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

September 28, 2001

SARIS, U.S.D.J.

I. INTRODUCTION

The government brings this action for civil penalties and equitable relief against defendant Boston Scientific Corporation ("BSC") alleging that it violated a consent order of the Federal Trade Commission that was designed to ensure competition in the intravascular ultrasound ("IVUS") catheter market.

Defendant moves to dismiss the complaint under Fed. R. Civ. P. 12(b)(6) while the government moves for partial summary judgment. Defendant's motion to dismiss (Docket #9) is **DENIED** on Counts 1 and 5, and **ALLOWED** on Counts 2 to 4. Plaintiff's motion for partial summary judgment (Docket #17) is **ALLOWED** as to Counts 1 and 5 and **DENIED** on Counts 2 to 4.

II. BACKGROUND

This case is the civil contempt counterpart to an earlier private action in this Court brought by Hewlett-Packard Company



("HP") against BSC for the latter's alleged monopolization and attempted monopolization of the IVUS catheter market. The Court denied BSC's motion to dismiss in that case, Hewlett-Packard Co.v. Boston Scientific Corp., 77 F. Supp. 2d 189 (D. Mass. 1999), which eventually settled out of court. The following facts are undisputed and mirror those recited in the Court's Hewlett-Packard opinion. Id.

A. The Products: Catheters and Consoles

IVUS catheters are medical devices used to diagnose and treat cardiovascular ailments. They are flexible, tubular objects that are inserted into a blood vessel. A transducer, located at the forward end of the catheter, generates and transmits ultrasound waves. These waves reflect off of the arterial walls, and a receiver measures the amount of returned energy. The catheter compares the transmitted and received energy and sends a signal to a console that displays a 360-degree image of the blood vessel. The image allows physicians to assess the amount of plaque deposits in blood vessels.

There are two types of IVUS catheters. Phased array catheters use several stationary transducers to create a 360-degree image of the blood vessel. Mechanical catheters also create a 360-degree image, but do so with a single transducer that is spun by an external motor drive unit called a console. This case centers around mechanical catheters.

B. Market Conditions Prior to 1995

BSC, headquartered in Natick, Massachusetts, develops and manufactures medical products. HP's headquarters are in Palo Alto, California, and its Medical Products Group is located in Andover, Massachusetts. Both companies are veteran players in the IVUS market: BSC sells catheters and HP sells consoles. Until 1995, they had a history of cooperation and, on occasion, engaged in joint ventures to design BSC catheters specifically to operate on HP consoles. As of mid-1994, BSC and Cardiovascular Imaging Systems, Inc. ("CVIS") were the market leaders with respect to the development, manufacture, and sale of IVUS catheters. BSC held 40% of that market, and CVIS accounted for 50%. The market for IVUS consoles was equally concentrated, with CVIS controlling 40% and HP drawing 50% of business.

In August 1994, BSC dramatically shifted the balance of market power by seeking to acquire CVIS. Three months later, BSC took steps to acquire SCIMED Life Systems, Inc. ("SCIMED"), which was preparing to enter the IVUS catheter market within the next two to three years.

Believing that BSC's acquisitions would substantially lessen competition and tend to create a monopoly power in the IVUS catheter market, the Federal Trade Commission ("FTC") filed suit against BSC in January 1995 for violation of the FTC Act, 15

U.S.C. § 45, and the Clayton Act, 15 U.S.C. §§ 18, 21. The FTC sought an injunction to prevent the CVIS acquisition and by mid-February 1995, planned to oppose the SCIMED acquisition as well by amending its complaint.

C. The Licensing Agreement

As part of settlement negotiations with the FTC, BSC sought a suitable competitor in the IVUS catheter market. On February 21, 1995, BSC entered into a licensing agreement granting HP the right to use BSC's IVUS technology ("Licensed Technology") in conjunction with the manufacture and sale of certain products ("Licensed Products").

The licensing agreement defined Licensed Technology as all BSC, SCIMED, and CVIS patents used for the "development, manufacture and sale of Licensed Products . . . and all existing know-how" relating to the development, manufacture, and sale of those products. (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25, App. II ¶ 2 at 2.) The License Agreement provides:

"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.

(Def.'s Mem. Supp. Opp'n Summ. J. Ex. 26 at 3.) Among several

patents listed on Exhibit A was BSC's Webler patent, which describes an automatic pullback device ("APD") for use with IVUS catheters. This technology allows a physician to retrieve an inserted catheter at a fixed rate of speed, enabling her to measure plaque accumulations more accurately. BSC agreed that it would not "in perpetuity" assert any of its rights "in a way that would prevent HP from practicing any of the Licensed Technology to manufacture, use or sell Licensed Products." (Id. at ¶2.)

The licensing agreement 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.

The licensing agreement also 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. This arrangement was designed to allow HP to compete in the catheter market while developing its own line of catheters.

The licenses granted by the HP/BSC agreement were to become effective upon the FTC's approval and the entry of the Consent Order. (Id. at ¶1.) If the order did not win FTC approval, the agreement would be null and void, but BSC agreed to "negotiate in

¹U.S. Patent No. 5,361,768 (issued Nov. 8, 1994). Patents for related technologies have since been issued (U.S. Patent Nos. 5,485,846 (issued Jan. 23, 1996); 5,592,942 (issued Jan. 14, 1997); and 5,759,153 (issued June 2, 1998)).

good faith exclusively with HP during the first thirty days following such FTC action in an effort to arrive at license terms satisfactory to HP and the FTC." (Id.)

