

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FILED
OCT 31 3 35 PM '00

UNITED STATES OF AMERICA

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION

Defendant.

00-12247 PBS
CIVIL ACTION NO.

RECEIPT # N/A
AMOUNT \$ 7200 N/A
SUMMONS ISS. YES
LOCAL RULE 4.1 YES
WAIVER OF SERV. /
MCF ISSUED /
AO 120 OR 121 /
BY DPTY CLK SS
DATE 10-31-00

COMPLAINT FOR CIVIL PENALTIES, INJUNCTIVE AND OTHER RELIEF
PURSUANT TO
SECTION 5(I) OF THE FEDERAL TRADE COMMISSION ACT

Plaintiff, the United States of America, by its undersigned attorneys, acting upon notification and authorization to the Attorney General from the Federal Trade Commission, alleges as follows:

INTRODUCTION, JURISDICTION AND VENUE

1. Plaintiff brings this action under Section 5(I) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(I), for civil penalties, injunctive and other equitable relief against defendant Boston Scientific Corporation ("BSC") for defendant's violations of a final order of the Federal Trade Commission ("FTC" or "Commission").

2. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 45(I) and 28 U.S.C. §§ 1331, 1337 (a), 1345, and 1355.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1395(a).

(1)

4. BSC is a corporation organized and existing under the laws of Delaware with its principal place of business located at 1 Boston Scientific Place, Natick, Massachusetts, 01760-1537. BSC is and has been at all times pertinent to this proceeding engaged in the research, development, manufacture, and sale of intravascular ultrasound ("IVUS") catheters, including imaging catheters, imaging cores, and imaging guidewires, and of IVUS consoles in the United States. BSC, at all times relevant to this proceeding, has been engaged in commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. Section 5(l) of the FTC Act, 15 U.S.C. § 45(l), authorizes this Court to award monetary civil penalties, to grant mandatory injunctions and to order such other and further equitable relief as appropriate for each violation of a Final Order of the FTC. The Court may award a civil penalty of not more than \$10,000 for each violation, or for each day of a continuing violation, prior to and including November 19, 1996. Pursuant to the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), and FTC Rule 1.98, 16 C.F.R. § 1.98, the maximum civil penalty for violations that occurred after November 19, 1996, is \$11,000 per violation or for each day of a continuing violation.

PRIOR FTC PROCEEDING

6. On January 27, 1995, the FTC filed a complaint in the United States District Court for the District of Columbia seeking a preliminary injunction to prevent BSC's acquisition of Cardiovascular Imaging Systems, Inc. ("CVIS"). The complaint alleged, in part, that the effect of the proposed acquisition, if consummated, may be substantially to lessen competition or tend to create a monopoly and that substantial interim harm to competition would occur even if suitable

divestiture remedies could be devised. *Federal Trade Commission v. Boston Scientific Corporation*, Civil Action No. 1:95 CV00198 (D.D.C. 1995). On February 15, 1995, the FTC authorized an action, alleging the same violations, to enjoin BSC's acquisition of SCIMED Life Systems, Inc. ("SCIMED").

7. Before amending its complaint in district court to include the SCIMED acquisition, the FTC entered into settlement negotiations with BSC. To resolve the FTC's competitive concerns regarding BSC's acquisitions of CVIS and SCIMED, on or about February 21, 1995, BSC entered into an agreement containing consent order ("proposed consent order") that included an agreement BSC had entered into with Hewlett-Packard Company ("HP") on or about February 21, 1995 ("Agreement") to license IVUS patents and technology and to undertake other obligations.

8. On February 23, 1995, the FTC accepted the proposed consent order, including the Agreement, referred to as Confidential Appendix II, resolving the charges related to BSC's acquisitions of CVIS and SCIMED. Pursuant to 16 C.F.R. § 2.32, the FTC placed its proposed administrative complaint and the proposed consent order, with a public version of the Agreement, on the public record for comment. On February 27, 1995, the FTC withdrew its pending complaint in *Federal Trade Commission v. Boston Scientific Corporation*, Civil Action No. 1:95 CV00198 (D.D.C. 1995), and allowed the acquisitions of CVIS and SCIMED to proceed.

