UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

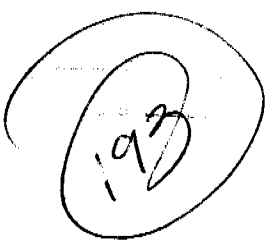
MEMORANDUM AND ORDER

March 28, 2003

SARIS, U.S.D.J.

INTRODUCTION

The government seeks the maximum possible civil penalty of $35 million against defendant Boston Scientific Corporation ("BSC") on the ground that BSC violated a consent order of the Federal Trade Commission ("FTC") that was designed to ensure competition in the intravascular ultrasound ("IVUS") catheter market. The FTC argues that BSC's transgressions decreased competition in the IVUS market by driving Hewlett-Packard Company ("HP") out of the market, which reduced the number of IVUS competitors from three to two; that BSC's violations impaired innovation in catheter technology; that BSC acted in bad faith; and that a large sanction is necessary to vindicate the authority of the FTC. Arguing no-harm-no-foul, BSC argues that any violations were minimal; that it did not profit from any



violations; that innovation and competition flourished; and that HP would have left the market in any event. BSC urges a rock bottom fine.

After a trial on the penalties on August 5-9, 2002 and September 17-20, 2002, and review of the submissions, the court orders entry of judgment against BSC in the amount of $7,040,000.

FINDINGS OF FACT

Assuming familiarity with United States v. Boston Scientific, 167 F. Supp.2d 424 (D. Mass. 2001), I make the following findings of fact:

I. Background on Intravascular Ultrasound

A. Coronary Artery Disease and its Treatment

Coronary artery disease is the leading cause of death in this country. Many Americans build up cholesterol and other fatty substances in their arteries, which narrow the arteries and allow less room for blood to flow. The result of this build-up, called plaque, can be chest pain, a heart attack, or a stroke.

Angiography is the basic method of trying to assess the condition of a coronary artery. Angiography involves injecting dye into the coronary arteries and then taking an X-ray that produces a silhouette of how much blood is flowing though the artery. The two-dimensional projection provided through angiography is, however, of limited value in making a diagnosis and determining the best type of treatment. Although angiography

shows the width of the artery that remains open, it cannot measure how much plaque has built up in the artery's walls or detect the presence of calcium.

Intravascular ultrasound refers to ultrasound imaging from inside the vascular system, or arteries. IVUS produces a three-dimensional picture of the artery that precisely measures the degree to which the artery has narrowed, what type of plaque has collected, and the length and distribution of that plaque. IVUS reveals the coronary pathology and the coronary measurements with a much better level of precision than angiography. One study showed that 36% of the participants had plaque not seen on the angiograms. Many leading physicians believe that both angiography and IVUS should be used to diagnose the situation, determine whether treatment is necessary, guide which type of treatment is appropriate, and follow up afterward to determine whether the treatment was successful.

The two most common methods of treating diseased arteries are angioplasty and stents. Angioplasty involves the dilation of a balloon to further open the artery. A stent is a metal scaffold that is placed in the artery to prop it open. IVUS shows whether a stent was positioned properly, and enables the doctor to correct the misplacement. Catheters can also be used to cut through plaque.

In addition to diagnosing and treating artery disease that

already exists, IVUS is an important tool for research aimed at preventing the disease. Because coronary artery disease is such a significant health problem, pharmaceutical companies are working to develop drugs to help prevent the accumulation of plaque, and the precise measurement that IVUS affords is being used to evaluate the effectiveness of new drugs in FDA-approved clinical trials.

B. How Intravascular Ultrasound Works

An IVUS console attaches to the patient interface unit (sometimes called a "motor drive unit") that in turn connects to the IVUS catheter. The IVUS catheter is a flexible narrow tube that contains a hub on the near end, a drive cable, and a transducer on the far tip. The transducer sends out ultrasound waves that reflect off the artery's walls; a receiver measures the amount of returned energy, producing the 360-degree image of the artery and blood vessel.

There are two forms of IVUS imaging technology. "Phased array" catheters use several stationary transducers. Endosonics Corporation ("Endosonics") manufactured and sold phased array catheters. "Mechanical" catheters contain a single transducer that is spun by a drive cable. The hub of the catheter plugs into the patient-interface unit, which spins the core of the catheter and transmits the electrical impulses. The console controls the catheter and processes the images that come back.

BSC and Cardiovascular Imaging Systems, Inc. ("CVIS") manufactured and sold mechanical catheters.

In an IVUS procedure, a guidewire is inserted into the guide catheter and advanced into the coronary arteries. The IVUS catheter then rides the guidewire like a railroad track into the coronary arteries and takes pictures of the artery. The IVUS catheter is pulled back, either manually by the physician or at a fixed rate of speed by an automatic pullback device. If angioplasty or a stent is used to treat the artery, the IVUS procedure often is repeated to determine the effectiveness of the treatment.

IVUS catheters are distinguished by their diameter size and ultrasound-wave frequency. A catheter's diameter size is measured in "French" (e.g., "3.2 F"). One French is approximately one-third of a millimeter, which means that a 3 F catheter is about 1 millimeter in diameter. The smaller the catheter, the easier it is to maneuver inside the artery and the harder it is to incorporate a transducer that produces an adequate image. Ultrasound-wave frequency is measured in megahertz (e.g., "30 MHz"). Generally, the greater the wave frequency, the better the image.

IVUS catheters include both coronary catheters and peripheral catheters. Coronary catheters are used primarily by interventional cardiologists who treat coronary artery disease;

coronary catheters account for approximately 95% of the IVUS catheter market. Peripheral catheters are used primarily by vascular surgeons and interventional radiologists in the larger, non-coronary arteries, such as the carotid and iliac arteries.