D. The FTC Consent Order

The FTC agreed to withdraw its suit and allow the CVIS and SCIMED acquisitions after BSC entered into the licensing agreement with HP. On February 23, 1995, the FTC and BSC entered into an agreement containing a consent order ("Consent Order"), requiring BSC to license its IVUS Technology Portfolio to HP "pursuant to, and in accordance with, the February 21, 1995 agreement" between BSC and HP "which agreement is appended to [the] Order in Confidential Appendix II." (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 II.B.1 at 4.)² The preamble of the Consent

IT IS FURTHER ORDERED that:

² Section II of the Decision and Order provides:

A. Within six (6) months of the date this Order becomes final, Respondent shall, absolutely and in good faith, grant pursuant to Paragraph II.B of this Order, at no minimum price and with no continuing royalties, a perpetual, non-exclusive license of the IVUS Technology Portfolio, together with the right to grant exclusive sub-licenses to any part of such IVUS Technology Portfolio, the right to grant exclusive sub-licenses to manufacture or sell any product pursuant to such IVUS Technology Portfolio, and the right to have IVUS Catheters manufactured and sold on its behalf by any person.

B. Respondent shall license the IVUS Technology Portfolio

^{1.} to Hewlett-Packard Company, within ten

Order states: "The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order of the [FTC/BSC] Agreement may be used to vary or contradict the terms of the order." (Def.'s Mem. Supp. Mtn. Dismiss Ex. 1, ¶6.) The order's stated 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 the SCIMED Acquisition as alleged in the Commission's Complaint." (Id. at II.B.) IVUS catheters were defined in the Consent Order as "intravascular ultrasound catheters, intracardiac ultrasound catheters, removable imaging cores used in intravascular or intracardiac ultrasound imaging, and intravascular imaging guidewires." (Id. at I.G.) Without modification, the Consent Order formed the basis for the FTC's

days after the date this Order becomes final, pursuant to, and in accordance with, the February 21, 1995 agreement between Respondent and Hewlett-Packard Company, which agreement is appended to this Order in Confidential Appendix II; or

^{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.

The purpose of the license is 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 the SCIMED Acquisition as alleged in the Commission's Complaint.

April 28, 1995 Decision and Order on the matter, which became final on May 5, 1995 after being served on Defendant BSC.

Three main provisions of the FTC's final order are relevant to this litigation. First, the order required BSC to license its "IVUS Technology Portfolio" to HP or another suitable company. It defined "IVUS Technology Portfolio" to include: a) all rights to BSC, CVIS, and SCIMED United States and foreign patents and patent applications relating to IVUS catheters; b) all CVIS and SCIMED trade secrets, technology, and know-how relating to IVUS catheters; and c) all BSC and CVIS IVUS catheter customer lists. Second, it required BSC to provide technical assistance to the licensee in manufacturing the catheters and obtaining regulatory approval. Third, BSC was required to provide HP with an interim supply of catheters for resale.

In exchange for these commitments, the FTC withdrew its suit and request for an injunction. BSC then acquired CVIS and SCIMED.

E. Alleged Violations

The government claims that BSC violated the FTC's final order by failing to license the Webler patent to HP (Count 1); by withholding from HP the technical specifications needed for console interface with three of BSC's Sonicath Ultra model catheters before they were introduced to the market (Counts 2-4); and by refusing to supply Discovery model catheters for sale as

requested by HP (Count 5). These alleged violations will be discussed more fully below in connection with the Court's analysis.

III. DISCUSSION

A. Motion to Dismiss Standard

A motion to dismiss under Fed. R. Civ. P. 12(b)(6) is subject to limited inquiry, focusing not on "whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). Under Fed. R. Civ. P. 12(b)(6), a court may grant dismissal only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Roeder v. Alpha Indus., Inc., 814 F.2d 22, 25 (1st Cir. 1987) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). The Court must "take the allegations in the complaint as true and grant all reasonable inferences in favor of the plaintiff." Monahan v. Dorchester Counseling Ctr., Inc., 961 F.2d 987, 988 (1st Cir. 1992); Coyne v. Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992); Greebel v. FTP Software, Inc., 194 F.3d 185, 195 (1st Cir. 1999).

B. Summary Judgment Standard

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party

is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). To prevail on "summary judgment, the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). Once the moving party satisfies this requirement, the burden shifts to the nonmoving party to establish the existence of at least one factual issue that is both genuine and material. LeBlanc v. Great Am. Ins. Co., 6 F.3d 836, 841 (1st Cir. 1993); see also Anderson v. <u>Liberty Lobby, Inc.</u>, 477 U.S. 242, 247-48 (1986). To oppose summary judgment successfully, "the nonmoving party 'may not rest upon mere allegation or denials of his pleading, "" but must set forth specific facts showing that there is a genuine issue for trial. LeBlanc, 6 F.3d at 841 (quoting Anderson, 477 U.S. at 256). "If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990) (quoting Anderson, 477 U.S. at 249-50). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36.