9. On April 28, 1995, following the close of the public comment period, the Commission issued its Complaint and Order in Docket No. C-3573 (the "Order"). *In the Matter of Boston Scientific Corporation*, FTC Docket No. C-3573, 119 F.T.C. 549 (1995). The administrative complaint charged that BSC's agreements to acquire CVIS and SCIMED violated

Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and the proposed acquisitions, if consummated, would violate Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. The Order, including the Agreement attached as Confidential Appendix II, was entered in settlement of the complaint and was duly served upon BSC. The Order became final on May 5, 1995. BSC was required by the Commission to comply with the terms of the Agreement as part of the Order. A violation of the Agreement is, accordingly, a violation of the Order. The Order is attached to this Complaint and made a part hereof.

10. On January 5, 1996, the FTC reopened and modified Paragraph VI of the Order. None of the allegations of this Complaint is altered or affected by the revisions to Paragraph VI. The Order has not otherwise at any time been modified or set aside, and is now and has been at all times since May 5, 1995, in full force and effect.

THE ORDER

11. Paragraph II of the Order provides, in part, that BSC must grant a license to defined assets ("IVUS Technology Portfolio") either to HP, pursuant to and in accordance with the Agreement, within ten days after the date the Order becomes final, or to a person that receives the prior approval of the FTC, within six months of the date the Order becomes final.

12. The "IVUS Technology Portfolio" is defined in the Order to include, in part: "All rights of Boston Scientific, CVIS and SCIMED under United States and foreign patents and patent applications filed in any country relating to IVUS Catheters, . . . including but not limited to the right to manufacture, use, sell, or offer for sale for any purpose or application any product suitable for use as an IVUS Catheter"

13. The Agreement further grants HP a license to defined “Licensed Technology” for use in the manufacture and sale of defined “Licensed Products.” “Licensed Technology” was defined in the Agreement as “all issued patents of BSC, SCIMED and CVIS used for the development, manufacture and sale of Licensed Products, including but not limited to, those listed on Exhibit A” “Licensed Products” is defined in the Agreement as “ultrasound imaging catheters, imaging cores and imaging guidewires This definition includes and is no narrower than the collective claims of the patents . . . listed on Exhibit A.”

14. The Order and Agreement further require BSC to provide to HP, as the licensee of the IVUS Technology Portfolio, an interim supply of such quantities and types of IVUS Catheters as may be requested by HP.

15. The Agreement requires BSC to provide HP, 180 days prior to the commercial introduction of a new catheter, the information needed to interface that catheter to the HP console.

VIOLATIONS ALLEGED

FIRST COUNT

BSC Violated the Order by Failing to License the Webler Patent

16. Plaintiff realleges and incorporates by reference paragraphs 1 to 13 above. One of the patents owned by CVIS prior to its acquisition by BSC was United States patent number 5,361,768 Webler *et al.* (“Webler Patent”).

17. The Webler Patent, which includes claims describing an automatic pullback device, relates to IVUS catheters.

18. The Order requires BSC to license the Webler Patent to HP as part of the IVUS Technology Portfolio.

19. The Agreement grants HP a license to practice all the claims of patents listed in the attached Exhibit A, and the Webler Patent is listed on Exhibit A.

20. BSC refused to license the Webler Patent to HP and has refused to allow HP to practice all the claims of the Webler Patent.

21. BSC violated the Order and Agreement when it refused to license the Webler Patent to HP and when it refused to allow HP to practice all the claims of the Webler Patent.

22. BSC has been continuously in violation of the Order and Agreement since May 18, 1995, the date by which BSC was required to license the IVUS Technology Portfolio to HP pursuant to the Order.

SECOND COUNT

BSC Violated the Order By Not Providing Interface Information Regarding the 6F/20MHz Sonicath Ultra Catheter

23. Plaintiff realleges and incorporates by reference paragraphs 1 to 15 above.

24. Paragraph 7 of the Agreement provides in part:

Each party will take all reasonable and appropriate steps to assure that in interfacing such party's devices to the other party's consoles, the other party suffers no delay times or other disadvantages. These time-to-market safeguards will mean that, in interfacing such party's devices to the other party's consoles, no later than 180 days prior to such party's commercial introduction of any new device, all necessary technical specifications, regulatory information and the like shall be provided to the other party for the purpose of interface.

25. On or about February 24, 1997, BSC commercially introduced the 6F/20MHz Sonicath Ultra IVUS catheter, which was a "new device" within the meaning of the Agreement.

26. BSC did not provide HP with the information required by the Agreement 180 days prior to commercially introducing the 6F/20MHz Sonicath Ultra catheter.

