IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| BOSTON SCIENTIFIC CORPORATION and, BOSTON SCIENTIFIC SCIMED, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. 07-333-SLR |
| JOHNSON AND JOHNSON, INC. and CORDIS CORPORATION, | ) | |
| Defendants. | ) | |
| BOSTON SCIENTIFIC CORPORATION and, BOSTON SCIENTIFIC SCIMED, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. 07-348-SLR |
| JOHNSON AND JOHNSON, INC. and CORDIS CORPORATION, | ) | |
| Defendants. | ) | |

**OPENING MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

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## INTRODUCTION

Defendants Cordis Corporation and Johnson & Johnson, Inc. (collectively "Cordis") respectfully submit this opening memorandum in support of their accompanying motion to dismiss the declaratory judgment Complaints filed by Boston Scientific Corporation and Boston Scientific Scimed, Inc. ("BSC") for lack of subject matter jurisdiction.[1]

BSC's Complaints seek declaratory judgments that Cordis's U.S. Patent Nos. 7,217,286 (the "'7286 patent") and 7,223,286 (the "'3286 patent") (collectively the "patents-in-suit") are invalid or not infringed by BSC's Promus drug-eluting stent, which is a private-labeled version of the Xience V stent manufactured by Abbott Laboratories ("Abbott"). In order for jurisdiction to exist under the Declaratory Judgment Act, the Complaints must allege "a substantial controversy, between parties having adverse legal interests, *of sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *See MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007) (emphasis added). BSC's Complaints fail to allege such a controversy because they do not point to any actual or imminent act of infringement by BSC.

Neither BSC nor Abbott has sold or offered for sale in the United States the stent at issue in this case, and neither has even obtained the required FDA approval to make such offers or sales. Abbott presently manufactures the Xience V stent in the United States for sale in Europe, and therefore Abbott – unlike BSC – does presently infringe the patents-in-suit. BSC does not allege that it makes, uses, sells, offers to sell, or imports the Promus stent in the United States, and it is therefore not currently committing any act of infringement of the patents-in-suit

[1] BSC filed two Complaints, one on May 25, 2007 (C.A. No. 07-333-SLR), seeking a declaratory judgment concerning the '7286 patent, and another on June 1, 2007 (C.A. No. 07-348-SLR), seeking a declaratory judgment concerning the '3286 patent. This double-captioned Motion seeks dismissal of both Complaints.

in the United States. Nor, given the lack of FDA approval, has BSC alleged any imminent acts of infringement by BSC in the immediate future. BSC's sole allegations on this point are that "BSC has been taking title to the Promus stent from Abbott in the United States and then exporting those stents to the European market." (C.A. No. 07-333-SLR Compl. ¶ 18 ("07-333 Compl.")); C.A. No. 07-348-SLR Compl. ¶ 18 ("07-348 Compl.").) Neither taking title to the stent or selling it in Europe is an act of infringement. *See* 35 U.S.C. § 271(a). Nor does BSC identify any imminent or concrete act of future infringement. BSC merely alleges, in essence, that it hopes to begin selling the Promus stent in the United States sometime in the future, when and if it receives FDA approval.

BSC's allegations do not come close to demonstrating any "injury-in-fact" that is "actual or imminent." *See Teva Pharm. USA, Inc. v. Novartis Pharm., Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007). BSC is not infringing the patents-in-suit, and thus there can be no prospect of any actual injury-in-fact now. And, because future sales of the Promus stent in the United States are at this point speculative (they will not occur until 2008 at the earliest and are wholly contingent on FDA approval), there is no imminent prospect of injury. The Court therefore should dismiss this case under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction.

## STATEMENT OF RELEVANT FACTS

BSC sells a variety of medical devices including drug-eluting stents. (07-333 Compl. ¶ 14; 07-348 Compl. ¶ 14.) In 2006, BSC entered into an agreement with Abbott permitting BSC to sell under the label "Promus" the Xience V drug-eluting stents manufactured by Abbott. (*Id.* ¶ 19.) BSC received CE Mark approval for the Promus stent in October 2006 and since that time has been selling in Europe Promus stents manufactured by Abbott in the

United States. (*Id.* ¶¶ 17, 18.) BSC, however, has not received FDA approval for the Promus stent in the United States, and the Complaints do not allege that BSC has infringed the patents-in-suit by making, using, selling, offering for sale or importing the Promus stent in the United States. BSC's Complaints merely allege that, "BSC has been taking title to the Promus stent from Abbott in the United States and then exporting those stents to the European market." (*Id.* ¶ 18.)