C. Civil Contempt of a Consent Decree

In evaluating the government's allegations that BSC has violated the FTC consent order, the Court engages in a two-step inquiry: (1) construction and interpretation of the consent order itself; and (2) determination of whether the challenged conduct falls within the order's proscription. United States v. Reader's Digest Assoc., 662 F.2d 955, 960 (3d Cir. 1981); United States v. J.B. Williams Co., 498 F.2d 414, 430-31 (2d Cir. 1974).

"A motion for contempt will be granted only if the complainant can offer clear and convincing evidence that a lucid and unambiguous consent order has been violated." Porrata v. Gonzalez-Rivera, 958 F.2d 6, 7 (1st Cir. 1992).

D. Interpretation of a Consent Decree

The meaning and breadth to be given consent decrees in antitrust cases are frequently litigated issues. <u>United States v. Beatrice Foods Co.</u>, 493 F.2d 1259, 1269 (8th Cir. 1974).

"[C]onstruing the meaning of a consent order, even an ambiguous one, is a question of law for the court" <u>Reader's Digest</u>, 662 F.2d at 961; <u>accord J.B. Williams</u>, 498 F.2d at 431.

"[A] consent decree or order is to be construed for enforcement purposes basically as a contract . . ." <u>United States v. Charter Int'l Oil Co.</u>, 83 F.3d 510, 517 (1st Cir. 1996) (quoting <u>United States v. ITT Cont'l Baking Co.</u>, 420 U.S. 223, 238 (1975)). Therefore, the Court relies upon "the usual considerations of contract interpretation," including the

language of the decree; the circumstances surrounding its formation; its purposes; any technical meaning words used may have had to the parties; and any other documents expressly incorporated in the decree. AMF, Inc. v. Jewett, 711 F.2d 1096, 1102 (1st Cir. 1983) (citing ITT Cont'l Baking, 420 U.S. at 238); Charter, 83 F.3d at 517.

Courts should read consent decrees "to mean rather precisely what they say. Decrees must 'be specific;' they must 'describe in reasonable detail' just what 'acts' they forbid." NBA Prop.'s, Inc. v. Gold, 895 F.2d 30, 32 (1st Cir. 1990) (quoting Fed. R. Civ. P. 65(d)). Any ambiguities or omissions should be read as "redound[ing] to the benefit of the person charged with contempt." Id. (quoting Ford v. Kammerer, 450 F.2d 279, 280 (3d Cir. 1971)) (alteration in original). At the same time, however, the Court may rely upon the intent of the FTC and BSC at the time that they negotiated the order to resolve ambiguities in that order. Reader's Digest, 662 F.2d at 960. Similarly, the "consent order must be interpreted in light of its principal purpose." Id.; accord AMF, 711 F.2d at 1100; J.B. Williams, 498 F.2d at 431. Nonetheless, if the decree is "too vague to inform the burdened party" of what is required and what is forbidden, then it will not be enforced. AMF, 711 F.2d at 1101.

E. Count 1: Failure to License the Webler Patent

The government contends that BSC violated the first

provision of the FTC consent order (i.e., that requiring BSC to license its IVUS technology to HP or another suitable company) by refusing to license the APD described in the Webler patent.

Defendant argues that the APD is not encompassed by the order and that even if it were, BSC did not violate its licensing obligations.

1. Incorporation

The essence of BSC's motion to dismiss is that the consent decree does not explicitly incorporate the licensing agreement with HP into the FTC order. Under the FTC order, BSC was required to "license the IVUS Technology Portfolio . . . to Hewlett-Packard Company . . . pursuant to, and in accordance with, the February 21, 1995 agreement between [BSC] and Hewlett-Packard Company, which agreement is appended to [the] Order in Confidential Appendix II." (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 ¶ II.B.1 at 4.) BSC claims that phrases such as "incorporate by reference," "made a part hereof," and "comply with the terms" are needed to indicate an intent to incorporate a document. In support, Defendant points out that the latter two phrases were used to incorporate the Agreement to Hold Separate³ into the FTC

The Agreement to Hold Separate was entered to "preserve CVIS as a viable and competitive business, independent of Boston Scientific, and engaged in the research and development, manufacture and sale of IVUS Catheters and IVUS Consoles," pending final acceptance of the Consent Order and licensing of the IVUS Technology Portfolio pursuant to Paragraph II of the Consent Order, among other variables. (Def. Mem. Supp. Opp'n

order. (Id. ¶ II.F. at 5 ("Respondent shall comply with all the terms of the Agreement to Hold Separate, attached to this Order and made a part hereof as Appendix I.").) Additionally,

Defendant notes that the FTC has used the phrase "comply with the terms" in other consent orders to indicate its intention to enforce the terms of another agreement. E.g., In re Sensormatic Elecs. Corp., 119 F.T.C. 520, 526, 1995 FTC LEXIS 84, at *11

(Apr. 18, 1995) ("Respondent shall comply with the terms and conditions of the Supply Agreement."). The government contends that there is no requirement that the FTC employ any particular magical incantation to indicate that the licensing agreement is part of the order.

