IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. JOHNSON & JOHNSON, INC. and CORDIS CORPORATION, Defendants.	Civil Action No. 07-333-SLR
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. JOHNSON & JOHNSON, INC. and CORDIS CORPORATION, Defendants.	Civil Action No. 07-348-SLR
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. JOHNSON & JOHNSON, INC. and CORDIS CORPORATION, Defendants.	Civil Action No. 07-409-SLR

REPLY 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 reply memorandum in support of their motion to dismiss the declaratory judgment Complaints filed by Boston Scientific Corporation and Boston Scientific Scimed, Inc. ("BSC") for lack of subject matter jurisdiction.

BSC's Answering Brief does not dispute the key facts showing a lack of declaratory judgment jurisdiction. BSC does not dispute that it does not presently make, use, or sell the Promus stent in the United States. BSC also does not dispute that it has not received FDA approval for the Promus stent and that without FDA approval it cannot market or sell the Promus stent in the United States. Nor can BSC say with any certainty if or when FDA approval will occur in the future. Thus FDA approval could occur in months, years, or never. Consequently, BSC has not established any acts that could constitute actual or imminent infringement, and there is no "actual controversy" of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). BSC's Complaints should be dismissed.

ARGUMENT

I. CORDIS HAS APPLIED THE TEST FOR JURISDICTION SET FORTH BY THE SUPREME COURT IN *MEDIMMUNE*

BSC argues that Cordis has applied an "overly-narrow test" for standing under the Declaratory Judgment Act. (BSC Br. (D.I. 14(07-333), 12(07-348), 11(07-409)) at 6.) But, as is clear from Cordis's opening brief, Cordis applied the standard for jurisdiction set forth in the Supreme Court's recent *MedImmune* case. (Cordis Op. Br. (D.I. 11(07-333), 9(07-348)) at 3-5.) Under this test, jurisdiction is only proper if there is an "actual controversy" of "sufficient

immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune*, 127 S. Ct. at 771.

Instead, it is BSC who is applying an improper test by attempting to read the "immediacy and reality" requirement out of the "actual controversy" test. As BSC would have it, as long as BSC can identify some potential harm that it may suffer in the future, declaratory judgment jurisdiction is proper. That is not the law. The "immediacy and reality" prong requires that there be a present or imminent dispute that is both "'concrete and particularized' and 'actual or imminent.'" *Teva Pharm. USA, Inc. v. Novartis Pharm., Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007). BSC must also show that Cordis's actions "have harmed, are harming, or are about to harm" BSC. *Id.* BSC has not demonstrated any actual or imminent harm here.

II. BSC DOES NOT DENY THAT IT CANNOT MARKET OR SELL THE PROMUS STENT UNTIL FDA APPROVAL AT SOME INDETERMINATE TIME IN THE FUTURE

BSC admits that it is not making, using or selling the Promus stent in the United States. (BSC Br. at 3.) Therefore BSC is not presently infringing the patents-in-suit. Nor does BSC set forth facts that would demonstrate any imminent infringement. To the contrary, BSC acknowledges that the Promus stent is under FDA review and has not been approved by the FDA. (BSC Br. at 4.) Although BSC alleges that it has the "immediate intention of selling the Promus stent in the U.S." and "expects to begin selling the Promus stent in the United States in the first or second quarter of 2008" (BSC Br. at 12), BSC cannot do so without first obtaining FDA approval. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992). And, BSC does not set forth any facts showing that it will in fact receive FDA approval by the first or second quarter of 2008, or at any particular time. Indeed, BSC does not even set forth facts establishing the current status of the FDA's review. The sum total of BSC's allegations on this point is the statement that "[a]n FDA application has been made for the

Promus stent." (BSC Br. at 4.) Thus, BSC's assertion that it plans to launch the Promus stent in the first or second quarter of 2008 appears to be little more than a present hope based on BSC's speculation about what the FDA may do. This is insufficient to create an actual controversy of "sufficient immediacy and reality" to support a declaratory judgment action. *See MedImmune*, 127 S. Ct. at 771.