C. IVUS Competition before the BSC-CVIS-SCIMED Merger

Prior to 1995, HP was a leader in the sale of IVUS consoles, which it manufactured for use with BSC's IVUS catheters. Before the merger, HP did not make catheters and BSC did not make consoles. CVIS made both catheters and consoles. The BSC catheters had hubs that, prior to the merger, were interfaced solely to the HP consoles. The CVIS catheters had hubs that, prior to the merger, were interfaced solely to the CVIS consoles. BSC and HP had a joint marketing agreement from 1992 to 1995 under which, in addition to selling its catheters, BSC assisted in the sale of HP consoles and provided support to customers who used the BSC-HP IVUS system.

Before the merger, the BSC-HP system competed vigorously against the CVIS system, with each system controlling roughly half of the IVUS customers. Of the IVUS hospitals or other medical facilities in the United States, about 50% had installed HP consoles and about 40% had installed CVIS consoles. Of the IVUS catheters sold every year, about 40% were BSC catheters and about 50% were CVIS catheters. Endosonics, with its phased-array catheters and consoles, held the remaining shares of the console

and catheter markets.

HP's long experience in general ultrasound gave HP an edge in the manufacture of consoles and transducers, the key components for image quality. The images created by the BSC catheter (the "Sonocath") on the HP console (the "SONOS 100") were considered the "gold standard" in the industry, generally superior to the images created on the CVIS or Endosonics systems. However, the Sonocath catheter had poor quality ergonomics because it was hard to insert. The CVIS catheter (the "Ultracross"), in contrast, had good handling capabilities.

At the time of the merger, only CVIS had an automatic pullback device ("APD"), a sled-like tool designed to allow the catheter's transducer to be pulled back automatically within the artery in a smooth manner at a fixed rate of speed, allowing better measurement of the length of lesions and blockages within the artery. CVIS held the Webler patent on the APD device. The APD was essential to many research projects and also was preferred by some physicians for day-to-day clinical use. Prior to the merger, CVIS was in the marketplace touting the advantages of APD.

The doctors who regularly used and endorsed the APD, such as Dr. Steve Nissen, Dr. Gary Mintz, and Dr. Peter Fitzgerald, were among the leading IVUS physicians, and their opinions were enormously important in this emerging field of diagnostic

technology. Dr. Nissen is vice chairman of the department of cardiology at the Cleveland Clinic, one of the country's leading IVUS research institutions. The Washington Hospital Center, where Dr. Mintz was director of the coronary ultrasound program, was the largest IVUS catheter customer in the world. Doctors Fitzgerald, Mintz, and Nissen all were members of BSC's Physician Advisory Board, all were considered among a handful of "luminaries" in the field, and all were involved in teaching other doctors how to use IVUS. BSC believed in 1995 that it was important from a marketing perspective to be in a position to provide APDs with the consoles and catheters.

II. The BSC-CVIS-Scimed Merger and its Fallout

A. The Proposed Merger and the FTC Suit

In 1994, BSC announced that it planned to acquire CVIS and SCIMED Life Systems, Inc. ("SCIMED"). SCIMED was in the process of developing an IVUS catheter and was preparing to enter the IVUS catheter market. The jewel of the prospective merger, however, was CVIS. BSC wanted to obtain CVIS's intellectual property; at that time, BSC and CVIS were engaged in a patent infringement action over the IVUS technology. Competition between the two was intense, and the competition was a major catalyst for catheter innovation. In a game of one down-manship, each company competed to create smaller and smaller diameter catheters. CVIS and SCIMED were also involved in an intellectual

property dispute, which BSC resolved by buying them both.

With these acquisitions, BSC would become a manufacturer of both catheters and consoles. The merger would virtually clear the field of catheter competition: The BSC-CVIS-SCIMED entity would have 90% of the total IVUS catheter market, would have no mechanical IVUS catheter competitor, and would become the sole supplier of catheters to its only IVUS console competitor, HP. The FTC filed suit in the District Court for the District of Columbia, seeking an injunction on the ground that the merger would substantially lessen competition and tend to create a monopoly in the market for IVUS catheters.

Initially BSC was unable to persuade the FTC to permit a merger that gave it a 90% share of the IVUS catheter market in the United States. However, shrewdly playing the inside-the-beltway game, BSC replaced New York counsel with Michael Sohn of Arnold and Porter, who was the former General Counsel of the FTC. With Sohn's assistance, the FTC retreated, and allowed the acquisitions to go ahead on the condition that BSC share its technology to allow HP to enter the catheter field as a competitor.

B. The Negotiations between BSC and HP

Cognizant of the need to license its technology to prevent the FTC from derailing its merger plans, BSC began negotiating a technology transfer agreement with HP in late 1994; the parties

signed an agreement (the "Agreement") on February 21, 1995. Nancy Kerins, the general manager of HP's interventional cardiology program, was HP's lead negotiator. Also participating in the negotiations for HP were Cynthia Danaher, Mark Low, and Al Kyle. The lead negotiator for BSC was Joseph Ciffolillo, the company's chief operating officer. Also involved was Paul Sandman, Esq., the Senior Vice President and General Counsel of BSC. During the negotiations, drafts of the proposed Agreement were exchanged and reviewed by attorneys for BSC.

Danaher, a graduate of Harvard's MBA program, began at HP in 1984, and within a year became general manager of imaging systems, which included HP's flagship ultrasound systems. When HP decided to enter the IVUS catheter market, Danaher's division took responsibility for developing the business, although Danaher, herself, was lukewarm on the project. HP's business objective was to protect and maximize its console program, which was HP's core IVUS business. IVUS was a niche product at HP and represented only 5% of the profits of the Imaging Systems Division.