Generally speaking, courts have held that incorporation by reference requires that the document be specifically referred to and described in the contract. NBA Props., 895 F.2d at 34 (a court decree could not be read "as incorporating a contract to which it makes no reference"); Charter, 83 F.3d at 519 ("The prior settlements are explicitly referenced and described in the Charter decree. Under such circumstances we may consider these prior settlements in interpreting the decree"); Lowney v. Genrad, Inc., 925 F. Supp. 40, 47 (D. Mass. 1995) (requiring that the referenced document be identified beyond doubt). While courts have consistently observed that a document may be incorporated by

Summ. J. Ex. 25, App. I at 2.)

reference, no court has mandated that special language be used to accomplish incorporation. See ITT Cont'l Baking, 420 U.S. at 238 (holding that an 'appendix' incorporated by reference into a consent order, as well as a complaint that the consent order noted "may be used in construing the terms of the order," were "proper aids to the construction of the order and of the agreement of which it is part."); Crumpton v. Bridgeport Educ.

Ass'n, 993 F.2d 1023, 1028 (2d Cir. 1993) (stating that documents incorporated by reference become an intrinsic part of the consent decree); SEC v. Levine, 881 F.2d 1165, 1179 (2d Cir. 1989) (holding that consent judgments should be interpreted in a way that gives effect to what the parties have agreed to, as reflected in the judgment itself or in documents incorporated by reference).

By using the words "pursuant to, and in accordance with," the plain language of the consent decree clearly and unequivocally indicates the parties' intent to incorporate the license agreement into Section II of the consent decree which sets forth BSC's licensing obligations if it exercised the option to license the IVUS technology portfolio to HP.4 Therefore, in

⁴The conclusion that there is a meeting of the minds on this point is fortified by Defendant's own letters to the FTC acknowledging that the HP licensing agreement was incorporated into the FTC order by reference. (Gov.'s Mem. Supp. Summ. J. Ex. 3 at 2 ("Accordingly, we request that the April 19 letter be incorporated as part of the February 21 [Licensing] Agreement and, therefore, incorporated by reference in . . . the Order . .

order to determine the FTC's claim that BSC violated the order, the Court must read the FTC order and the license agreement in tandem.

2. Interpretation

Under the FTC order, BSC was required to license its IVUS
Technology Portfolio to HP "pursuant to, and in accordance with"
the licensing agreement between BSC and HP. (Def.'s Mem. Supp.
Opp'n Summ. J. Ex. 25 ¶ II.B.1 at 4.) The IVUS Technology
Portfolio was defined within the order as: "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 . .
. . " (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 ¶ I.H.1. at 2
(emphasis added).)

The government asserts that because the Webler APD is used in conjunction with IVUS catheters, it is "relat[ed] to" IVUS catheters within the definition of the IVUS Technology Portfolio and urges a broad definition consistent with the purposes of the

^{..&}quot; (emphasis added)); (Gov.'s Mem. Supp. Summ. J. Ex. 4 at 1 ("Thus, my earlier request that the April 19 letter be incorporated as part of the February 21, 1995 [Licensing] Agreement between BSC and HP and therefore, incorporated by reference in . . . the Order . . . appears to be unnecessary." (emphasis added)).)

consent decree. <u>See AMF</u>, 711 F.2d at 1099 (holding that "the term related components" can be sensibly interpreted only as a broad description of parts, accessories and equipment related to chemical metering pumps). Defendant contends that the government's position is overbroad because many patents that do not cover catheter design "relate to" IVUS catheters, but will not promote competition in the IVUS catheter market.

This dispute over the breadth of interpretation of the term "relating to" in the Consent Order need not be resolved in a This term's meaning is easily understood by consulting vacuum. the referenced licensing agreement itself which obligates BSC to license its technology for the "collective claims of the patents . . . listed on Exhibit A" of the licensing agreement. Defendant argues that the definition of licensed products contains an unstated field of use restriction which limits the meaning of the term Licensed Products only to the catheter claims of the patents listed on Exhibit A. This reading is inconsistent with the unambiguous language that the definition of licensed products "includes and is no narrower than the collective claims of the patents" in Exhibit A. The Court should not read limitations into a license agreement which could readily have been inserted by sophisticated parties. Amgen, Inc. v. Chugai Pharm. Co., 808 F.Supp. 894, 901 (D. Mass. 1992).

Even if the licensing agreement were not expressly

incorporated (which it was), a court can read two closely related documents together to interpret the terms of the document and the intent of the parties. See Fenoglio v. Augat, Inc., 254 F.3d 368, 371 (1st Cir. 2001) (construing two closely related contracts); Langton v. Hogan, 71 F.3d 930, 933 (1st Cir. 1995) (holding that although consent decree was not "in the classic mold" and did not officially integrate certain orders, these orders could be considered in construing the settlement). Thus, the fact that all the claims of the Webler patent were included in the definition of the licensed products in the license agreement supports the broad interpretation of the term "relating to IVUS catheters" in the FTC Consent Order urged by the FTC.

BSC seeks to create ambiguity in the consent decree through the introduction of extrinsic evidence about the contract negotiations, making the otherwise plain language fuzzier. This tactic is contrary to law. See Charter, 83 F.3d at 519 ("While in routine contract interpretation extrinsic evidence may be considered when the disputed terms are ambiguous . . . [if the court] do[es] not find the decree ambiguous . . . such evidence may not be considered to contradict the written terms of the agreement.") An order is not "unenforceably vague simply because a dispute later arises over the meaning of some of its terms."

