

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION,)
ROCHE DIAGNOSTICS OPERATIONS, INC.,)
and CORANGE INTERNATIONAL LTD.,)

Plaintiffs,)

vs.)

Civil Action No. 1:04-CV-00358-LJM-VSS

APEX BIOTECHNOLOGY CORP.,)
HYPOGUARD USA, INC., MEDLINE)
INDUSTRIES, INC., and HOME)
DIAGNOSTICS, INC.,)

JURY TRIAL DEMANDED

Defendants.)

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

The Plaintiffs, Roche Diagnostics Corporation (“RDC”), Roche Diagnostics Operations, Inc. (“RDOI”), and Corange International Ltd. (“CIL”), for their Complaint against the Defendants, Apex Biotechnology Corp. (“Apex”), Hypoguard USA, Inc. (“Hypoguard”), Medline Industries, Inc. (“Medline”), and Home Diagnostics, Inc. (“HDI”) (collectively, “Defendants”), allege and state:

PARTIES

1. RDC is an Indiana corporation with its principal place of business in Indianapolis, Indiana.
2. RDOI is a Delaware corporation with its principal place of business in Indianapolis, Indiana.
3. CIL is a Bermuda corporation with its principal place of business in Puerto Rico.

4. On information and belief, Apex is a Taiwanese corporation with its principal place of business in Hsinchu City, Taiwan.

5. On information and belief, Hypoguard is a Delaware corporation with its principal place of business in Minneapolis, Minnesota, and doing business in Indianapolis, Indiana, among other places.

6. On information and belief, Medline is an Illinois corporation with its principal place of business in Mundelein, Illinois, and doing business in Indianapolis, Indiana, among other places.

7. On information and belief, HDI is a Delaware corporation with its principal place of business in Fort Lauderdale, Florida, and doing business in Indianapolis, Indiana, among other places.

JURISDICTION AND VENUE

8. This is a complaint for patent infringement pursuant to 35 U.S.C. § 271 *et. seq.* This Court has subject matter jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1338.

9. Apex is subject to personal jurisdiction in this district because it places its products into the stream of commerce knowing such products will be and are sold in Indiana.

10. Hypoguard is subject to personal jurisdiction in this district because it places its products into the stream of commerce knowing such products will be and are sold in Indiana.

11. Medline is subject to personal jurisdiction in this district because it places its products into the stream of commerce knowing such products will be and are sold in Indiana.

12. HDI is subject to personal jurisdiction in this district because it places its products into the stream of commerce knowing such products will be and are sold in Indiana.

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

SUBSTANTIVE ALLEGATIONS

A. Plaintiffs' Business and Patents.

14. RDC is the past owner of U.S. Patent No. Re. 36,268 (“the ‘268 patent”) and U.S. Patent No. 5,366,609 (“the ‘609 patent”).

15. RDOI owns an undivided half-interest in the ‘268 patent and an undivided half-interest in the ‘609 patent. RDOI acquired its interest in the patents from RDC by assignment and has the right to recover damages accruing after the date of assignment.

16. CIL owns an undivided half-interest in the ‘268 patent and an undivided half-interest in the ‘609 patent. CIL acquired its interest in the patents from RDC by assignment and has the right to recover damages accruing after the date of assignment.

17. RDC retains the right to recover damages suffered prior to the date of assignment of the ‘268 and ‘609 patents.

18. RDC is a leading healthcare company active in, among other things, the development, manufacture, marketing and sale of blood glucose meters and test strips used in the monitoring of diabetes.

19. Beginning in 1987, RDC invested years of research and development effort and millions of dollars to develop its popular Accu-Chek® Advantage and Accu-Chek® Complete meters and the Accu-Chek® Advantage and Accu-Chek® Comfort Curve test strips. The success of this product line, which offers diabetes patients a portable, reliable, and easy to use electrochemical blood glucose meter and corresponding test strips, is exemplified by the increase in the U.S. market share of the Accu-Chek® Advantage and Accu-Chek® Comfort Curve test strips from one and seven tenths percent shortly after the Accu-Chek® Advantage strips were

introduced in 1994 to nearly 29% in 2003. Annual worldwide sales of these meters and test strips now exceed \$1 billion.

B. Defendant Apex's Infringing Activities.

20. Apex is in the business of manufacturing and distributing medical diagnostic products, including products to monitor diabetes.

21. Apex manufactures, markets and sells the Sensorex Blood Glucose Monitoring System. The Sensorex product line includes blood glucose meters and test strips.

22. On information and belief, Apex sells the Sensorex Blood Glucose Monitoring System to Hypoguard, and Hypoguard sells the Sensorex product line under the brand name Assure®.

23. Apex manufactures, markets, and sells the GlucoSure Blood Glucose Monitoring System. The GlucoSure product line includes blood glucose meters and test strips.

24. On information and belief, Apex sells the GlucoSure Blood Glucose Monitoring System to Hypoguard, and Hypoguard sells the GlucoSure product line under the brand names Assure® II and Assure® 3. On information and belief, Apex sells a portion of the GlucoSure product line to Medline, and Medline resells the product under the brand name EvenCare.