Because the customers and medical luminaries (like Dr. Mintz, Dr. Fitzgerald, and Dr. York) told HP that the APD was important for success in the field, Danaher and other negotiators at HP fought for the rights to the APD in the negotiation with BSC. She told Ciffolillo how important APD was to the deal.

Because obtaining rights to the APD was important to HP, HP's negotiators consistently told BSC that the APD must be included in the licensing agreement.

Catheter availability was essential to placing consoles into the field (the "installed base"). The early and mid-1990s were an era of rapid innovation, as BSC and CVIS came out with a series of new catheters. While IVUS catheters cost several hundred dollars and are used once and then discarded, IVUS consoles cost around $125,000 and can be used indefinitely. In making the big, long-term capital investment in a console, buyers wanted to make sure that the console would continue to have access to the latest technology and be able to operate newly developed catheters. Hospitals did not want to spend well over $100,000 on a machine that quickly would become antiquated and would be unable to run the newest, best catheters. Consequently, HP wanted to make sure that its console customers would have access to the latest developments in IVUS catheter technology. Indeed, while HP expected its catheter business to be profitable, much of its commitment to developing an IVUS catheter was motivated by its desire to protect its console base.

The negotiations over the BSC-HP agreement concluded over a hurried President's Day weekend in February 1995. On February 17, while reviewing HP's proposed agreement, one of BSC's lawyers crossed out ¶ 2's last sentence, which incorporated an attachment

listing the Webler patent claiming the APD technology; the BSC lawyer also added the margin notation "delete last sentence." The attachment that listed the Webler patent was prepared by someone asked to list all the CVIS intellectual property. The harried legal staff reviewing the agreement did not edit the list to contain only the technology BSC intended to transfer. Indeed, BSC points out that the list was over-inclusive; for example, some of the patent claims pertained to consoles. Top managers at BSC (like Paul Sandman) did not intend to include the APD for the same reason that HP wanted the APD: because they all believed exclusive rights to the APD were important to maintain a competitive edge.

Nonetheless, when the February 21, 1995 Agreement with HP was reached, it provided:

> 2. BSC hereby grants to HP, as of the Effective Date, a license to certain patents and technology (the "Licensed Technology") for use in the manufacture and sale of Licensed Products, as defined below. The Licensed Technology shall include all issued patents of BSC, SCIMED and CVIS used for the development, manufacture and sale of Licensed Products, <u>including but not limited to, those listed on Exhibit A</u> and all exiting know-how of SCIMED and CVIS that is used or intended for use in the development, manufacture and sale of Licensed Products. BSC further agrees that it will not in perpetuity assert any of its rights including but not limited to patents derived from CVIS and SCIMED under issued patents and patents which subsequently issue on presently pending applications and continuations thereof, or patent rights

> arising from inventions disclosed to BSC, CVIS or SCIMED prior to the Effective Date, in a way that would prevent HP from practicing any of the Licensed Technology to manufacture, use or sell Licensed Products. "Licensed Products" are ultrasound imaging catheters, imaging cores and imaging guidewires which are designed for diagnostic or therapeutic use, or both, in the human coronary and peripheral vascular system. This definition includes and is no narrower than the collective claims of the patents (for coronary and peripheral vascular applications) listed on Exhibit A.

(Pl's. Ex. 2 (Agreement) ¶ 2 (emphases added).) The Webler patent claiming APD technology was expressly included in Exhibit A, which listed the intellectual property that BSC was agreeing to license to HP in the Agreement.

In addition to the technology-transfer provision, the Agreement also (1) required that 180 days before the commercial introduction of a new catheter, BSC would provide to HP the technical specifications needed to interface the catheter with HP consoles (¶ 7), and (2) contained an interim supply commitment under which BSC agreed to supply HP with all BSC catheters at a below market price for resale by HP, for a period of several years (¶ 8).

C. The FTC's Authorization of the Merger

On February 23, 1995, the FTC and BSC entered into an agreement containing a consent order (the "Order"), and the FTC allowed the BSC-CVIS-SCIMED merger to go forward. The FTC Order explicitly stated that its purpose was "to create an independent

competitor in the development, production and sale of IVUS catheters and to remedy the lessening of competition resulting from the CVIS Acquisition and SCIMED Acquisition." The Order required BSC to license its IVUS technology to HP. The FTC's goal was to ensure that a new competitor emerge to replace the competition in the IVUS catheter market lost by BSC's acquisition of CVIS and SCIMED. Previously BSC and CVIS competed in the IVUS catheters market, and HP and CVIS competed in the console market. Under the FTC order, the FTC hoped HP and the merged BSC/CVIS/SCIMED entity would compete in both markets. From the public's point of view, however, the deal had few teeth: HP made no guarantees it would stay in the market, and BSC got 90% of the catheter market. The FTC withdrew its suit and request for an injunction.

The FTC Order defined "IVUS Technology Portfolio" to mean BSC's, CVIS's and SCIMED's patent rights "relating to IVUS catheters." The Order required BSC "absolutely and in good faith" to license the IVUS technology portfolio

> 1. to Hewlett-Packard Company, within ten days after the date this Order becomes final, pursuant to, and in accordance with, the February 21, 1995 agreement between Respondent and Hewlett Packard, which agreement is appended to this Order in Confidential Appendix II; or
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> 2. to a person that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.

(Pl's. Ex. 422 at 5 (emphasis added).)