AMF, 711 F.2d at 1102. Accord Bank v. IBM Corp., 145 F.3d 420, 424 (1st Cir. 1998); Blackie v. Maine, 75 F.3d 716, 721 (1st Cir.

1996). Moreover, if Defendant was uncertain of the reach of the licensing requirement, it "clearly had an obligation to do more than show how close it could come with safety to that which it was enjoined from doing." AMF, 711 F.2d at 1107 (internal quotation marks and citation omitted). "[O]ne who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line." Boyce Motor Lines, Inc. v. United States, 342 U.S. 337, 340 (1952); accord J.B. Williams, 498 F.2d at 432.

2. Challenged Conduct

The government argues that BSC refused to license the APD to HP and impeded HP's efforts to practice the Webler patent claims in violation of the order. Defendant contends that this argument is logically defective, for if the licensing agreement covers APD technology, then the license agreement remains intact regardless of Defendant's statements to the contrary. What's more, BSC asserts, HP behaved as though its APD license was legitimate. In support of this contention, BSC points to the deposition testimony of Jonathan Rourke, HP's IVUS R&D manager, who stated,

[I]t was my position then and now that our contract was unambiguous, that we had the rights to the claims of the Webler patent. . . . We went ahead and developed a device that included automatic pull-back. . . . I would have been pleased to continue to ignore what Boston Scientific said about automatic pull-back.

(Def.'s Mem. Supp. Opp'n Summ. J. Ex. 1 at 400.) In essence, BSC

argues, no harm, no foul.

The record contains the following undisputed evidence. the latter part of 1995, HP and INDEC Systems, Inc. ("INDEC") marketed the SONOS IVUS System, a catheter and console combination, for use with an APD based on the Webler patent and manufactured by INDEC. Upon learning of this, BSC wrote to INDEC in January 1996, stating that BSC "owns the entire right, title, and interest" in the Webler patent. (Gov.'s Mem. Supp. Summ. J. Ex. 25 at 1.) After recognizing that INDEC manufactured the APD for HP's SONOS IVUS System, BSC stated that INDEC's Carol Hubber had given "her assurance that INDEC would not be marketing their automated pullback device in the United States." (Id.) BSC then observed that INDEC's APD literature was distributed, nonetheless, from the HP booth at the November 1995 American Heart Association meeting. (Id.) BSC concluded by asserting, "[I]f you agree that your sale of this product in the United States would infringe the [Webler] patent, Boston Scientific Corporation expects that you will also agree that it would be appropriate for you to terminate sales of this product." (Id. at 2.)

In addition, BSC proclaimed exclusive ownership and practice of the APD patent to customers. In a January 14, 1998 memorandum to its sales representatives entitled "APD Justification," SCIMED stated,

SCIMED has the exclusive right to manufacture and sell APDs covered by CVIS APD patents. SCIMED will only sell APDs alongside CVIS/SCIMED systems or to accounts with CVIS/SCIMED systems. . . . If a customer who is currently using a competitive product requests the purchase of an APD you should discuss our rationale for selling APDs only to CVIS customers. . . At this time, SCIMED is the only company approved to sell APDs.

(Gov.'s Mem. Supp. Summ. J. Ex. 36 (emphasis added).) Similarly, Paul Buckman, Director of Marketing and Business Development for SCIMED, testified that SCIMED sales people were told that HP "did not have access or rights to our automatic pull back device, which was the issue that always was being, always coming up with customers." (Gov.'s Mem. Supp. Summ. J. Ex. 17 at 459.) BSC sent its staff documents like the "HP Situation Update," which stated, "BSC owns the only patent for the Automatic Pullback Device. If any competitor markets an APD we will take action." (Gov.'s Mem. Supp. Summ. J. Ex. 27.) BSC sent letters to customers stating it had the only "commercially available" APD (Gov.'s Mem. Supp. Summ. J. Ex. 31), that it had the "only FDA cleared (patented)" APD (Gov.'s Mem. Supp. Summ. J. Ex. 32), or "only FDA approved, patent protected" APD (Gov.'s Mem. Supp.

While not disputing this evidence, BSC claims that it did not violate the consent order because its actions had no adverse impact on HP's APD research, development or marketing. BSC states that it never sued or threatened to sue any customer for

infringement with respect to the APD and that it may not be held liable for braggadocio. See Thermo Electron Corp. v. Schiavone Constr. Co., 958 F.2d 1158, 1164 (1st Cir. 1992) ("A party's expressions of doubt as to its willingness or ability to perform do not constitute a repudiation." (quoting E. Allen Farnsworth, Contracts § 8.21, at 663 (2d ed. 1990))).

Defendant fails to grasp its obligations under the FTC order. BSC had an affirmative obligation to "license the IVUS Technology Portfolio," including the APD, to HP "within ten days after the date" the order became final. (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 ¶ II.B.1. at 4); United States v. Swingline, Inc., 371 F. Supp. 37, 45 (E.D.N.Y. 1974) (finding that defendant subject to FTC order was "required to take energetic steps to see that the orders of the court were carried out"); Dorn v. Astra <u>USA</u>, 975 F. Supp. 388, 394 (D. Mass. 1997) ("[P]laintiffs cannot treat their settlement agreements as binding and rescinded at the same time."). The order specifically directs BSC to "absolutely and in good faith, grant . . . a . . . license of the IVUS Technology Portfolio." (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 \P II.A. at 4.) Defendant also had a negative obligation under the licensing agreement to refrain from asserting in perpetuity any of its rights under its patents "in a way that would prevent HP from practicing any of the Licensed Technology to manufacture, use or sell Licensed Products." (Def.'s Mem. Supp. Opp'n Summ.

