IN THE UNITED STATES DISCTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION and ROCHE DIAGNOSTICS GMBH

Plaintiffs,

v.

POLYMER TECHNOLOGY SYSTEMS, INC.

Defendant.

CIVIL ACTION NO. 1:03-CV-0848 JDT-WTL

COMPLAINT

Plaintiffs, Roche Diagnostics Corporation and Roche Diagnostics GmbH, (hereinafter "Plaintiffs"), present this Complaint of patent infringement against defendant, Polymer Technology Systems, Inc., (hereinafter "PTS"), and plaintiffs state as follows:

PARTIES

1. Plaintiff Roche Diagnostics Corporation ("RDC") is a corporation organized under the laws of the State of Indiana and having its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46256. RDC is engaged in the business of researching, developing, manufacturing, and selling diagnostic products for the human healthcare market.

2. Plaintiff Roche Diagnostics GmbH ("RDG") is a corporation organized under the laws of Germany and having its principal place of business at Sandhofer Strasse 116, D-68298 Mannheim Germany. RDG is engaged in the business of researching, developing, manufacturing, and selling diagnostic products for the human healthcare market.

3. Defendant Polymer Technology Systems, Inc. ("PTS") is a corporation organized under the laws of the State of Indiana and having its principal place of business at 7736 Zionsville Road, Indianapolis, Indiana 46268. PTS is in the business of researching, developing, manufacturing, and selling point-of-care diagnostic products for the human healthcare market.

JURISDICTION AND VENUE

4. This is a complaint for patent infringement. The jurisdiction of this Court is properly founded under 28 U.S.C. §§ 1331 and 1338(a).

5. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 28 U.S.C. § 1400(b).

6. PTS is a diagnostic company that is incorporated in Indiana and having its principal place of business in the State of Indiana and the Southern District of Indiana. Moreover, PTS sells the accused products throughout the United States, including the State of Indiana. Thus, PTS is subject to personal jurisdiction in this judicial district.

CLAIM FOR RELIEF

The Patents In Suit

7. RDG is the owner of U.S. Patent No. 6,171,849 ("the '849 patent"), entitled "Method for the Determination Of HDL Cholesterol by Means of a Rapid Diagnostic Agent with an Integrated Fractionating Step" (attached as Exhibit A), which is a valid patent, legally issued by the U.S. Patent and Trademark Office on January 9, 2001.

8. RDG is the owner of U.S. Patent No. 5,786,164 ("the '164 patent"), entitled "Method for Separating Non-High Density Lipoproteins from Lipoprotein Containing Body Fluid Samples" (attached as Exhibit B), which is a valid patent, legally issued by the U.S. Patent and

Trademark Office on July 28, 1998. Although the '164 patent on its face was issued to Boehringer Mannheim GmbH, that entity has, through merger, acquisition, and name change, become Roche Diagnostics GmbH.

9. RDG is the owner of U.S. Patent No. 6,214,570 ("the '570 patent"), entitled "Method for Separating Non-HDLs from HDLs and Determining HDL Cholesterol" (attached as Exhibit C), which is a valid patent, legally issued by the U.S. Patent and Trademark Office on April 10, 2001.

10. RDG is the owner of U.S. Patent No. B1 4,816,224 ("the '224 Patent"), entitled "Device for Separating Plasma or Serum From Whole Blood and Analyzing the Same" (attached as Exhibit D), which is a valid patent, legally issued by the U.S. Patent and Trademark Office on March 28, 1989. The U.S. Patent and Trademark Office reconfirmed the validity of this patent, after reexamination, on March 10, 1992. Although the '224 patent on its face was issued to Boehringer Mannheim GmbH, that entity has, through merger, acquisition, and name change, become Roche Diagnostics GmbH.

11. RDC is the owner of U.S. Patent No. 5,366,609 ("the '609 patent"), entitled "Biosensing Meter with Pluggable Memory Key" (attached as Exhibit E), which is a valid patent, legally issued by the U.S. Patent and Trademark Office on November 22, 1994. Although the '609 patent on its face was issued to Boehringer Mannheim Corporation, that entity has, through merger, acquisition, and name change, become Roche Diagnostics Corporation.

12. At all relevant times, Plaintiffs have complied with their obligations pursuant to 35 U.S.C. §287.

The Infringing Conduct by Defendant

13. PTS manufactures, sells, offers for sale, and uses and induces others to use its diagnostic products, including, *inter alia,* the BioScanner 2000™ and the CardioChek™ devices (hereinafter "PTS devices"), which are hand held monitors designed for point-of-care patient blood testing. On information and belief, PTS exports the PTS devices for use and sale by others outside of the United States.

14. These PTS devices use disposable PTS test strips for testing various markers, including: (i) blood glucose, (ii) triglyceride, (iii) total cholesterol, (iv) HDL cholesterol, (v) ketone, and (vi) a Lipid Panel. The disposable test strips include highly specialized structure that is designed to separate out red blood cells and, also, memory chips that are designed to work as integral parts of and with the PTS device. The HDL test strip and the Lipid Panel test strip also contain highly specialized structure that is designed to determine the amount of HDL in a patient's circulating blood. PTS manufactures, sells, and offers for sale such disposable test strips for use with its PTS devices with instructions for use by the customer. On information and belief, PTS exports test strips for use and sale by others outside the United States.

