

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RETRACTABLE TECHNOLOGIES, INC.,
and THOMAS J. SHAW,

Plaintiffs,

v.

SAFETY MEDICAL INTERNATIONAL, INC.,

Defendant.

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Civil Action No. 6:08-cv-353

Jury Trial Demanded

PLAINTIFFS' ORIGINAL COMPLAINT

Plaintiffs, Retractable Technologies, Inc. (“Retractable”) and Thomas J. Shaw (“Shaw”), by their undersigned attorneys, bring this action against Safety Medical International, Inc. (“Defendant” or Safety Medical”) and allege as follows:

I. PARTIES

1. Plaintiff Retractable is a Texas corporation with its principal place of business in Texas. Founded, in 1994, Retractable is a public company based in Little Elm, Texas. Retractable manufactures and sells safety needle devices that incorporate patented designs retracting the needle into the device so that it cannot accidentally stick anyone after use.

2. Plaintiff Shaw is an individual residing in Frisco, Denton County, Texas.

3. Upon information and belief, Defendant Safety Medical International is a Tennessee corporation with its principal place of business at 2072 Sprint Blvd., Apopka, Orange County, FL 32703. The registered agent for service of process on Defendant is Bill West, Commerce Ctr. #1000, 211 Commerce St., Nashville, Davidson County, TN 37201.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction over the claims made in this Complaint under the Patent Laws as set forth in Title 35 of the United States Code and under Title 28 United States Code §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over the parties. Upon information and belief, Defendant regularly transacts business in the Eastern District of Texas, including the sale of in the infringing Saf-T-Syringe retractable syringe products. Representatives of Retractable have purchased in this Court's jurisdiction, in Allen, Texas, Collin County, retractable syringe products in packaged labeled in part "Retractable Needle Syringe ... Saf-T-Syringe ... Safety Medical International, Incorporated, Apopka, Florida."

6. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), 28 U.S.C. § 1400(b).

III. FACTUAL BACKGROUND

7. In 1995 Shaw developed and patented a new safety syringe. The design offers protection against potentially deadly needle-stick injuries and does not require the user to take any additional steps to render the syringe safe. The VanishPoint syringe automatically retracts the needle back into a cavity in the plunger when the plunger is fully depressed after it has delivered medicine into a patient. There is no chance for a nurse or doctor to be accidentally stuck by a needle that has been in contact with a patient's blood as the needle is no longer exposed after an injection has been given. Because the nurse or doctor only needs to push the syringe plunger completely to retract the needle, the VanishPoint is designed to require no separate action to retract the needle – when the syringe is used as designed, the needle will retract as the nurse or doctor finishes injecting medicine into the patient. This is referred to as a

passive safety device as opposed to an active device that requires the user to take affirmative action to engage it.

8. Plaintiff Shaw formed Plaintiff Retractable, a small Texas company located in Little Elm, Texas, to manufacture and market the novel retractable syringe in the world. Retractable markets the novel syringe under the name “VanishPoint.” The VanishPoint syringes are covered by a number of patents, including U.S. Patent Nos. 5,578,011 (“the ‘011 patent”), 5,632,733 (“the ‘733 patent”), 6,090,077 (“the ‘077 patent”), 7,351,224 (“the ‘224 patent”), and 6,572,584 (“the ‘584 patent”). The VanishPoint syringes have helped thousands, if not millions, of health care workers avoid contracting HIV AIDS and other life threatening blood diseases through needle stick accidents. The new safety syringe and Retractable have been featured in major news publications and on CBS’ *60 Minutes*.

9. In 2000, President Clinton signed a federal law requiring hospitals to keep track of needle stick injuries and to consider various safety syringes. Shaw was present at the signing of the legislation, as he was instrumental in getting the legislation passed. That legislation was intended to improve safety for consumers and health care workers by requiring hospitals to keep track of needlestick accidents and consider using safety syringes. The VanishPoint syringes sold by Retractable have been recognized as a superior safety product by independent rating agencies, studies and scholarly reviews, and polls and questionnaires of nurses and doctors.

10. On information and belief, Defendant manufacture and/or have manufactured the Saf-T-Syringe in China with the express purpose and intent of importing it into the United States for sale. On information and belief, Defendant has imported the Saf-T-Syringe into and has used, marketed, distributed, offered to sell, and sold the Saf-T-Syringe in the United States generally and the Eastern District of Texas particularly. Representatives of Retractable have

purchased in this Court's jurisdiction, in Allen, Texas, Collin County, retractable syringe products in packaged labeled in part "Retractable Needle Syringe ... Saf-T-Syringe ... Safety Medical International, Incorporated, Apopka, Florida." Upon information and belief, the Saf-T-Syringe infringes one or more claims of each of the '011, '733, '077, '224 and '584 patents.