J. Ex. 25, App. II ¶ 2 at 2-3.)

The documents in the record demonstrate that Defendant's unabashed repudiation of HP's APD license in the marketplace constituted a breach of its duty to comply with these provisions. Moreover, there is a good faith requirement "implicit in the language and purpose of [a] consent decree." Porrata, 958 F.2d at 9; accord Ricci v. Okin, 537 F. Supp. 817, 824-25 (D. Mass. 1982) (finding parties to a consent decree required to take "all reasonable steps within their power" to comply with terms of decree and to demonstrate a good faith effort to comply with decree for modification to be warranted). As the Court warned BSC once before in the private litigation with HP, "the licensing agreement is a shield only if the defendant acts in good faith to comply with its terms." Hewlett-Packard Co. v. Boston Scientific Corp., 77 F. Supp. 2d 189, 197 (D. Mass. 1999).

Waving the Constitution, BSC argues that its statements to its sales staff, customers and other third parties about its belief that it had not licensed the APD are protected by the First Amendment. BSC may not abjure a clear requirement of the order and the licensing agreement in the market; then scurry to hide under the skirts of the First Amendment for protection. See Reader's Digest, 662 F.2d at 965 ("Any remedy formulated by the FTC that is reasonably necessary to the prevention of future violations does not impinge upon constitutionally protected

commercial speech.")

While BSC may be correct that its efforts to undercut its licensing obligations were unsuccessful and caused no harm to HP or the public, a finding of public harm is not required to assess civil penalties for the violation of an order. See United States v. Louisiana-Pacific Corp., 967 F.2d 1372, 1377-78, 1380 (9th Cir. 1992) As the FTC points out, these contentions as to lack of public harm and harm to HP are relevant to the amount of the penalty, but not to liability. Accordingly, the Court DENIES defendant's motion to dismiss this claim and ALLOWS the government's motion for partial summary judgment.

G. Counts 2-4: Withholding Technical Specifications for Sonicath Ultra Catheters

1. Open Interface Provision

The licensing agreement includes a so-called "open interface provision" which states:

[E]ach party will provide on all of its IVUS consoles offered to its customers open interfaces to the IVUS products of the other party, whether currently owned or acquired in the future. . . 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.

(Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25, App. II ¶ 7 at 7-8.) The government alleges that BSC violated this provision by failing to deliver to HP technical specifications for three different Sonicath Ultra model catheters, the 6F/20MHz, the 6F/12.5 MHz, and the 3.2F/20MHz, 180 days before each of these new catheters was launched into the market.

This is a difficult issue because unlike the requirement that BSC license certain technology to HP that appears in both the agreement and the order, there is no reference to an open interface provision in the consent order. The FTC again parries with the argument that because the licensing agreement was incorporated by reference in Section II of the Consent Decree, each and every one of the terms of the license agreement becomes part of the order, even if they do not relate directly to the terms of the licensing. BSC responds that the "open interface" provisions of paragraph 7 were not mandated by the consent order, and that any requirements that are contained exclusively in the License Agreement are enforceable only through private contract remedies. As BSC points out, the License Agreement contains several provisions that are not mentioned in the Consent Order, or are inconsistent with it. For example, the supply requirements of the Consent Order covered a three-year time period, while the HP license agreement's supply provision covers a four-year period. Further, the License Agreement creates an

exception for "removable imaging cores or removable imaging guidewires" while the order does not. (Id. at ¶8(f)). To resolve this issue, it is useful to compare the language in the Order with respect to the appended Hold Separate Agreement and the language incorporated in the License Agreement. The order provides: "Respondent shall comply with all terms of the Agreement to Hold Separate, attached to this Order and made a part hereof as Appendix I" (Id. ¶II (F)). If the FTC had wanted to enforce each and every term of the license agreement with the contempt sanction, why did it not use this clear and unambiguous language?

The government has not introduced any extrinsic evidence to resolve this ambiguity as to whether the parties intended to include this provision in the Order. Because any ambiguities and sloppiness in draftsmanship must redound to BSC's favor, BSC wins this round of the battle. The Court **DISMISSES** Counts Two through Four.

H. Count 5: Refusal to Supply Discovery Catheters

1. Interim Supply Agreement

Under the FTC order, BSC was obligated for a period of years to supply HP with BSC IVUS catheters in the quantities and types requested. However, the length of the interim supply period stated in the FTC order conflicts with that contained in the licensing agreement. Additionally, the interim supply provision

in the order does not clearly indicate the date from which its three-year period should run. Under the provision found in the FTC order, BSC was obligated to:

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.

(Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 ¶ III at 5.)

According to the licensing agreement, however, BSC agreed that "at HP's option, BSC shall make available to HP all BSC IVUS Catheters" (as that term is defined in the agreement) until the "fourth anniversary of the Effective Date" of the order. (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25, App. II ¶¶ 8(a),(e) at 8, 11.) The licensing agreement defined "BSC IVUS Catheters" as

"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 quidewires . . . "

(Id. \P 8(f) at 11.) (Emphasis added).