The Order was poorly drafted, in that it was inconsistent with portions of the HP/BSC agreement, and did not plainly incorporate all of the provisions of the full agreement. Taken together, the Order and/or Agreement required BSC to carry out three essential activities. First, both the Order and the Agreement required BSC to license its IVUS intellectual property to HP. Second, the Agreement (but not the Order) required BSC to give HP certain technological information about any new BSC catheter 180 days before bringing the new catheter to the market. Third, both the Order and Agreement required BSC to sell its IVUS catheters to HP for resale for several years under an interim supply agreement.

The first requirement would permit HP to develop its own IVUS catheter. The other requirements were meant to secure the continuing viability of HP's console in the marketplace - by ensuring that HP's console base would be fed the same supply of catheters as BSC's base. The 180-day requirement would allow HP's console to operate any new BSC catheter the moment the new catheter became available. The interim supply agreement would enable HP to sell BSC's catheters to HP's console customers until HP's own catheter was ready.

Although the inclusion of the APD in Exhibit A satisfied HP that BSC was, in fact, obligated to license the patent for the APD to HP, the FTC itself never focused on the APD during

negotiations over the Order.

D. Implementation Issues

From the get-go, HP's relations with BSC in implementing the Order and Agreement were complicated. HP was not allowed to go into BSC's factory initially while a confidentiality agreement was being negotiated. This delay lasted about three weeks, but eventually the initial technology transfer went relatively smoothly and in good faith. John Rourke was the pointperson for the technology transfer at HP, and John Maroney (whom he later worked for) was the key person at BSC. They developed a grudging respect for one another. However, throughout this 1996 to 1998 time period, HP's Peter Dorward complained that he engaged in a letter writing contest with BSC about the implementation of the open interface agreement, the interim supply agreement, getting information about BSC's catheters, and, notably, the APD.

Within days after the HP-BSC agreement was signed, a heated dispute ignited over the APD. HP's counsel Robert Skitol sent a draft letter of understanding, which stated: "The term 'Licensed Products' in Paragraph 2 as well as the term 'Catheters' in Paragraph 8 are also understood to include all existing BSC and CVIS catheter accessories." (Pl's. Ex. 692 ¶ 1.) BSC's attorney annotated the margin, "No!" (Id.) BSC informed HP that the inclusion of the Webler patent was in error. Ciffolillo told Danaher, "We did not mean it," to which Danaher retorted, "Well,

it's in there." BSC's Maroney told HP's Dorward and Rourke that the Webler patent was included in the list as a mistake. BSC took the position that the field of use language in the Agreement ("catheters, cores, and guidewires") narrowed the rights to the patents.

BSC did not want to approach the FTC staff to resolve the dispute, believing that FTC involvement would worsen the situation for BSC. HP did not tattletale to the FTC because Danaher wanted to build a relationship based on trust and did not want to jeopardize a good working relationship, which was necessary for the transfer of technology; she also believed the rights to the APD were clearly in the agreement. In a meeting on April 11, 1995, according to contemporaneous HP notes, General Counsel Paul Sandman said:

> FTC was interested in having a credible licensee in hand and therefore willing to accept a variety of discrepancies between Consent Order and Licensing Agreement. Licensing agreement prevails over Consent Order, wherever there are discrepancies.
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> [I] [f]eel[] the Agreement is a flawed one, but that it cuts both ways. BSC wants to stay with the Agreement and not open it up for re-negotiation.
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> Change to Agreement will require further review by Staff and Commission. "Anytime the Staff has looked at this, it's gotten worse for us." Also, any changes will delay the close of the Hold Separate Agreement, which is a daily irritant.

(Pl's. Ex. 298.) BSC's consistent position was that the Agreement with HP would trump the Order to the extent there were

inconsistencies.

BSC and HP worked to clarify parts of the Agreement that were unclear or that conflicted with the terms of the Order. As part of these clarification discussions, BSC disputed HP's rights to the APD, claiming that the inclusion in Exhibit A of the intellectual property for the APD was a mistake. After BSC claimed it had not licensed rights to the APD, HP, thinking BSC's position "laughable" (John Rourke's words), rebuffed BSC's effort during the clarification talks to strip the APD patent from the Agreement. When BSC refused to move from its position that HP did not have rights to the APD, HP dropped the matter, concluding the "[p]ullback is ours under Exhibit A" and that to continue to negotiate on the point "would undercut that position." (Pl's. Ex. 74 (cover marginalia).) The clarification letter to which HP and BSC ultimately agreed on April 19, 1995 contained no reference to APD.

BSC's August 7, 1995 compliance report to the FTC[1] did not

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[1] The Order required that

> [w]ithin sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until Respondent has fully complied with the provisions of Paragraph II and V of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall include in its compliance reports, among other things that are required from

appraise the FTC of the ongoing dispute over the inclusion of the APD. BSC attached the clarification letter and related correspondence to the compliance report. The clarification letter suggested that there was no ongoing dispute, when BSC knew that was not true. Nothing in the clarification letter altered BSC's obligation to license to HP the Webler Patent which covered the APD technology. The Court does not credit BSC's explanation that it believed the matter was resolved in its favor as a result of the clarification discussions. Because BSC's compliance report to the FTC did not fairly present the "substantive contacts" over the ongoing dispute regarding the APD, it was materially misleading.

E. Competition between BSC and HP

Competition between HP and BSC intensified over the development of new catheters. As a business strategy, HP decided not to do a "me-too" catheter, and began development of the "Scout" catheter. HP charged its top talent with achieving optimal image quality. Dorwood, an engineer with a master's

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> time to time, a full description of the efforts being made to comply with Paragraph II of the Order, including a description of all substantive contacts or negotiations for the licensing and the identity of all parties contacted. Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

(Pl's. Ex. 422 (Order) ¶ VII.A.)

degree in electrical engineering from Dartmouth, became the IVUS program manager; Roarke, a gifted engineer with a master's degree in mechanical engineering from MIT, became the point person for catheter research and development. In the spring of 1996, HP developed a distribution partnership with Guidant to develop the Scout device. Although the development of the catheter was impeded to some degree by an unrelated problem with the FDA in the ultrasound quality area in June 1997, which diverted personnel for several months, Scout was ready to come to market in 1998.

