

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

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

Plaintiffs,

v.

MINRAD, INC. ,

Defendant.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

In this patent infringement action, Plaintiffs Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare SA (collectively "Plaintiffs"), for their complaint against Defendant, Minrad, Inc., allege as follows:

**PARTIES**

1. Plaintiff Baxter Healthcare Corporation ("BHC") is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015.
2. Plaintiff Baxter International Inc. ("BII") is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015.
3. Plaintiff Baxter Healthcare SA ("BHSA") is a corporation incorporated in Switzerland, having its principal place of business at Hertistrasse 2, Wallisellen, CH-8304, Switzerland.
4. On information and belief, Defendant Minrad, Inc. ("Minrad") is a corporation incorporated in Delaware, having its principal place of business at 50 Cobham Drive, Orchard Park, New York 14127.

## JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(a), (b), (c) and (e)(2) specifically.

6. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Minrad because it is incorporated in Delaware.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

## GENERAL ALLEGATIONS

9. On April 8, 1997, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 5,617,906 ("the '906 Patent"). A true and correct copy of the '906 Patent is attached hereto as Exhibit A.

10. BII and BHSA are the owners of the '906 patent.

11. BHC is the holder of the United States Food and Drug Administration ("FDA")-approved New Drug Application ("NDA") No. 20-118 and sells and distributes the drug covered by the NDA and marketed under the tradename Suprane®, the active ingredient of which is desflurane ((±)1,2,2,2-tetrafluoroethyl difluoromethyl ether) (hereinafter "Suprane®" or the "Suprane® drug product), by exclusive license, in the United States.

12. BHSA manufactures Suprane® (desflurane, USP), a nonflammable liquid administered via vaporizer and used as a general inhalation anesthetic.

13. Plaintiffs jointly own all rights, title and interest in the '906 Patent, including all rights needed to bring this action in Plaintiffs' names.

14. The '906 Patent is listed in the list of Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), maintained by the Food and Drug Administration ("FDA"), as a patent "with respect to which a claim of patent infringement could

reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug” Suprane®. 21 U.S.C. § 355(b)(1).

15. On information and belief, Minrad filed an abbreviated new drug application (ANDA) No. 90-363 with the FDA seeking approval to market a generic copy of the Suprane® drug product (hereinafter "Torrane (Desflurane)").

16. On information and belief, Minrad included in its ANDA, or amended its ANDA to include, a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '906 Patent is invalid or will not be infringed by the manufacture, use, or sale of Torrane (Desflurane) covered by Minrad’s ANDA.

17. Plaintiffs received a letter on or about December 12, 2008 from Minrad dated December 11, 2008, purporting to be a notice of Minrad's ANDA and “Paragraph IV” certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii).

#### **COUNT ONE**

#### **(Infringement of the '906 Patent Against Minrad)**

18. Plaintiffs incorporate and reallege paragraphs 1 through 17 above, as if set forth in full herein.

19. Pursuant to 35 U.S.C. § 271(e)(2)(A), Minrad’s filing of an ANDA, or amended ANDA, seeking approval to market Torrane (Desflurane) is an act of infringement of one or more claims of the '906 Patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Minrad’s ANDA be a date which is not earlier than October 8, 2014, the expiration date of the '906 Patent, including any extensions of this date.

20. Upon FDA approval of Minrad's ANDA No. 90-363, Minrad will infringe the '906 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and or/importing Minrad's Torrane (Deflurane) in the United States, and/or by

actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271 (a), (b) and/or (c), unless this Court orders that the effective date of any FDA approval of Minrad's ANDA shall be no earlier than the expiration date of the '906 Patent and any additional periods of exclusivity.

21. Plaintiffs will be substantially and irreparably harmed by Minrad's infringing activities unless those activities are enjoined by the Court.

22. Plaintiffs have no adequate remedy at law for Minrad's infringement of the '906 Patent.

23. On information and belief, Minrad did not have an adequate good-faith basis for filing the "Paragraph IV" certification(s) accompanying its ANDA and/or amended ANDA.

24. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorneys' fees.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Minrad's submission to the FDA of ANDA No. 90-363 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Minrad's Torrane (Desflurane) before the expiration of the '906 Patent was an act of infringement of the '906 Patent;

(2) declaring that Minrad's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Minrad of Torrane (Desflurane) would constitute infringement of the '906 Patent;

(3) ordering that the effective date of any FDA approval of Minrad's Torrane (Desflurane) shall be no earlier than October 8, 2014, the expiration date of the '906 Patent and any additional dates of exclusivity, in accordance with 35 U.S.C. §271 (e)(4)(A);

(4) enjoining Minrad, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering for sale, or selling Minrad's Torrane (Desflurane) within the United States or importing into the United States Minrad's Torrane (Desflurane), until the expiration of the '906 Patent, in accordance with 35 U.S.C. §271 (e)(4)(B);

(5) ordering that judgment be entered that Plaintiffs be awarded monetary relief if Minrad, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, commercially uses, offers for sale or sells Torrane (Desflurane) within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

(6) enjoining Minrad, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from directly infringing, contributorily infringing, or inducing infringement of the '906 Patent;

(7) enjoining Minrad, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining final approval of Minrad's ANDA No. 90-363 until the expiration of the '906 Patent;

(8) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;


(9) awarding Plaintiffs their costs and expenses in this action; and

(10) awarding Plaintiffs any further and additional relief as this Court may deem just and proper.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

David T. Pritikin  
Richard T. McCaulley, Jr.  
Sidley Austin LLP  
One South Dearborn  
Chicago, IL 60603  
(312) 853 -7000

By:   
Philip A. Rovner (#3215)  
Hercules Plaza  
P.O. Box 951  
Wilmington, Delaware 19899  
(302) 984-6000  
[provner@potteranderson.com](mailto:provner@potteranderson.com)

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David W. Woodward  
Sidley Austin LLP  
1501 K Street, N.W.  
Washington, D.C. 20005  
(202) 736 - 8000

*Attorneys for Plaintiffs  
Baxter Healthcare Corporation,  
Baxter International Inc. and  
Baxter Healthcare SA*

Dated: January 23, 2009  
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