Defendant argues that the licensing agreement does not amend the FTC order and, therefore, the interim supply provision contained in the order should control, requiring BSC to supply catheters to HP for three years from the effective date of the

order, which was May 5, 1995, until May 5, 1998. The government asserts that it makes no difference whether the three-year term of the order applies or the four-year term of the licensing agreement controls, because both periods extended to May 1999. The government contends that because the three-year supply term under the order did not begin until HP requested its first shipment of catheters in May 1996, the interim supply period under the order did not terminate until May 1999. Similarly, the four-year supply term under the licensing agreement also ended in May 1999, because that period did not start until the effective date of the order, which was May 5, 1995. At oral argument, however, the government pressed for the three-year period from May 1996 to May 1999.

This Court adopts the most restrictive interpretation: the three-year period ending in May 1998 that is advocated by BSC. Especially when the license agreement and the order are read in sync, it is unlikely that the three year obligation to sell catheters commences on the date of the request, rather than the effective date of the order, as in the licensing agreement. Even if the government's interpretation was plausible, the Order is not a paragon of clarity. A restrictive interpretation again honors the principle that "any ambiguities or omissions in the decree are construed against the person alleging a violation of the consent decree and invoking the contempt sanction." Porrata,

958 F.2d at 8 (citing NBA Props., 895 F.2d at 32). Therefore, the liability analysis will assume the most restrictive reading, with the interim supply period beginning on May 5, 1995 and terminating three years later on May 5, 1998.

2. Challenged Conduct

After the CVIS acquisition, BSC developed a new line of catheters called "Discovery" that contained removable imaging cores. HP began inquiring about purchase of Discovery catheters as early as July 30, 1997. (Gov.'s Mem. Supp. Summ. J. Ex. 35 at 6.) Despite HP's requests, BSC never supplied HP with Discovery for resale, because BSC believed the Discovery catheter to be "a removable core device" that was "clearly excluded from the interim supply provisions" of the licensing agreement. (Gov.'s Mem. Supp. Summ. J. Ex. 11 ¶ 94 at 8; Gov.'s Ex. 35 at 6.) However, the government claims that this violates BSC's obligation under the licensing agreement to supply all BSC IVUS catheters to HP.

In its sworn response to an FTC Civil Investigative Demand, BSC stated that the Discovery catheter was commercially introduced in March 1998. (Gov.'s Mem. Supp. Summ. J. Ex. 15.) The other evidence submitted on summary judgment is consistent with this assertion, and one document indicates a slightly earlier launch date for the product line. (Gov.'s Mem. Supp. Summ. J. Supp. Ex. 135 (February 26, 1998 e-mail from Dave White

stating "THE DISCOVERY 2.6 40 MHz CATHETER HAS BEEN

LAUNCHED!!!"); Gov.'s Mem. Supp. Summ. J. Supp. Ex. 136 at 6387

(BSC Quarterly Manufacturing Review dated August 26, 1998 stating "Discovery 2.6F catheter short rail launched [sic] March 1998.");

Gov.'s Supp. Ex. 137 at 1325 (IVUS Physicians Advisory Board notes dated 3/4/98 stating "Discovery short rail 40 MHz - Monday in USA"); Gov.'s Mem. Supp. Summ. J. Supp. Ex. 138 at 17559

(March 26, 1998 e-mail from Roberto Benetello entitled "RE:

Discovery Launch" discussing the performance of Discovery at customer locations); Gov.'s Mem. Supp. Summ. J. Ex. 14 at 45-46

(BSC's sworn Interrogatory Response No. 31 in Agilent Techs.,

Inc. v. Boston Scientific Corp., No. 99-cv-10244-PBS stating that the Discovery catheter "was available on the market by the second quarter of 1998").

BSC has submitted an affidavit stating that "the first month in which there were sales for the Discovery 2.6 F/40MHZ Short Rail Product is June 1998." (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 21 ¶4 at 2). In response to the Civil Investigative Demand, BSC stated that the "date of commercial introduction" of these Discovery catheters was March 1998. (Gov.'s Mem. Supp. Summ. J. Ex. 15). It is not inconsistent to say that Discovery catheters were available for purchase and being marketed three months before the first sale was actually made. Even if one were to regard BSC's affidavit as contrary to the other documents

submitted to the Court, BSC is bound by its sworn response to the FTC Civil Investigative Demand that the Discovery catheter was commercially introduced in March 1998, because BSC has offered no explanation under oath for the variation in dates. (Id.) "It is settled that '[w]hen an interested witness has given clear answers to unambiguous questions, he cannot create a conflict and resist summary judgment with an affidavit that is clearly contradictory, but does not give a satisfactory explanation of why the testimony is changed." Torres v. E.I. Dupont De Nemours & Co., 219 F.3d 13, 20 (quoting Colantuoni v. Alfred Calcagni & Sons, Inc., 44 F.3d 1, 4-5 (1st Cir. 1994)) (alteration in original). At best, BSC's counsel explains in a footnote that March, 1998 was the month the product was ready for manufacturing. (Def.'s Mem. Reply at 55, n. 49). That assertion does not help BSC, which was under an obligation to supply the catheters to HP, an obligation that is triggered by HP's request for the catheters. The obligation does not begin on the date the first actual sale was made.