HP was also eager to develop an APD. Its first partner was INDEC. However, on January 9, 1996, BSC's patent counsel sent INDEC an ominous letter suggesting infringement of BSC's Webler patent as a result of the distribution of INDEC APD-related product literature from the HP booth at a November 1995 American Heart Association meeting. INDEC, which had only a crude APD prototype, pulled back from any further work on APD development, dealing a setback to HP. BSC protests any suggestion that its patent counsel's letter was written in bad faith, pointing to the Agreement's provision allowing HP to sell licensed products manufactured for it by a third party, but not allowing the same manufacturer to sell the licensed product.[2] While BSC was

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[2] ¶ 3 of the Agreement provides in pertinent part:

> HP shall have the right to have Licensed Products made on its behalf by a third party,

correct that INDEC could not itself sell the APD, the letter to INDEC from BSC's patent counsel did not draw this distinction. Meanwhile, BSC was training its sales representatives that it had exclusive rights to manufacture and sell the APD covered by the CVIS patent, and that HP did not have any right to the APD. The sales force transmitted this information to customers in the marketplace.

On December 11, 1997, HP, after a lengthy negotiation, entered into a deal with Quinton Instrument Co. to develop the APD as part of a larger manufacturing and distribution relationship between the two parties. It contained an indemnity provision in the event of patent infringement litigation with BSC.

On July 30, 1997, the FDA approved Quinton's APD device. It was on the market by early 1998. No one legally challenged Quinton's right to manufacture the APD.

> so long as for a period of two years HP does not directly or indirectly sell such Licensed Product back to such third party or its affiliates or use sales support services of such third party or its affiliates with respect to such Licensed Product. Commencing on the Second Anniversary of the Effective Date, HP may not directly or indirectly contract with the same third party for both the manufacture and sale of all or substantially all of the Licensed Products.

(Pl's. Ex. 2 ¶3(a).)

F. The Discovery Catheter

Spurred on by reports of the nascent Scout catheter, BSC also pursued the development of new catheters. In 1995 and 1996, BSC began developing the Discovery Catheter, the next-generation catheter after CVIS's Ultracross. Discovery was intended to be smaller, have better handling characteristics, and have improved imaging qualities by increasing the ultrasound-wave frequency from 30 to 50 MHz. BSC planned to launch Discovery in March 1998 to beat out the Scout catheter. The first Discovery Catheters were shipped to customers in the United States on June 3, 1998, although BSC had been distributing samples and sales promotional materials earlier. Discovery was recalled temporarily because of technical problems with the sheath in September 1998, and was permanently recalled in June 1999.

In 1997 and 1998, BSC touted the Discovery catheter in the marketplace, while making it clear to customers (like Dr. Nissen) that HP would not be able to sell this "next generation" device.[3] Though HP was eventually given the opportunity to provide an interface to its console for the Discovery, there was some initial marketplace confusion on that point as well.

HP requested the Discovery Catheters under the Agreement's

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[3] In the Court's Memorandum and Order dated August 8, 2002 (Docket No. 157), the Court described the timeline for the sales and promotional activity in 1998 pertaining to the Discovery Catheter.

interim supply provision. Denying this request, BSC took the position that HP was not entitled to the Discovery catheter because it had a "removable imaging core," which allowed the core to be salvaged if the sheath were damaged in the factory. This was a pretext. While the removable core had some manufacturing benefits, it had little discernible medical purpose. Indeed, part of the reason for creating the removable core was to impede HP's access to it under the interim supply agreement. Contemporaneous notes from an October 14, 1997 BSC staff meeting state that the Discovery catheter could "replace Ultracross 30 MHz & screw over H.P." (Pl's. Ex. 155 at 2 (emphasis added).) Other than the Discovery catheter, BSC sold (or offered to sell) all other catheters to HP in 1995, 1996 and 1997. Altogether, BSC sold over 15,000 catheters to HP.[4]

HP and BSC had minor skirmishes over other issues. For example, in 1997 BSC failed to meet the Agreement's 180-day notification requirement for two new and different peripheral, low-volume catheters.

G. The FTC Enters the Fray

On July 9, 1997, the FTC compliance division issued its interpretation of the Order, as applied to BSC's Discovery catheter and APD:

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[4] In 1996, BSC met the 180-day requirement for providing technical information on the Ultracross catheter, which became BSC's best selling catheter in 1997.

BSC argues that HP has had the requisite 180 day notice to interface its console with BSC's removable core catheter, and HP, therefore, is not competitively disadvantaged if it is unable to purchase these catheters pursuant to the interim supply agreement. Additionally, BSC asserts that HP could make its own removable core catheter. The Order is clear that BSC has no role in determining what it must supply to HP to assure HP's effectiveness as an independent competitor. Paragraph III of the Order requires BSC to supply the License for up to three years with the "quantities and types of IVUS Catheters as may be requested by the Licensee . . . ." Order Paragraph I defines IVUS Catheters to mean "intravascular ultrasound catheters, intracardiac ultrasound catheters, removable imaging cores used in intravascular or intracardiac ultrasound imaging and intravascular imaging guidewires." Emphasis added. The Order clearly anticipates, therefore, that, for up to three years, HP may determine the types and amounts of IVUS Catheters to be provided under the interim supply agreement.