25. The use and sale of the Sensorex and GlucoSure Blood Glucose Monitoring Systems in the United States infringes the '268 patent.

26. The use and sale of the Assure 3® in the United States infringes the '609 patent.

27. Apex directly infringes the '609 patent.

28. Apex contributorily infringes and/or induces infringement of the '268 and '609 patents.

29. Apex will continue to infringe unless enjoined by this Court.

C. Defendant Hypoguard's Infringing Activities.

30. Hypoguard is in the business of manufacturing and distributing medical diagnostic products, including products to monitor diabetes.

31. Hypoguard markets and sells in the United States the Assure®, Assure II®, and Assure 3® Blood Glucose Monitoring Systems that it acquires from Apex. All of the Assure product lines include blood glucose meters and test strips. Hypoguard sells the Guide-me-Curve™ test strip for use with the Assure® II and Assure® 3 meters. Hypoguard markets and sells all of the Assure product line in Indiana and elsewhere in the United States.

32. The use and sale of the Assure®, Assure® II, and Assure® 3 Blood Glucose Monitoring Systems infringes the '268 patent.

33. The use and sale of the Assure® 3 Blood Glucose Monitoring System infringes the '609 patent.

34. Hypoguard directly infringes the '609 patent.

35. Hypoguard contributorily infringes and/or induces infringement of the '268 and '609 patents.

36. Hypoguard will continue to infringe unless enjoined by this Court.

D. Defendant Medline's Infringing Activities.

37. Medline is in the business of manufacturing and distributing medical diagnostic products, including products to monitor diabetes.

38. Medline markets and sells the EvenCare® Blood Glucose Monitoring System that it acquires from Apex. The EvenCare® product line includes blood glucose meters and test strips. Medline markets and sells the EvenCare® product line in Indiana and elsewhere in the United States.

39. The use and sale of the EvenCare® Blood Glucose Monitoring System infringes the '268 patent.

40. Medline contributorily infringes and/or induces infringement of the '268 patent.

41. Medline will continue to infringe unless enjoined by this Court.

E. Defendant HDI's Infringing Activities.

42. HDI is in the business of manufacturing and distributing medical diagnostic products, including products to monitor diabetes.

43. HDI manufactures and sells the TrueTrack Smart System™ Blood Glucose Monitoring System and the TrackEASE Smart System® Blood Glucose Monitoring System. The TrueTrack Smart System™ and TrackEASE Smart System® product lines include blood glucose meters and test strips. HDI markets and sells the TrueTrack Smart System™ and TrackEASE Smart System® product lines in Indiana and elsewhere in the United States.

44. HDI sells the TrueTrack Smart System™ to national pharmacy chains, including among others, Walgreens, CVS, and Meijer. HDI sells the TrackEASE Smart System® through mail service and healthcare distributors.

45. The use and sale of the TrueTrack Smart System™ Blood Glucose Monitoring System and/or the TrackEASE Smart System® Blood Glucose Monitoring System infringes the '268 patent.

46. The manufacture, use, and sale of the TrueTrack Smart System™ Blood Glucose Monitoring System and/or the TrackEASE Smart System® Blood Glucose Monitoring System infringes the '609 patent.

47. HDI directly infringes the '609 patent.

48. HDI contributorily infringes and/or induces infringement of the '268 and '609 patents.

49. HDI will continue to infringe unless enjoined by this Court.

F. The Harm to Plaintiffs.

50. Plaintiffs have suffered and will suffer monetary damages as a result of the Defendants' infringing activities.

51. If the Defendants continue to sell the infringing products after their receipt of this Complaint, their infringement will be willful at least thereafter.

COUNT I
(Patent Infringement)

52. Plaintiffs incorporate the allegations of paragraphs 1 through 51 above as if fully set forth herein.

53. The Defendants are infringing and/or contributing to and/or inducing infringement of the '268 patent. Apex, Hypoguard, and HDI are infringing and/or contributing to and/or inducing infringement of the '609 patent

54. Plaintiffs have suffered damages and are suffering damages on an ongoing basis as a result of the Defendants' infringement.

55. Plaintiffs are entitled to a permanent injunction against the Defendants' infringement.

WHEREFORE, Plaintiffs pray that this Court:

1. Permanently enjoin Apex, Hypoguard, and HDI and their officers, agents, servants, employees, and attorneys, and those in active concert or participation with them who receive actual notice of the Order, from importing, manufacturing, using, selling, and/or offering for sale devices which infringe the '268 or '609

patents and from contributing to or inducing infringement of the '268 or '609 patents.

2. Permanently enjoin Medline and its officers, agents, servants, employees, and attorneys, and those in active concert or participation with them who receive actual notice of the Order, from importing, manufacturing, using, selling, and/or offering for sale devices which infringe the '268 patent and from contributing to or inducing infringement of the '268 patent.
3. Award Plaintiffs monetary damages adequate to compensate it for past infringement consistent with 35 U.S.C. § 284, up to and including treble the amount of actual damages, together with costs and prejudgment interest.
4. Award Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.
5. Award Plaintiffs all other just and proper relief.

JURY DEMAND

Plaintiffs request a trial by jury on their claims.

Respectfully submitted,

/s/

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