Having established that the Discovery catheter was available roughly two months before BSC's interim supply commitment ended and that BSC never supplied HP with these catheters, the question remaining is whether Discovery catheters were subject to the interim supply requirement. Defendant argues that it was not obligated to sell the Discovery catheter to HP, because the

licensing agreement excludes catheters with removable imaging cores from the interim supply requirement. Defendant claims that BSC specifically negotiated for this exception with the technology used in the Discovery catheter in mind. The government insists that the exemption in the licensing agreement is limited to removable imaging cores, which does not include the Discovery product since it is a catheter.

IVUS catheters are defined in the order as "intravascular ultrasound catheters, intracardiac ultrasound catheters, removable imaging cores used in intravascular or intracardiac ultrasound imaging, and intravascular imaging guidewires." (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25 ¶ I.G. at 2.) The licensing agreement defines "BSC IVUS Catheters" to mean "all IVUS Catheters listed by BSC on any price list . . . [or] otherwise marketed by BSC to the public . . .; provided, however, that BSC IVUS Catheters does not include removable imaging cores or removable imaging guidewires " (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 25, App. II ¶ 8(f) at 11.) Defendant argues that the reference in the licensing agreement to "removable imaging cores" denotes a catheter with a removable imaging core, since a catheter is the only medium through which a removable imaging core is put to use. There are two weaknesses in this argument. First, in the definition of an IVUS catheter under the order, "catheters" and "removable imaging cores" are named as

separate units. Therefore, the phrase "removable imaging cores" should be regarded as having a meaning different from "catheter" under the order and the licensing agreement. United States v. Olin Ski Co., 503 F. Supp. 141, 145 (S.D.N.Y 1980) (noting that "courts should always strive to find internal consistency when interpreting documents such as [a] consent order"). Second, it is undisputed that the Discovery was a catheter, with a "removable imaging core." However, the licensing agreement did not exclude catheters with removable imaging cores. It just excluded the core itself.

Defendant maintains that the Discovery catheter is exempt from the interim supply provisions, because the Discovery technology is a removable imaging core product that could be installed in different sheaths. To emphasize the significance of the removable imaging core composing the Discovery catheter, Defendant points to deposition testimony (Def.'s Mem. Supp. Opp'n Summ. J. Exs. 11, 12, 13); product literature about the Discovery catheter that mentions the removable imaging core feature (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 130, 131, 134, 135, 137); BSC's pre-release marketing of a long sheath and a short sheath (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 136; Gov.'s Ex. 104 (noting that the stand alone sheath is "not necessary now that HP is out")); and a filed patent application for a tool to load a removable imaging core (Def.'s Mem. Supp. Opp'n Summ. J. Ex. 132).

However, the government counters by pointing to BSC's sworn answers to interrogatories in <u>Agilent Techs.</u>, <u>Inc. v. Boston</u>
<u>Scientific Corp.</u>, No. 99-cv-10244-PBS, where Defendant stated,

BSC never promoted the Discovery core as a separate product or included it as a separate item in promotional materials or regulatory filings, nor was it intended for such use. BSC never sold the Discovery imaging core outside of the Discovery catheter. BSC did promote Discovery's removable imaging core as next-generation technology and a key feature of the new catheter.

(Gov.'s Mem. Supp. Summ. J. Ex. 14, Interrog. Resp. No. 34, at Similarly, in its regulatory statements to the Food and Drug Administration regarding the Discovery catheter, BSC asserted that the modifications to create this catheter "do not result in a new type of device for BSC . . . The device changes considered patient safety and the changes are not to achieve a new use." (Gov.'s Mem. Supp. Summ. J. Ex. 95 at 2.) The product label and the Directions for Use for the Discovery catheter both state that the item is a "Coronary Imaging Catheter." (Gov.'s Mem. Supp. Summ. J. Exs. 92, 93.) In addition, the directions do not mention that the imaging core can be removed from the sheath. (Gov.'s Mem. Supp. Summ. J. Ex. 93.) Finally, the very same promotional materials that Defendant cites to support its position characterize the Discovery product as BSC's "latest catheter" and as a "high performance diagnostic IVUS catheter." (Gov.'s Mem. Supp. Summ. J. Ex. 90 at 4315; Ex. 91 at 6388.)

Therefore, the Court concludes that the plain language of

both the Agreement and the Order includes the Discovery Catheter, and that it was commercially available in March. Accordingly, the motion to dismiss Count 5 is **DENIED**, and the motion for partial summary judgment is **ALLOWED** with respect to liability for failing to supply the Discovery Catheter between March and June 1998.

VI. ORDER

For the foregoing reasons, Defendant's motion to dismiss (Docket #9) is <u>DENIED</u> on Counts 1 and 5, and <u>ALLOWED</u> on Counts 2 to 4. Plaintiff's motion for partial summary judgment (Docket #17)⁵ is <u>ALLOWED</u> as to Counts 1 and 5, and <u>DENIED</u> on Counts 2 to 4.

PATTI B. SARIS

United States District Judge

be specific evidence that it would glean in discovery under Fed. R. Civ. P. 56(f) that would affect the outcome of the probable specific evidence that it would affect the outcome of the waste Mgmt., Inc., 137 F.3d 41, 45 (1st Cir. 1998).