The cases cited in Cordis's opening brief establish that there is no actual controversy of "sufficient immediacy and reality" to support a declaratory judgment action where, as here, FDA approval is pending and the product at issue will be sold, if at all, at some indeterminate time in the future. *See* Cordis Op. Br. at 7-8. BSC attempts to distinguish these cases as involving declaratory judgment actions filed by the patentee rather than the accused infringer, but BSC fails to explain why that makes a difference. The "actual controversy" test for standing under the Declaratory Judgment Act does not differentiate between actions brought by the patentee and those brought by the accused infringer. *See SanDisk v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375-76 (Fed. Cir. 2007); *Benitec Australia, Ltd. v. Nucleonics, Inc.*, __ F.3d __, 2007 WL 2069646 *2-*3 (Fed. Cir. Jul. 20, 2007). BSC cites no authority suggesting that the "actual controversy" standard is somehow more lenient for an accused infringer than for a patentee.

BSC's attempts to distinguish the specific cases cited by Cordis from the facts of this case are no more persuasive. BSC attempts to distinguish *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761 (Fed. Cir. 1990), on the basis that the accused infringer had not "engaged in any activity indicating that the [accused infringing] ship would soon be ready for sea." (BSC Br. at 13.) But at the time the suit was filed, the defendant in *Lang* was in the process of manufacturing a hull that the plaintiff contended would, when finished, infringe its patent. *Id.* at

763. The Federal Circuit found that there was no actual controversy of "sufficient immediacy and reality" because the "accused infringing ship's hull would not be finished until at least 9 months after the complaint was filed." *Id.* at 764-65. Similarly here, it will likely take at least 9 months after the Complaints were filed before FDA approval is granted on BSC's Promus stent allowing it to be sold in the United States.

BSC also tries in vain to distinguish *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, 2006 WL 2375035 (D. Del. Aug. 16, 2006), but *Abbott Diabetes Care* is directly analogous to the present case. In *Abbott Diabetes Care*, the Court dismissed a declaratory judgment action where the FDA had not approved the accused product, finding that "the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate." *Id.* at *3. As the Court explained:

> At the time Abbott filed its complaint, the FDA had not approved DexCom's product and Abbott could not predict when, or if, the FDA would approve the product. Indeed, Abbott states as much in its complaint, alleging that 'DexCom … expects FDA approval for marketing by the second quarter of 2006.' Additionally, Abbott did not, and could not, allege with any certainty that the device when approved would be the same device that began clinical trials, as product changes during testing are contemplated by statute. Most important, Abbott did not allege nor does it now contend that DexCom has distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity with regard to [the accused product].

Id. (citations omitted). Similarly here, at the time BSC filed its Complaints, the FDA had not approved the Promus stent, and BSC could not know with any certainty when or if the FDA would approve the product. As in *Abbott Diabetes Care*, BSC merely stated that it "expects" to begin selling the Promus stent in the United States in the first or second quarter of 2008. (BSC Br. at 12.) Nor does BSC allege with any certainty that the device approved would be the same device that began clinical trials. And, BSC does not contend that it distributed sales literature,

prepared to solicit orders, or engaged in any sales or marketing activity with respect to the Promus stent in the United States.

BSC also halfheartedly tries to distinguish *Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925 (N.D. Ill. 1995), which further confirms the lack of an actual controversy under the facts in this case. (BSC Br. at 14, n. 6.) In *Zenith Labs.*, the court found jurisdiction lacking even though the expected time between the filing of the Complaint and FDA approval of the allegedly infringing product was a mere three months. As the Court explained:

> In our case, Defendant may receive FDA approval for its generic form of Hytrin three months from the date that Plaintiff filed its Complaint. However, in our case … FDA approval had not been granted at the time that Plaintiff requested declaratory judgment. In addition, there is no guarantee that FDA approval will be forthcoming on any particular date in the future.