Cordis and Abbott have filed a series of lawsuits in this Court and in the District of New Jersey relating to Abbott's Xience V stent, which is currently being manufactured in the United States and is therefore infringing under 35 U.S.C. § 271(a). Abbott filed a declaratory judgment action in September 2006 concerning three Cordis patents that Cordis has never asserted and that are not at issue in BSC's Complaints.[2] In May 2007, Cordis first brought actions for infringement of the patents-in-suit against Abbott in New Jersey, and then Abbott later filed corresponding Complaints or motions to supplement in Delaware. Jurisdiction existed for Cordis's lawsuits because Abbott is committing acts of infringement by making the Xience V stent in the United States. Cordis, however, did not bring and has not brought suit against BSC because it is not aware of any activities by BSC that would constitute infringement by BSC of the patents-in-suit.

## ARGUMENT

### I. LEGAL STANDARD FOR DECLARATORY JUDGMENT JURISDICTION

Subject matter jurisdiction under the Declaratory Judgment Act requires an "actual controversy." *See* 28 U.S.C. § 2201. The Supreme Court recently reviewed the "actual controversy" requirement as it applies to patent cases in its recent *MedImmune* case. *See*

[2] C.A. No. 06-613-SLR. Cordis has moved to dismiss that action for lack of subject matter jurisdiction.

*MedImmune*, 127 S.Ct. at 767. Before *MedImmune*, the Federal Circuit applied a two-part test for declaratory judgment jurisdiction requiring "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity." *See Teva Pharm.*, 482 F.3d at 1339.

In *MedImmune*, however, the Supreme Court stated that "[t]he reasonable-apprehension of suit test … conflicts with" other Supreme Court precedent finding jurisdiction where the defendant could not have sued or gave no indication that it would sue the declaratory-judgment plaintiff. *MedImmune*, 127 S.Ct. at 774 n.11. [3] Instead, the Court explained, "'the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, *of sufficient immediacy and reality* to warrant the issuance of a declaratory judgment.'" *Id.* at 771 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (emphasis added)). Thus, immediacy and reality are key components of the "actual controversy" requirement. *Id.*

As a result of the *MedImmune* decision, the Federal Circuit has altered its test to remove the "reasonable apprehension of suit" formulation. *See Teva Pharm.*, 482 F.3d at 1339. The Federal Circuit, however, has continued to emphasize the immediacy and reality of the conflict as a key requirement for declaratory judgment jurisdiction, which requires standing and ripeness. Among the Article III standing requirements, the Federal Circuit explained, "injury-in-

[3] *MedImmune* held that an actual controversy existed between a patent licensee and licensor when the licensee alleged that the patent was invalid, unenforceable, and not infringed, even when the licensee continued to pay royalties. It is footnote 11 of the *MedImmune* opinion, which questioned the Federal Circuit's two-part test in light of Supreme Court precedent, that the Federal Circuit has recognized as requiring a change to its two-part test.

fact is the most determinative…." *Id.* at 1337 (citing *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 218 (1974)). And, an "injury-in-fact" must be "'concrete and particularized' and 'actual or imminent'" *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)) The plaintiff must also demonstrate that the case is "ripe for judicial review," that is, "the defendant's actions have harmed, are harming, or are about to harm the plaintiff." *Id.*

The plaintiff, BSC, has the burden to show that it has alleged an injury-in-fact and the issue is ripe, showing an "actual controversy" exists, and that therefore, declaratory judgment jurisdiction is proper. *See id.* at 1338. BSC has not met that burden.

## II. BSC HAS NOT ALLEGED AN "ACTUAL CONTROVERSY" OF "SUFFICIENT IMMEDIACY AND REALITY" AS REQUIRED BY THE DECLARATORY JUDGMENT ACT.

### A. BSC Has Not Alleged Any Current or Past Activity That Could Constitute Infringement.

Typically, a declaratory judgment plaintiff establishes the existence of an injury-in-fact by, *inter alia*, alleging that it is performing acts that could constitute infringement of the patent-in-suit. *See, e.g., MedImmune*, 127 S.Ct. at 767-68 (plaintiff selling allegedly infringing products in the United States); *Teva Pharm.*, 482 F.3d at 1340 (plaintiff filed Paragraph IV certification constituting an act of infringement under the Hatch-Waxman Act); *SanDisk v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375-76 (Fed. Cir. 2007) (plaintiff selling products allegedly infringing patents-in-suit).