27. BSC violated the Agreement and Order by not providing the required information and was in continuous violation of the Agreement and Order from the date it commercially introduced the 6F/20MHz Sonicath Ultra catheter until at least 180 days from the date it gave the required information to HP.

THIRD COUNT

BSC Violated the Order By Not Providing Interface Information Regarding the 6F/12.5MHz Sonicath Ultra Catheter

28. Plaintiff realleges and incorporates by reference paragraphs 1 to 15 and 24 above.

29. On or about March 17, 1997, BSC commercially introduced the 6F/12.5MHz Sonicath Ultra IVUS catheter, which was a "new device" within the meaning of the Agreement.

30. BSC did not provide HP with the information required by the Agreement 180 days prior to commercially introducing the 6F/12.5MHz Sonicath Ultra catheter.

31. BSC violated the Agreement and Order by not providing the required information and was in continuous violation of the Agreement and Order from the date it commercially introduced the 6F/12.5MHz Sonicath Ultra catheter until at least 180 days from the date it gave the required information to HP.

FOURTH COUNT

BSC Violated the Order By Not Providing Interface Information Regarding the 3.2F/20MHz Sonicath Ultra Catheter

32. Plaintiff realleges and incorporates by reference paragraphs 1 to 15 and 24 above.

33. On or about June 19, 1997, BSC commercially introduced the 3.2F/20MHz Sonicath Ultra IVUS catheter which was a "new device" within the meaning of the Agreement.

34. BSC did not provide HP with the information required by the Agreement 180 days prior to commercially introducing the 3.2F/20MHz Sonicath Ultra catheter.

35. BSC violated the Agreement and Order by not providing the required information and was in continuous violation of the Agreement and Order from the date it commercially introduced the 3.2F/20MHz Sonicath Ultra until at least 180 days from the date it gave the correct required information to HP.

FIFTH COUNT

BSC Violated the Order By Refusing To Supply the Discovery Catheter to HP

36. Plaintiff realleges and incorporates by reference paragraphs 1 to 15 above.

37. Paragraph III of the Order required BSC to supply to HP, for such period as HP may request, up to three years, such quantities and types of "IVUS Catheters" as may be requested by HP. The Order defines "IVUS Catheters" as "intravascular ultrasound catheters, intracardiac ultrasound catheters, removable imaging cores used in intravascular or intracardiac ultrasound imaging, and intravascular imaging guidewires."

38. Paragraph 8 of the Agreement required BSC to supply all BSC IVUS Catheters to HP for a period of four years from the Effective Date of the Agreement, *i.e.*, until May 5, 1999. The Agreement defines "BSC IVUS Catheters" as, in part, "all IVUS catheters listed by BSC on any price list, and, to the extent otherwise marketed by BSC to the public, any intravascular

ultrasound catheter; provided, however, that BSC IVUS Catheters does not include removable imaging cores or removable imaging guidewires”

39. The Discovery catheter, manufactured and marketed by BSC, was an IVUS Catheter within the meaning of the Order and a BSC IVUS Catheter within the meaning of the Agreement.

40. BSC refused to supply Discovery catheters to HP.

41. BSC violated the Agreement and Order by not supplying Discovery catheters to HP pursuant to the Interim Supply Agreement and was in continuous violation of the Agreement and Order from the date it commercially introduced Discovery until at least November 6, 1998, the day HP announced that it was exiting the IVUS market.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

42. That the Court adjudge and decree that Defendant BSC violated the Order for each day it failed to license to and allow HP to freely practice the Webler Patent, for each day it failed to give the information to HP that was required under the Agreement to interface each of the three Sonicath Ultra catheters, and for each day it failed to supply Discovery catheters to HP;

43. That this Court enter judgment against BSC for an appropriate civil penalty as provided by law, 15 U.S.C. § 45(I), and the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), and FTC Rule 1.98, 16 C.F.R. § 1.98;

44. That Plaintiff have such other and further relief as the Court may deem just and proper; and

45. That Plaintiff be awarded its costs of this suit.

Dated: _____

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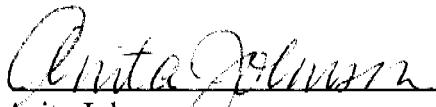
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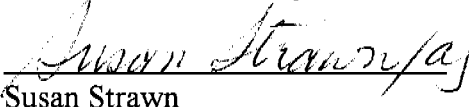
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