UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	CIVIL ACTION NO. 00-12247-PBS

MEMORANDUM AND ORDER

August 8, 2002

SARIS, U.S.D.J.

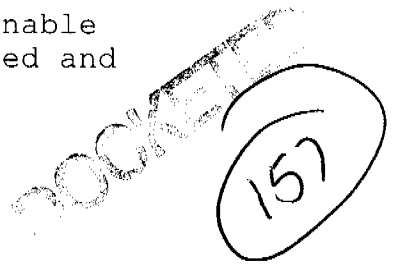
INTRODUCTION

Defendant Boston Scientific Corporation has moved for reconsideration as to Count V. The essence of Boston Scientific's argument is that it did not violate the Interim Supply Provision of the FTC Order between March 1998 and May 1998 because the Discovery 2.6F/40 Mhz catheter, as redesigned, was first sold to customers on June 3, 1998, after the supply provision had expired. After hearing, the motion for reconsideration is **DENIED**.

DISCUSSION

The Interim Supply Provision of the FTC Order reads:

> Respondent shall supply to the Licensee, for such period as the Licensee may request, up to three (3) years . . . such quantities and types of IVUS Catheters as may be requested by the Licensee, upon reasonable notice, from among the various types manufactured and



> sold by Boston Scientific during the period of such supply arrangement.

(Paragraph III). In United States v. Boston Scientific Corp., 167 F. Supp. 2d 424 (D. Mass. 2001), I ruled that this three-year period expired on May 5, 1998, and that BSC was obligated to provide Discovery catheters to HP at the time the Discovery catheter was being marketed and was available for purchase. Id. at 436-437. This obligation was triggered upon request, and did not begin "on the date the first actual sale was made." Id.

The summary judgment record contains the following undisputed facts. As early as March 1997, BSC was promoting and marketing the Discovery catheter as the "next generation of IVUS imaging device," which "HP is not entitled to purchase." (Summ. J. Ex. 85). This Discovery catheter was internally approved for release on February 25, 1998, and, according to the sworn response to the FTC Civil Investigation Demand, it was "commercially introduced in March 1998." There were special sales promotions through March 31, 1998. (Docket No. 126, Attachments A, B). BSC sales representatives shipped at least 364 catheters as samples (the so-called "trunk stock") for sales promotions, testing and training purposes. (Id., Attachment C, Aff. of Thomas Ressemann). According to production records, 404 catheters were manufactured during the first quarter of 1998, and 7,418 catheters during the second quarter. (Id., Attachment K). Discovery catheter invoices show five sales to foreign customers

in March 1998. (Id., Attachment G). Six catheters were sold at cost to Swedish hospitals from stock in the trunk of a BSC European sales representative's car on April 28, and April 29, 1998. (See Docket No. 129, Dec. of Paul F. Stephenson). Other Discovery catheters were shipped to Swedish hospitals for training purposes in March and April. (Id.)

Although Discovery catheters were being dispensed to customers in the United States and abroad in March and April 1998, there is a dispute in the record as to whether the domestic distributions generated any revenue during this period. One document suggests that "First Sales began April 7, 1998." (Ex. 18, Bates No. 11477). But another suggests that units manufactured to the original design "were not commercially released by Marketing" until May 1998. (Def. Ex. 4). Although BSC sales records indicate that money changed hands, the Director of IVUS Marketing submitted an affidavit stating this was a database error and the units that were delivered were probably free samples. (Docket No. 129, Aff. of Thomas Ressemann).

In either event, as this promotional campaign was gearing up, BSC received reports of problems with the Discovery catheter when used in human patients, and began a process to redesign the Discovery catheter in March 1998. A report written the same month explains the deficiency:

> Several Discovery catheters were evaluated in human trials at various cardiology catheter labs around the

> country. The feedback suggests that the Discovery distal sheath is softer than desired and has a propensity to kink when meeting resistance with the coronary anatomy. Based upon previous testing the distal section of the catheter may be vulnerable to tolerance shifts in material and dimensions, from lot to lot. In order to address this, the tips have been redesigned and will be evaluated clinically and quantitatively.

(Tab 6). The redesign was expected to delay the project schedule by six to eight weeks. The design modifications were approved by a document dated May 12, 1998. The first invoices for domestic sales of the redesigned Discovery catheters were dated June 3, 1998. There is no evidence that the Discovery catheters, as originally designed, were ever recalled because they were perceived as hazardous.[1] Thus, while the redesigned Discovery catheters were not sold or delivered until June, the original Discovery catheters were being produced and marketed in the first two quarters of 1998, and were being distributed in March and April.

Although there is a disputed issue of fact as to whether the catheters distributed in March and April were free samples or revenue-producing units, this dispute is immaterial because they were distributed as part of a sales effort. They could and should have been provided to HP upon its request. Thus, the FTC has proven that the Order was violated because: (1) HP requested

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[1] In contrast, in late summer the Discovery catheter was recalled temporarily because of problems with the tips. A year later, it was permanently recalled.

the Discovery catheter; (2) it had been manufactured; and (3) it was being marketed for sale and distributed as part of a sales promotion effort. BSC's argument that the obligation to provide BSC with catheters was not triggered until title to the goods passed, or until the catheters were actually invoiced, is unpersuasive. Such an interpretation would vitiate the core purpose of the order — to create an independent competitor - by giving BSC a giant headstart in capturing the market for new catheters, and leaving Hewlett Packard in perpetual catch-up mode.

ORDER

The motion to reconsider (Docket No. 113) is **DENIED**.

PATTI B. SARIS
UNITED STATES DISTRICT JUDGE