The dispute concerning the automatic pullback device also remains to be resolved. Although BSC does not argue that the patent for this device is not included in the Exhibit A list of patents covered by License Agreement, it does argue that the License Agreement's definition of Licensed Products places a use limitation on the enumerated patents to exclude uses of a patent other than for the development, manufacture, and sale of ultrasound imaging catheters. Specifically, BSC states that the automatic pullback device is not part of a catheter but is, instead, an enhancement to the console. Attempting to define the device as part of the catheter or part of the console, is not, however, productive. The patent for the automatic pullback device is indisputably included in the list of patents to be licensed. BSC further alleges,

> however, that significant time pressures prevented it from identifying non-catheter patents to be excluded from the License. The interpretation of this use limitation BSC now wishes to impose on the meaning of the patent list is not only unclear, it seems to contradict other language in that very paragraph stating that the definition is "no narrower" than the claims of the patents listed in Exhibit A. To agree with BSC's position, moreover, would yet again thwart the purposes of the Order. Without access to the automatic pullback device, catheters compatible with that device cannot be used to their full capability on HP's console, which would limit the open interface objective of Paragraph 7.

(Pl's. Ex. 724 at 3-4.) BSC disagreed with both positions but did not seek an advisory opinion from the FTC.

As the dispute with the FTC and HP intensified in March 1998, BSC made a settlement offer to license the Webler Patent to HP and to sell a limited number of Discovery Catheters to HP until the Scout Catheter was commercially available. HP rejected the settlement offer.

H. HP Exits the IVUS Market

In February 1998, the HP Scout catheter was trumpeted as a great success at a national trade show. The Scout catheter had an integrated "fishing reel" automatic pullback device, instead of the separate APD sled. It was a tremendous success in the initial human studies.

But only one month later, Danaher tentatively decided to withdraw from the catheter field, and began the process of

vetting the decision with her team and HP management. Three reasons factored into Danaher's decision. First, the IVUS market did not grow as much as originally hoped. Second, the heartland business of HP, which was ultrasound, was tottering and HP was losing market position and profitability; she wanted to refocus on HP's profit center.

Third, implementation of the HP-BSC agreement was so tedious that it was like a "walk through molasses." Disputes with BSC took up 50-75% of Dorward's time. Danaher's perception was that BSC battled over everything. Danaher spent 30% of her time while she was manager of the Ultrasound Division working out disputes with BSC. Having trusted Ciffolillo of BSC, she was personally hurt at BSC's intransigence. From her sales force, Danaher heard that customers were discouraged because they believed that HP could not supply them with the Discovery Catheters or the APD. Danaher felt that this catheter unavailability would hurt HP's position in the market place. While HP did not anticipate making money on the catheters it bought from BSC under the interim supply agreement, the availability of these catheters was necessary to make a profit on the consoles and to maintain the installed console base.

Of apparent concern, HP's share in the console market in the United States dropped from approximately 40-45% of the market in late 1995 and early 1996 to around 20% when it exited. While

BSC's expert Dr. James Langenfeld disagreed that HP lost a significant amount of installed console base at the time it departed, there is no dispute that HP's sales of new consoles was declining. According to Langenfeld, HP sold 70 consoles in 1995; 44 consoles in 1996, 49 consoles in 1997, and 19 consoles in 1998.[5] The FTC's expert, Dr. Laurence Schumann, showed an even steeper decline in sales. Danaher attributed HP's decline in console sales to the uncertainty in the marketplace as to whether BSC's catheters (including the Discovery Catheter) would interface with HP's console and whether HP could supply them with its own catheters or the APD, and to the fact that the IVUS market did not expand as explosively as predicted.

The catheter issues particularly troubled HP. Leaders in the IVUS industry were vocal to Danaher about concerns that HP would not be able to supply catheters. In addition, BSC took the position that it would not permit the Scout catheter to interface with its new consoles because it was not "native technology."[6]

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[5] By comparison, BSC/CVIS's sales were 136 consoles in 1995, 95 consoles in 1996, 126 consoles in 1997, and 104 consoles in 1998. Endosonics sold 41 units in 1995, 76 units in 1996, 56 units in 1997, and 29 units in 1998.

[6] Although BSC's position was not a violation of the consent order, it violated ¶ 7 of the Agreement:

> The parties agree that during a period commencing with FDA regulatory approval or product introduction of each device released, whichever first occurs, and ending on the tenth anniversary of the Effective Date, each party will provide on all of its IVUS

Therefore, HP was faced with the prospect of the Scout catheter being able to run on only 25% of the installed console base. This problem could have been exacerbated by the emerging practice of "bundling," where console customers would receive a discount in return for agreeing to a long-term contract to buy catheters from the console manufacturer; customers would be less willing to enter into bundling agreements with HP, if there were uncertainty over the supply of catheters to HP's console. While bundling contracts represented only 20% of BSC's console sales prior to

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> consoles offered to its customers open interfaces to the IVUS products of the other party, whether currently owned or acquired in the future, provided the native console for such device is compatible with the Licensed Technology. For products already in existence, each party shall cooperate as requested by the other party in furthering this open interface objective. Each party has the option of upgrading its own consoles. 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 disadvantage. 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.

(Pl's. Ex 2 ¶ 7.)

As Danaher understood it, this provision gave the parties the option to upgrade existing consoles in order to interface with new catheters, but required BSC to interface HP's catheters with new consoles. The Court agrees this is a reasonable interpretation.

HP's exit, bundling was growing in significance before HP exited.