COUNT I - PATENT INFRINGEMENT OF THE '849 PATENT

15. Plaintiffs re-allege and incorporate by reference paragraphs 1-14.

16. By engaging in the commercial manufacture, use, sale, offer for sale and exportation of its HDL strip and/or Lipid Panel strip, *i.e.*, those used with its PTS devices, PTS has infringed the '849 patent under 35 U.S.C. § 271(a), (b), (c) and (f).

17. PTS's actions constitute knowing and willful infringement of Plaintiffs' patents.

COUNT II - PATENT INFRINGEMENT OF THE '164 PATENT

18. Plaintiffs re-allege and incorporate by reference paragraphs 1-17.

19. On information and belief, PTS has manufactured, used, sold, offered for sale and exported its HDL strip and/or Lipid Panel strip for use with its PTS devices. The use of these products practices a method claimed in the '164 patent, and constitutes a material part of the invention. PTS has sold its HDL strip and/or Lipid Panel strip for use with its PTS devices, with information sufficient to actively induce its customers to infringe the '164 patent.

20. On information and belief, PTS makes, uses, sells and exports its products knowing that such HDL strip and/or Lipid Panel strips are especially made or especially adapted for use in an infringement of the '164 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

21. By engaging in the commercial manufacture, use, sale, offer for sale, and exportation of the PTS Device and its related disposable test strips for testing HDL content in body fluid, PTS has infringed the '164 patent under 35 U.S.C. §§ 271 (a), (b), (c) and (f).

22. PTS's actions constitute knowing and willful infringement of Plaintiffs' patents.

COUNT III - PATENT INFRINGEMENT OF THE '570 PATENT

23. Plaintiffs re-allege and incorporate by reference paragraphs 1-22.

24. The PTS device and its related HDL strip and/or Lipid Panel strip are used to practice a method claimed in the '570 patent, and constitutes a material part of the invention. PTS has made, used, sold, offered for sale and exported its PTS devices and its HDL strip and/or Lipid Panel strip for use with its PTS devices, with information sufficient to actively induce its customers to infringe the '570 patent.

25. PTS has engaged in the activity here complained of, knowing that such HDL strip and/or Lipid Panel strips are especially made or especially adapted for use in an infringement of the '570 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

26. By engaging in the commercial manufacture use, sale, offer for sale and exportation of the PTS device and its related disposable test strips that test HDL content in a body fluid, PTS has infringed the '570 patent under 35 U.S.C. § 271(a), (b), (c) and (f).

27. PTS's actions constitute knowing and willful infringement of Plaintiffs' patents.

COUNT IV - PATENT INFRINGEMENT OF THE '224 PATENT

28. Plaintiffs re-allege and incorporate by reference paragraphs 1-27.

29. PTS's disposable test strips used with the PTS devices employ the invention of the '224 patent and function in a manner set forth in the claims of the '224 patent. PTS has made, used, sold, offered for sale and exported its test strips for use with its PTS devices, with information sufficient to actively induce its customers to infringe the '224 patent.

30. PTS has engaged in the activity here complained of, knowing that such test strips are especially made or especially adapted for use in an infringement of the '224 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

31. By engaging in the commercial manufacture use, sale, offer for sale and exportation of the PTS device and its related disposable test strips, PTS has infringed the '224 patent under 35 U.S.C. § 271(a), (b), (c) and (f).

32. PTS's actions constitute knowing and willful infringement of Plaintiffs' patents.

COUNT V - PATENT INFRINGEMENT OF THE '609 PATENT

33. Plaintiffs re-allege and incorporate by reference paragraphs 1-32.

34. The PTS Devices utilize a pluggable memory key as set forth in one or more claims of the '609 patent. PTS has made, used, sold, offered for sale and exported its PTS devices with a pluggable memory key and the associated test strips. Moreover, PTS includes with the PTS devices and the associated test strips information sufficient to actively induce its customers to infringe the '609 patent.

35. PTS has engaged in the activity here complained of, knowing that such PTS devices with a pluggable memory key and the associated test strips are especially made or especially adapted for use in an infringement of the '609 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

36. By engaging in the commercial manufacture use, sale, offer for sale and exportation of the PTS devices with a pluggable memory key and the associated test strips, PTS has infringed the '609 patent under 35 U.S.C. § 271(a), (b), (c) and (f).

37. PTS's actions constitute knowing and willful infringement of Plaintiffs' patents.

RELIEF REQUESTED

Wherefore, Plaintiffs pray for judgment and relief including:

(A) A declaration that Defendant has infringed, contributorily infringed and/or induced the infringement of one or more claims of United States Patents Nos. 6,171,849, 5,786,164, 6,214,570, B1 4,816,224, and 5,366,609 by its manufacture, use, sale, offer to sell, and exportation of the its PTS devices and test strips in the manner explained above;

(B) A permanent and preliminary injunction pursuant to 35 U.S.C. §283, enjoining Defendant and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing of any claims of the patents in suit under 35 U.S.C. § 271(a), (b) (c) and/or (f);

(C) An accounting and award of damages incurred by Plaintiffs as a result of Defendant's infringement if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States;

(D) An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Plaintiffs their attorneys fees in pursuing this case; and

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

Date: June 9, 2003

John R. Schaibley, III
Stacy L. Prall
Baker & Daniels
300 N. Meridian Street
Suite 2700
Indianapolis, Indiana 46204
Telephone: (317) 237-0300
Facsimile: (317) 237-1000

Of Counsel:

Daniel A. Boehnen
Grant G. Drutchas
James C. Gumina
Leif R. Sigmond, Jr.
McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
Telephone: (312) 913-0001
Facsimile: (312) 913-0002

Brent A. Harris
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250