11. In September 2005, the United States Food and Drug Administration approved Defendant's Section 510(k) pre-market notification of the intent to market the Saf-T-Syringe retractable syringe. The application is required under the Federal Food, Drug, and Cosmetic Act before a company is allowed to market certain medical devices. In that application, Defendant compared the Saf-T-Syringe with Retractable's VanishPoint retractable syringes and another competitor's syringes that also infringe Retractable's patents. Specifically, Defendant stated that "[a]ll three syringes are similar, and in some cases the same, with regard to parts, design, material, operating procedure, and intended use."

IV. COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,578,011

12. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

13. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, U.S. Patent No. 5,578,011, issued November 26, 1996, a copy of which is attached as Exhibit A. Plaintiff Shaw is the inventor and owner of, and has the right to sue in his own name on, the '011 patent. The maintenance fees for the '011 patent has been timely paid, and the '011 patent has not been invalidated or found to be unenforceable in any prior litigation.

14. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '011 patent.

15. Retractable and Shaw have not granted any right or license under which Defendant can legally make, have made, use, offer to sell, sell, or import into the United States retractable syringes covered by the '011 patent.

16. Defendant Safety Medical International, Inc., has directly, indirectly, and/or contributorily infringed the '011 patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '011 patent, and has induced and/or contributed to the infringement of the '011 patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court. For example, and without limitation, Defendant has made, used, sold, offered for sale and/or imported the Saf-T-Syringe retractable syringe, which is covered by at least one claim of the '011 patent.

17. Upon information and belief, Defendant's acts of infringement of the '011 patent have been willful and in deliberate disregard of the '011 patent and that this is an exceptional case under 35 U.S.C. § 285.

18. Retractable and Shaw have been damaged by Defendant's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

V. COUNT II – INFRINGEMENT OF U.S. PATENT NO. 5,632,733

19. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

20. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, U.S. Patent No. 5,632,733, issued May 27, 1997, a copy of which is attached as Exhibit B. Plaintiff Shaw is the inventor and owner of, and has the right to sue in his own name

on, the '733 patent. The maintenance fees for the '733 patent has been timely paid, and the '733 patent has not been invalidated or found to be unenforceable in any prior litigation.

21. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '733 patent.

22. Retractable and Shaw have not granted any right or license under which Defendant can legally make, have made, use, offer to sell, sell, or import into the United States retractable syringes covered by the '733 patent.

23. Defendant Safety Medical International, Inc., has directly, indirectly, and/or contributorily infringed the '733 patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '733 patent, and has induced and/or contributed to the infringement of the '733 patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court. For example, and without limitation, Defendant has made, used, sold, offered for sale and/or imported the Saf-T-Syringe retractable syringe, which is covered by at least one claim of the '733 patent.

24. Upon information and belief, Defendant's acts of infringement of the '733 patent have been willful and in deliberate disregard of the '733 patent and that this is an exceptional case under 35 U.S.C. § 285.

25. Retractable and Shaw have been damaged by Defendant's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

VI. COUNT III – INFRINGEMENT OF U.S. PATENT NO. 6,090,077

26. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

27. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, U.S. Patent No. 6,090,077, issued July 18, 2000, a copy of which is attached as Exhibit C. Plaintiff Shaw is the inventor and owner of, and has the right to sue in his own name on, the '077 patent. The maintenance fees for the '077 patent has been timely paid, and the '077 patent has not been invalidated or found to be unenforceable in any prior litigation.

28. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '077 patent.

29. Retractable and Shaw have not granted any right or license under which Defendant can legally make, have made, use, offer to sell, sell, or import into the United States retractable syringes covered by the '077 patent.

30. Defendant Safety Medical International, Inc., has directly, indirectly, and/or contributorily infringed the '077 patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '077 patent, and has induced and/or contributed to the infringement of the '077 patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court. For example, and without limitation, Defendant has made, used, sold, offered for sale and/or imported the Saf-T-Syringe, which is covered by at least one claim of the '077 patent.

31. Upon information and belief, Defendant's acts of infringement of the '077 patent have been willful and in deliberate disregard of the '077 patent and that this is an exceptional case under 35 U.S.C. § 285.