In October 1998, the Scout catheter was complete. HP had FDA approval, it excelled in the largest cardiologic interventional show in the country, and the distribution arrangement with Guidant was in place. Leading cardiologists were "wildly" enthusiastic and "exuberant" about the Scout catheter because of its great image and integrated APD, which had better ease of use than the CVIS or Quinton APD. Nonetheless, in November 1998, HP withdrew from both the catheter and console markets. The Scout catheter has never been commercially released.[7]

In January 1999, HP commenced litigation against BSC. This has been settled. In October 2000, the FTC filed its complaint.

CONCLUSIONS OF LAW

On September 28, 2001, the court allowed the government's motion for summary judgment on the grounds that BSC had violated the FTC's final order by failing to license in good faith the APD claimed by the Webler patent, and by refusing to comply with the interim supply agreement required by the Order with respect to the Discovery catheter. See Boston Scientific, 167 F. Supp.2d at 430-40.

Pursuant to 15 U.S.C. § 45(l), the remedies available for FTC order violations occurring prior to November 19, 1996 include

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[7] Another company now has the rights to the technology.

civil penalties of up to $10,000 for each violation. For continuing violations, each day is a separate violation. The maximum civil penalty was increased to $11,000 per day for violations occurring after November 19, 1996, by the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s).

Courts traditionally have looked at six factors in determining the appropriate civil penalty under 15 U.S.C. § 45(1): (1) harm to the public; (2) benefit to the violator; (3) good or bad faith of the violator; (4) the violator's ability to pay; (5) deterrence of future violations by this violator and others; (6) vindication of the FTC's authority. See, e.g., United States v. Nat'l Fin. Servs., Inc., 98 F.3d 131, 140-41 (4th Cir. 1996); United States v. Louisiana-Pacific Corp., 967 F.2d 1372, 1379-81 (9th Cir. 1992); United States v. Danube Carpet Mills, Inc., 737 F.2d 988, 993-95 (11th Cir. 1984); United States v. Reader's Digest Ass'n Inc., 662 F.2d 955, 967-69 (3d Cir. 1981), cert. denied, 455 U.S. 908 (1982). I address each of these factors as follows:

1. Harm to the Public

The Court finds that BSC's conduct harmed the public because its violations of the Order were a substantial contributing cause of HP's decision to withdraw from the IVUS catheter market. BSC's statements to the marketplace that HP would not have access to BSC's next-generation Discovery catheter and that BSC had the

exclusive rights to the APD discouraged new customers from purchasing HP consoles. As a result, HP's percentage share of the new sales of consoles dropped precipitously.[8] Moreover, BSC's obstreperous approach on the Order's requirements as to the APD and the Discovery catheter (not to mention the Agreement's requirements as to interfacing the Scout Catheter on new BSC consoles and providing 180-day notification to HP of new BSC catheters) substantially contributed to HP's decision to leave. While HP's business decision also focused on unrelated trouble in its ultrasound business, the Court finds BSC's conduct tipped the balance in favor of abandonment of the Scout catheter and the IVUS console market.

BSC argues that competition was not harmed because of Endosonics' rocket-like rise to its present 35% market share. However, the elimination of competition immediately after HP left the marketplace led to a decline in catheter innovation, and resulting harm to the public. As Dr. Schumann (the FTC's expert) testified, the lack of competition eliminated BSC's incentive to invest in research and development in catheter innovation.[9] The

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[8] HP points out that there is no direct evidence that HP lost a single console sale due to BSC's statements to the market about the APD or Discovery Catheters. However, circumstantial evidence supports the reasonable inference that customer concerns about the availability of APDs and the Discovery catheter hurt HP's ability to compete for new sales of consoles.

[9] Indeed, on January 19, 1995, Dr. Schumann, then an economic expert for the staff of FTC, did an analysis of the

introduction of new and improved coronary and peripheral catheters sharply declined following BSC's acquisition of CVIS in 1995, and further diminished after HP exited from the market at the end of 1998. Over the three year period from 1999 to 2001, BSC's total expenditure on IVUS catheter research was less than its expenditure for 1998 alone. (Id. at ¶38) BSC cancelled the $4.1 million "Cadillac" project to design a new 3.5 French catheter - which was intended to stave off competition from the Scout - after HP decided to leave the market. No new catheters were introduced in 1999, after HP's exit, and only 1 new catheter was introduced in each of 2000 and 2001.

As Dr. Nissen pointed out, because Discovery was eventually withdrawn as a result of safety problems, doctors in 1999 were still using the Ultracross catheter, which was inferior to both the Scout and the original BSC Sonus catheter. It was not until the third quarter of 2000 that BSC introduced the 3.5 French Atlanta catheter, which some doctors still view as inferior to the Scout.

There has been a parallel lack of innovation in consoles. Not until late 2001 did BSC introduce its new console, the

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effects of the proposed merger that stated: "In my view, the elimination of the competition between Boston Scientific and CVIS in the area of research and development may ultimately cause the most harmful impact of this transaction on the ultimate consumers of these products -- the patients with cardio-vascular disease." (Pl's. Ex. 387 ¶ 42.) His views proved prescient.

"Galaxy," which is the first significant console innovation since 1995. While BSC points to two new catheters and the Galaxy as demonstrating continued innovation, these innovations coincided with Endosonics' emergence as a robust competitor. To be sure, as BSC points out, lower domestic IVUS sales account for some decrease in research and development spending. However, the Court finds that a critical contributing factor in BSC's failure to innovate energetically in catheters was the acquisition of 90% market share.

The most poignant concern is that people with heart disease were harmed. The 1995-vintage BSC Sonocath catheter/HP Sonus 100 console presented the best IVUS image quality to date - superior to later catheter/console combinations. In short, after HP's exit, patients with heart disease were left with technology inferior to that available in 1995.