BSC's Complaints do not allege that BSC has performed or is performing any act that could constitute infringement of the patents-in-suit. Infringement under Section 271(a) requires that a party "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention." 35 U.S.C. 271(a). BSC does not allege that it "makes" the stent. It is Abbott that "makes" the stent and sells it to BSC,

which then exports the stent. (07-333 Compl. ¶¶ 17, 18; 07-348 Compl. ¶¶ 17, 18); *see Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 527-529 (1972) ("makes" means creating an operable assembly of the patented invention); *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1366-67 (Fed. Cir. 2001) (same). BSC does not allege that it "sells" or "uses" the Promus stent in the United States. Finally, there is no allegation in the Complaints that BSC "offers to sell" the Promus stent in the United States. Indeed, because the FDA has not approved BSC's Promus stent, BSC is prohibited from marketing the product or offering it for sale in the United States, as the Federal Circuit has noted. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992).

BSC's only allegation is that it takes title to the stents in the United States and exports them to Europe, for sale there. (07-333 Compl. ¶ 18; 07-348 Compl. ¶ 18.) But neither selling a product in another country, taking title to a product, or exporting a product constitutes infringement in the United States. *See Dowagiac Manuf. Co. v. Minn. Moline Plow Co.*, 235 U.S. 641, 650 (1915) (patentee could not recover royalties for patented drills sold in Canada where infringer obtained the drills in the United States from the manufacturer and sold them in Canada); *see also Johns Hopkins Univ. v. Cell Pro, Inc.*, 152 F.3d 1342, 1366 (Fed. Cir. 1998) ("uses" means something more than mere possession of a product); *Ardco Inc. v. Page, Ricker, Felson Mktg. Inc.*, 25 USPQ2d 1382, 1384-86 (N.D. Ill. 1992) ("sells" means making a sale, not offering to sell or contracting for sale). Consequently, BSC cannot rely on alleged acts of infringement to support declaratory judgment jurisdiction.

**B. BSC Has Not Alleged Any Imminent Future Act of Infringement That Would Create a Controversy of Sufficient Immediacy or Reality to Support Jurisdiction.**

BSC also fails to allege any facts that would constitute an "imminent" infringement at some concrete time in the future. In essence, all BSC alleges is that it hopes to sell the Promus stent at some unspecified time in the future if and when it receives FDA approval. These kinds of speculative allegations about future conduct have been held insufficient to establish a controversy of "sufficient immediacy and reality" to support a declaratory judgment. *See Lang v. Pacific Marine and Supply Co., Ltd.*, 895 F.2d 761, 764-65 (Fed. Cir. 1990) (nine-month delay between the filing of the complaint and the completion of an allegedly infringing ship's hull not sufficient to demonstrate a "substantial controversy … of sufficient immediacy and reality to warrant" a declaratory judgment claim); *Telectronics Pacing*, 982 F.2d at 1527 (affirming dismissal of declaratory judgment action for device that had not received FDA approval); *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590, 2006 WL 2375035, at *2-3 (D. Del. Aug. 16, 2006) (dismissing case where the "FDA had not approved Dexcom's product and Abbott could not predict when, or if, the FDA would approve the product," even though FDA approval was expected within a year); *Alphamed Pharm. Corp. v. Arriva Pharm., Inc.*, 391 F.Supp.2d 1148, 1157-58 (S.D. Fla. 2005) (dismissing case where complaint provided no indication that FDA approval was forthcoming); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F.Supp.2d 104 (D. Mass 1998) (dismissing case where product had not received FDA approval); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925, 937-38 (N.D. Ill. 1995) (potential FDA approval of allegedly infringing product in three months was not imminent enough to warrant declaratory relief).[4]

[4] Although the cited cases were decided before *MedImmune*, the *MedImmune* case and those that

For example, in *Telectronics Pacing*, the plaintiff argued that there was a justiciable controversy because the defendant's implantable defibrillator "was being used clinically and was unlikely to be modified further" before it was sold. 982 F.2d at 1526. The court, however, found no "sufficient allegation of immediacy and reality" at the time the complaint was filed because the product was "years away from potential FDA approval" and the defendant "was prohibited by FDA regulations from distributing sales literature and soliciting orders." *Id.* at 1527.