32. Retractable and Shaw have been damaged by Defendant's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

VII. COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 7,351,224

33. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

34. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, U.S. Patent No. 7,351,224, issued April 1, 2008, a copy of which is attached as Exhibit D. Plaintiff Shaw is the inventor and owner of, and has the right to sue in his own name on, the ‘224 patent. The maintenance fees for the ‘224 patent has been timely paid, and the ‘224 patent has not been invalidated or found to be unenforceable in any prior litigation.

35. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the ‘224 patent.

36. Retractable and Shaw have not granted any right or license under which Defendant can legally make, have made, use, offer to sell, sell, or import into the United States retractable syringes covered by the ‘224 patent.

37. Defendant Safety Medical International, Inc., has directly, indirectly, and/or contributorily infringed the ‘224 patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the ‘224 patent, and has induced and/or contributed to the infringement of the ‘224 patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court. For example, and without limitation, Defendant has made, used, sold, offered for sale and/or imported the Saf-T-Syringe retractable syringe, which is covered by at least one claim of the ‘224 patent.

38. Upon information and belief, Defendant’s acts of infringement of the ‘224 patent have been willful and in deliberate disregard of the ‘224 patent and that this is an exceptional case under 35 U.S.C. § 285.

39. Retractable and Shaw have been damaged by Defendant's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

VIII. COUNT V – INFRINGEMENT OF U.S. PATENT NO. 6,572,584

40. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

41. Plaintiff Retractable is the owner of all right, title and interest in and to U.S. Patent No. 6,572,584, issued June 3, 2003, a copy of which is attached as Exhibit E. Plaintiff Shaw is the inventor of the '584 patent. The maintenance fees for the '584 patent has been timely paid, and the '584 patent has not been invalidated or found to be unenforceable in any prior litigation.

42. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '584 patent.

43. Retractable and Shaw have not granted any right or license under which Defendant can legally make, have made, use, offer to sell, sell, or import into the United States retractable syringes covered by the '584 patent.

44. Defendant Safety Medical International, Inc., has directly, indirectly, and/or contributorily infringed the '584 patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '584 patent, and has induced and/or contributed to the infringement of the '584 patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court. For example, and without limitation, Defendant has made, used, sold, offered for sale and/or imported the Saf-T-Syringe retractable syringe, which is covered by at least one claim of the '584 patent.

45. Upon information and belief, Defendant's acts of infringement of the '584 patent have been willful and in deliberate disregard of the '584 patent and that this is an exceptional case under 35 U.S.C. § 285.

46. Retractable and Shaw have been damaged by Defendant's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

IX. INJUNCTIVE RELIEF

47. The preceding paragraphs of the Complaint are incorporated herein by reference as if fully set forth at length.

48. Retractable and Shaw are entitled to an injunction to prevent Defendant from continuing to infringe the '011, '077, '733, '224, and '584 patents. The injury to Retractable and Shaw, and the public health far outweighs any potential damage that injunctive relief might cause to Defendant.

X. PRAYER FOR RELIEF

Wherefore, premises considered, Retractable and Shaw pray for judgment as follows:

(a) Defendant be adjudged and decreed to have directly, indirectly, and/or contributorily infringed the '011, '733, '077, '224 and '584 patents;

(b) Defendant be adjudged and decreed to have willfully and deliberately infringed the '011, '733, '077, '224 and '584 patents;

(c) Defendant be ordered to pay actual damages to Retractable and Shaw, but not less than a reasonable royalty, by reason of Defendant's infringement of the '011, '733, '077, '224 and '584 patents together with prejudgment interest, costs and increased damages pursuant to 35 U.S.C. § 284;

(d) A preliminary injunction be entered against Defendant, and its officers, agents, servants and employees, and all entities and individuals acting in concert with them, to restrain further infringement of the '011, '733, '077, '224 and '584 patents during the pendency of this case;

(e) A permanent injunction be entered against Defendant, and its officers, agents, servants and employees, and all entities and individuals acting in concert with them, to permanently restrain any further infringement of the '011, '733, '077, '224 and '584 patents;

(f) This case be declared an "exceptional case" within the meaning of 35 U.S.C. § 285 and reasonable attorneys' fees, costs and treble damages be awarded to Retractable and Shaw;

(g) Awarding Retractable and Shaw all reasonable attorneys' fees allowed by statute, expert fees, costs, pre-judgment interest, and post-judgment interest; and

(h) Granting all such other relief, at law or equity, to which Retractable and Shaw may be entitled.

XI. JURY DEMAND

Retractable and Shaw demand a trial by jury as is their right under the Seventh Amendment to the Constitution of the United States or as given by statute. FED. R. CIV. P. 38.

Date: September 8, 2008

Respectfully submitted,

/s/ Roy W. Hardin

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