2. Benefits to BSC

The FTC argues that BSC benefitted in two ways from the violations of the order which contributed to driving HP from the market. First, it was able to reduce its research and development costs by $12.9 million. Second, it gained sales worth $8-11 million that would have been made by HP in sales of catheters. The FTC also argues that internationally BSC has benefitted from the merger with $85.4 million in catheter profits through the end of 2001. Domestically, the FTC argues BSC had a

benefit of $12 million through the end of 2001.

BSC responds that it did not gain from HP's departure from the market because Endosonics has since captured 35% of the installed consoles, and BSC's domestic sales are dropping. It points out that from May 1995-May 1998 BSC sold only $1.8 million worth of APDs. BSC vigorously contends that the relevant market is not the international market, and argues that the Court must examine benefits from the violations only in the domestic market. BSC also disputes how the fixed costs should be allocated in determining economic benefits. The Court gave this factor little weight in determining sanctions because the record is not clear on the correct methodology for determining the value of domestic benefits.

3. BSC's Bad Faith

The Court finds that BSC acted in bad faith in certain of its violations of the Order. Of primary concern is BSC's apparent belief that the Agreement with HP trumped the Order and BSC's recalcitrance in not consulting with the FTC because of an apparent concern that the FTC staff would make things worse. If BSC believed that it mistakenly included the APD in the exhibit to the Agreement and Order, it had an obligation to disclose this issue to the FTC, not hide the ball.

The argument that this major ongoing dispute - which smoldered during the contract negotiations and ignited within

days of the effective date of the order - was fairly presented to the FTC in the first compliance report is untenable. At best, BSC attached correspondence alluding to the issue to its first compliance report, together with the clarification letter. By not flagging this flashpoint, the compliance report did not fully describe all substantive contacts regarding licensing issues between BSC and HP, as required by the Order. The failure to seek an FTC advisory opinion regarding potentially violative conduct is evidence of bad faith. See Reader's Digest, 662 F.2d at 968.

If BSC was uncertain of the reach of the Order, it had an obligation to do more than see how close to the sun it could fly with impunity. See Boston Scientific, 167 F. Supp.2d at 433. Finally, and most significantly, BSC chose to take the risk of ignoring the FTC's staff interpretation once it took a position on the APD dispute. At that point, an advisory opinion certainly should have been sought. See 16 C.F.R. §2.41(d) ("Any respondent subject to a Commission order may request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance with such order.").

With respect to the Discovery catheter, the Court finds that BSC refused to provide it to HP on the pretextual ground that the removable imaging core was not covered, despite the express coverage of the Order: "removable imaging cores used in

intravascular or intracardiac ultrasound imaging." (Pl's. Ex. 33 ¶ I.G.) While the Agreement provided arguably inconsistent language (¶ 8(f)), BSC showed insufficient respect for the terms of the Order. Moreover, while there were manufacturing benefits, there was no clinical purpose for the core, and numerous documents support the FTC's argument that the core was created in bad faith primarily to circumvent the consent decree and (in BSC's words) "screw over" HP.

While the Court gives BSC credit for initially transferring technology in good faith and providing HP access to most catheters, with respect to the Discovery catheter and the APD it did not act in good faith.

4. BSC's Ability to Pay

BSC does not raise an issue of inability to pay. As of May 10, 2002, its market capitalization exceeded $10 billion.

5. Vindication of the FTC's Authority/Deterrence of Future Violations

The FTC argues that its institutional interest in enforcing consent decrees warrants the maximum penalty of $35 million. From 1991-2000, the FTC resolved 164 anticompetitive mergers by consent orders and sought 32 injunctions. BSC argues that the FTC continues to settle the vast majority of cases challenging mergers, and that the FTC's requested sanction is out of kilter with other settlements. According to BSC, the highest fines imposed in settlement for consent decree violations to date have

been between $3 million and $4 million; and most fines have been well under $1 million and less than 5% of the maximum penalty.

The Court holds that there is a compelling interest in vindicating the authority of the FTC in enforcing its consent decrees, and in deterring parties from flouting the terms of consent decrees. FTC orders should not be disregarded with impunity. Here, BSC received a 90% market share by entering into a consent order and then proceeded to violate that order. It is clear to the Court from BSC's course of conduct that after the initial technology transfer, BSC's goal was to drive HP out of the catheter market - by means that included certain violations of the FTC's consent order. BSC violated not only the letter but also the spirit of the consent order, the very purpose of which was to create an independent competitor. The FTC's authority must be vindicated; otherwise, parties to anticompetitive mergers will have every incentive to sign a consent decree to induce the FTC to withdraw its injunction, and then breach the promises made in the order.

6. Calculation

With respect to the APD violation, the Court finds there was a continuing violation from May 5, 1995 until at least March 1998 when HP made its preliminary decision to leave the market. The Court finds that the fine should be $5,000 a day until the FTC issued its ruling in July 1997. BSC's actions must be viewed

more harshly after the FTC's staff compliance ruling on July 9, 1997, when BSC continued to violate the consent decree (and failed to seek an advisory opinion); for this period, the Court doubles the fine amount to $10,000. The total for the APD violation is $6,325,000 (($5,000 x 795) + ($10,000 x 235)).

The Court finds that the fine for the Discovery violation should be $11,000 for each day between March 1, 1998 (when samples of the Discovery catheter were available for promotion) and May 5, 1998 (the end of the supply period required by the FTC order). The total for the Discovery violation is $715,000 ($11,000 x 65).

ORDER

The Court orders that defendant Boston Scientific Corporation pay a civil penalty of $7,040,000.00 to the Federal Trade Commission.

Patti B. Saris

PATTI B. SARIS
United States District Judge