In *Abbott Diabetes Care*, the court denied jurisdiction where FDA approval for the defendant's glucose monitoring system was expected about a year after the complaint was filed. *See* 2006 WL 2375035, at *1. The court, citing *Telectronics*, dismissed Abbott's action, explaining that "the FDA had not approved Dexcom's product and Abbott could not predict when, or if, the FDA would approve the product." *Abbott Diabetes Care*, 2006 WL 2375035, at *3. Therefore, "no controversy of sufficient immediacy and reality existed…to support declaratory judgment jurisdiction in the present case." *Id.* In *Abbott Labs. v. Zenith Labs., Inc.*, the expected time between the complaint's filing and FDA approval of the allegedly infringing product was even shorter—three months—but the court nonetheless denied jurisdiction, explaining that:

> FDA approval had not been granted at the time that Plaintiff requested declaratory judgment. In addition, there is no guarantee that the FDA approval will be forthcoming on any particular date in the future.

*Abbott Labs.*, 934 F.Supp. at 938.

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have followed have continued to emphasize the need for a controversy of "sufficient immediacy and reality" to warrant jurisdiction and have not called into question the rationale of the decisions cited above.

The same logic applies here. The Promus stent is undergoing clinical trials and has not received FDA approval. Nor does BSC allege that FDA approval is imminent, or provide any particular date in the future when FDA approval will be forthcoming. BSC merely offers the hope that it will receive approval some time in 2008. Without FDA approval, BSC cannot market, sell or offer to sell the Promus stent in the United States. And, if BSC does not receive FDA approval, the Promus stent will never be marketed or sold in the United States. Thus, if the Court were to permit this case to go forward, Cordis would be litigating a case about patent infringement against an adversary that does not infringe and may *never* infringe. *See Abbott Labs*., 934 F.Supp. at 939 ("[A] controversy will only materialize if the FDA approves the accused [product]…."). The case thus decomposes into "an opinion advising what the law would be upon a hypothetical set of facts." *MedImmune*, 127 S.Ct. at 771.[5]

## III. EVEN IF THE COURT WERE TO FIND JURISDICTION, IT SHOULD EXERCISE ITS DISCRETION TO DECLINE TO HEAR THE CASE.

Even if the Court were to conclude that BSC's allegations are sufficient to meet the "actual controversy" requirement for declaratory judgment jurisdiction, that "does not mean that the district court is required to exercise that jurisdiction." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813 (Fed. Cir. 1996). The Declaratory Judgment Act "has long been understood 'to confer on federal courts unique and substantial discretion in deciding whether to declare the

[5] Cases finding jurisdiction based on anticipated future infringement are distinguishable from the facts here. For example, in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) the Court found declaratory judgment jurisdiction in a Hatch-Waxman case where there was a companion infringement action between the parties with respect to the generic drug at issue and the defendant had "submitted an ANDA accompanied by data sufficient to make FDA approval imminent." *Id.* at 1571. *See also Abbott Labs. v. Baxter Healthcare Corp.*, No. 04-C-836, 2004 WL 1878291, at *7 (N.D. Ill. Aug. 16, 2004) (finding jurisdiction in Hatch-Waxman case where generic product at issue was already approved by the FDA). Here by contrast, the Promus stent is not a generic product, is currently in clinical trials, and there is no indication that FDA approval is imminent.

rights of litigants.'" *MedImmune*, 127 S.Ct. at 776 (internal citations omitted). The Court's discretion is broad, and the Court need only "act[] in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration" in reaching its decision. *EMC*, 89 F.3d at 813-814.

These purposes and principles counsel against exercising jurisdiction here. BSC would not be substantially inconvenienced by waiting to adjudicate these patent claims and defenses until there is actual or imminent infringement. BSC can not begin marketing, selling, or offering to sell its Promus stent in the United States until it obtains FDA approval. (07-333 Compl. ¶ 18; 07-348 Compl. ¶ 18); *see Telectronics*, 982 F.2d at 1523, 1527. If FDA approval is denied, the litigation would be purely hypothetical and advisory. If design changes are required, the lawsuit may likewise be purely hypothetical. By contrast, when and if BSC receives FDA approval, the parties will know precisely the attributes of the product to be sold in this country, and the claims can be meaningfully applied. Cordis should not be forced to defend this case (and pay for its defense) absent any actual or imminent infringement by BSC.

## CONCLUSION

For the foregoing reasons, the Court should grant Cordis's motion and dismiss BSC's Complaints for lack of subject matter jurisdiction and/or on the principles of sound judicial administration.

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