Id. at 938. In the present case, FDA approval is likely to take significantly longer than three months, as BSC does not deny. BSC's only attempt to distinguish *Zenith Labs.* is that there purportedly were not sufficient facts to show that the accused infringer "intends to enter the market." (Br. at 14, n. 6.) In *Zenith Labs.*, however, the accused infringer "never indicated that it does not plan to enter the market" upon FDA approval, despite being given numerous opportunities to do so. *Id.* at 938. Consequently, the facts in *Zenith Labs.* are analogous to those in this case. *See also Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (affirming dismissal of declaratory judgment action for device that had not received FDA approval); *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).

After Cordis filed its opening brief, the Federal Circuit handed down its decision in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, which confirmed the analysis in these cases. In

Benitec, the Court dismissed a declaratory judgment counterclaim filed by the accused infringer where the accused infringer had "not met its burden of showing that it is engaged in any present activity that could subject it to a claim of infringement." 2007 WL 2069646 at *7. Therefore, the Federal Circuit found, the accused infringer did not show that its activities "meet the immediacy and reality requirement of *MedImmune*." *Id.*

The only cases BSC cites to support its position are clearly distinguishable from the facts of the present case. In *Abbott Labs. v. Baxter Healthcare Corp.*, 2004 WL 1878291 (N.D. Ill. Aug. 16, 2004), the court based its decision finding jurisdiction on the fact that the accused infringer "already has an ***approved*** ANDA" and therefore had FDA approval to market its product when the Complaint was filed. *Id.* at *7 (emphasis in original). Here, by contrast, BSC does ***not*** have FDA approval (nor is there any certainty when such approval will be granted, if ever), and thus the *Baxter* case is inapplicable. BSC attempts to brush aside this critical point by arguing that the *Baxter* court did not "rule out declaratory judgment jurisdiction when the accused infringer has not yet received FDA approval" (Br. at 14), but this argument provides no support for BSC's position because the *Baxter* court did not address such a situation. Indeed, the *Baxter* court expressly noted that its holding was "based only on the specific facts of this case, and is not meant to extend the allowable time frame in other potential declaratory judgment cases," such as those where the accused infringer did not have FDA approval. *Id.*

Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997), is also inapposite because the product at issue was a generic drug subject to an expedited FDA review process via an Abbreviated New Drug Application (ANDA) and the defendant had "submitted an ANDA accompanied by data sufficient to make FDA approval ***imminent***." *Id.* at 1571 (emphasis added). The Promus stent is not a generic drug, and requires a comprehensive FDA review as

well as extensive clinical trials before FDA approval can be granted. BSC provides no evidence that FDA approval of the Promus stent is imminent, nor does it set forth any facts establishing the status of the FDA's review. The situation here is therefore in no way comparable to that in *Glaxo*.

III. BSC'S ARGUMENTS IN SUPPORT OF JURISDICTION LACK MERIT

Because BSC cannot deny that it does not now and will not in the imminent future make, use or sell the Promus stent, it concocts other arguments to attempt to support jurisdiction. These arguments, however, are plainly insufficient to establish an "actual controversy" of sufficient "immediacy and reality" to warrant a declaratory judgment suit.

BSC argues that it has suffered a present injury because Cordis "is seeking to put BSC out of the business of selling its Promus stent," and that Cordis's suit against Abbott (who infringes by manufacturing the stent in the United States) could affect BSC's source of supply for the Promus stent. (BSC Br. at 2, 9.) But BSC is only selling the Promus stent *outside* the United States. (Complaint (D.I. 1), ¶¶ 17, 18.) Thus, any present or imminent future injury suffered by BSC would be suffered outside of the United States. BSC cites no authority for the proposition that declaratory judgment jurisdiction can be founded on injury occurring outside the United States that is not cognizable under U.S. patent laws. Extending declaratory judgment jurisdiction to such extraterritorial situations would significantly expand the scope of the Declaratory Judgment Act in a manner unwarranted by the statute or existing case law. Indeed, if BSC could satisfy the requirements of the Declaratory Judgment Act on this basis, the floodgates would be open to declaratory judgment lawsuits by any and all foreign customers purchasing products manufactured in the United States. That is not and never has been the law.

