Alternatively, upon information and belief, Baxter International Inc. and Baxter Healthcare Corporation's joint importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(g).

26. Talecris will be irreparably harmed if Baxter is not enjoined from infringing one or more claims of the '191 patent.

SECOND CLAIM FOR RELIEF;
DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '191 PATENT UNDER 35 U.S.C. § 271 (a)

27. Talecris realleges paragraphs 1 through 26 above as if fully set forth herein.

28. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

29. Upon information and belief, Baxter International Inc.'s importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(a).

30. Alternatively, upon information and belief, Baxter Healthcare Corporation's importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of

equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(a).

31. Alternatively, upon information and belief, Baxter International Inc. and Baxter Healthcare Corporation's joint importation into the United States and/or future importation, offer for sale, sale, or use within the United States of Baxter's GAMMAGARD LIQUID product infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent pursuant to 35 U.S.C. § 271(a).

32. Talecris will be irreparably harmed if Baxter is not enjoined from infringing one or more claims of the '191 patent.

THIRD CLAIM FOR RELIEF;
INDUCING INFRINGEMENT
OF THE '191 PATENT UNDER 35 U.S.C. § 271 (b)

33. Talecris realleges paragraphs 1 through 32 above as if fully set forth herein.

34. Baxter International Inc. infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent under 35 U.S.C. § 271(b) by actively inducing Baxter Healthcare Corporation to infringe one or more claims of the '191 patent.

35. Alternatively, Baxter Healthcare Corporation infringes literally or under the doctrine of equivalents, and/or will infringe literally or under the doctrine of equivalents, one or more claims of the '191 patent under 35 U.S.C. § 271(b) by actively inducing Baxter International Inc. to infringe one or more claims of the '191 patent.

36. Talecris will be irreparably harmed if Baxter is not enjoined from inducing the infringement of one or more claims of the '191 patent.

WHEREFORE, Talecris requests the following relief:

- A.** A declaratory judgment that Baxter's GAMMAGARD LIQUID Immune Globulin Intravenous (Human) is made according to the processes claimed in the '191 patent, and that its importation into the United States and/or its offer for sale, sale, and/or use in the United States is, or will imminently constitute, an infringement, literally or under the doctrine of equivalents, of one or more claims of the '191 patent;
- B.** A judgment permanently enjoining Baxter International Inc. and Baxter Healthcare Corporation from making, using, selling, offering to sell, and importing into the United States GAMMAGARD LIQUID Immune Globulin Intravenous (Human) prior to the expiration date of the '191 patent;
- C.** A judgment permanently enjoining Baxter International Inc. and Baxter Healthcare Corporation from inducing infringement of the '191 patent prior to the expiration date of the '191 patent;
- D.** Attorneys' fees in this action under 35 U.S.C. § 285;
- E.** Costs and expenses in this action; and
- F.** Such further and other relief as this Court may deem just and proper.

Respectfully submitted,
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