In a similar vein, BSC halfheartedly argues that there could be a case or controversy based on whether BSC is inducing infringement based on its supply agreement with

Abbott. BSC, however, cites no authority for the proposition that a customer's act of entering into a supply agreement is sufficient by itself to create a claim of induced infringement. Indeed, BSC's Complaints never alleged that this supply agreement was or could be a potential act of induced infringement.[1]

BSC further asserts that jurisdiction can be founded on "the relationship between BSC, Abbott and their respective stents," as well as the fact that BSC "has invested heavily" in the Promus stent. (BSC Br. at 8.) Neither provides a sufficient basis for jurisdiction. The law is clear that a company's investment in a particular product or technology is not sufficient to create an "actual controversy" of "sufficient immediacy or reality" to warrant a declaratory judgment suit where any sales or actual infringement will not occur until some indeterminate future time. *See, e.g., Lang*, 845 F.2d at 763; *Abbott Diabetes Care*, 2006 WL 2375035 at *3; *Alphamed*, 391 F.Supp.2d at 1157-58. Similarly, the fact that BSC and Abbott have a customer/supplier relationship is insufficient to create an actual controversy in the absence of any present or imminent infringement.

Finally BSC points to an order in a case in the Northern District of California between it and Medtronic Vascular. (Messal Decl. Ex. A (D.I. 15(07-333), 13(07-348), 12(07-409)).) The *Medtronic* order, however, involved a request to intervene under Fed. R. Civ. P. 24(a), not a declaratory judgment action. (*Id.* at 1-2.) As the *Medtronic* court explained, under Ninth Circuit law "it appears that a party seeking to intervene as of right under Rule 24(a) need not possess constitutional Article III standing." (*Id.*) Thus, the *Medtronic* court's remarks concerning standing were, at most, *dicta*, which the court did not explain in detail. Moreover,

[1] BSC further states that it "absolutely is in apprehension of suit on the Promus stent given Cordis's express infringement allegations against Abbott's same stent." (BSC Br. at 7.) But BSC never explains how it can expect to be sued by Cordis on the patents-in-suit when it is not infringing those patents.

the *Medtronic* court based this dicta on the purported fact that BSC was "actively promoting the medical device at issue … in the United States." (*Id.* at 2.) BSC has made no such allegation here, and specifically avoids doing so in its brief. Indeed, such an allegation would run counter to the legal prohibition against marketing medical devices in the United States that have not received FDA approval. Consequently, the *Medtronic* order does not support the exercise of declaratory judgment jurisdiction in this case.

IV. EVEN IF JURISDICTION WERE PRESENT, THE COURT SHOULD EXERCISE ITS DISCRETION NOT TO HEAR THIS CASE

BSC provides no persuasive reason why the Court should exercise its discretion to hear this case even if jurisdiction were present. BSC cannot begin marketing, selling, or offering to sell the Promus stent until it receives FDA approval. BSC has alleged no facts establishing when FDA approval will occur, or what the current status of the FDA's review is. FDA approval could potentially be years away, or could never occur. If FDA approval is denied (or if design changes to the Promus stent are required), this litigation would be purely hypothetical and advisory. Therefore, it would be more efficient to wait at least until it is known whether BSC will receive FDA approval and when the parties will know precisely the attributes of the product to be sold in the United States, so that the claims can be meaningfully applied.

CONCLUSION

For the foregoing reasons, and those set forth in Cordis's opening brief, 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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