

SUPREME COURT OF THE STATE OF NEW YORK – NEW YORK COUNTY

PRESENT: Fried
HON. BERNARD J. FRIED Justice

E-FILE PART 60

Biotronia

INDEX NO. 603751/07

MOTION DATE _____

MOTION SEQ. NO. 006

MOTION CAL. NO. _____

- v -

Conor Medsystems Ireland

The following papers, numbered 1 to _____ were read on this motion to/for _____

Notice of Motion/ Order to Show Cause – Affidavits – Exhibits ...

Answering Affidavits – Exhibits _____

Replying Affidavits _____

PAPERS NUMBERED

Cross-Motion: Yes No

Upon the foregoing papers, it is ordered that this motion

This motion is decided in accordance with the accompanying memorandum decision.

SO ORDERED

The parties are directed to make arrangements to retrieve the confidential documents, which were submitted in connection with this motion, from the Part 60 Clerk, by November 7, 2011 or they will be discarded.

Dated: 10/19/2011

[Signature]
HON. BERNARD J. FRIED J.S.C.

Check one: FINAL DISPOSITION NON-FINAL DISPOSITION

Check if appropriate: DO NOT POST REFERENCE

SUBMIT ORDER/ JUDG.

SETTLE ORDER/ JUDG.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: COMMERCIAL PART 60
----- X
BIOTRONIK, A.G.,

Plaintiff,

- against -

Index No. 603751/07

CONOR MEDSYSTEMS IRELAND, LTD.,
CONOR MEDSYSTEMS IRELAND LIMITED,
CONOR MEDSYSTEMS, INC., CONOR
MEDSYSTEMS, INC., as successor by merger of
CONOR MEDSYSTEMS, INC. and CONOR
MEDSYSTEMS LLC,

Defendants.
----- X

APPEARANCES:

For Plaintiff:

Proskauer Rose LLP
Eleven Times Square
New York, NY 10036-8299
(Ronald S. Rauchberg, Anna G.
Kaminska)

For Defendants:

Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, NY 10169
(Harold P. Weinberger, Kerri Ann Law)

FRIED, J.:

Defendants move, pursuant to CPLR 3212, for summary judgment dismissing the Amended Complaint.

This action arises out of a distribution agreement between plaintiff Biotronik, A.G. (plaintiff or Biotronik) and defendant Conor Medsystems Ireland Limited (Conor) for the sale and distribution of a heart stent used to treat coronary artery disease.

By the Spring 2004, Conor had developed a novel drug-eluting stent it called CoStar. Drug-eluting stents are inserted into diseased coronary arteries during angioplasty and then elute a drug, in this case Paclitaxel, to minimize the risk of restenosis, or the recurrence of narrowing of the affected artery. Defs. Ex. C at CON0087382, CON0087389.¹ By May 2004, the CoStar stent had been subjected to a variety of laboratory, animal, and human studies. An additional study called EuroStar I was in its early stages. The EuroStar I study was designed to produce evidence that would permit the CoStar stent to obtain a Conformité Européenne (CE) mark -- that is, the approval by the relevant regulatory agencies, analogous to the FDA in the United States, authorizing the sale of CoStar in the European Union and other countries accepting the CE mark. Martini Decl., ¶¶ 3, 4.

Biotronik and Conor signed a “Distribution Agreement” on or about May 25, 2004. Defs., Ex. A. The Distribution Agreement provided that Biotronik would be the exclusive distributor of CoStar in an area, defined to include Europe and much of the rest of the world, except the United States and nine other countries (the Territory). *Id.*, § 2.1 & Ex. B. The Distribution Agreement, which was set to expire on December 31, 2007, would be automatically extended for one year, unless either party opted out of the extension and gave notice prior to July 1, 2007. *Id.*, § 16.1

The Distribution Agreement recites that European regulatory approval is the essence of the agreement (Defs. Ex. A, § 8.2), and that Conor expects to obtain regulatory approval

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“Defs. Ex.” refers to the exhibits A through NN submitted with the moving affirmation of Harold P. Weinberger, Esq. “Pl. Ex.” refers to exhibits 1 through 58 submitted by Biotronik with the opposing affirmation of Anna G. Kaminska, Esq.

for CoStar in the European Union by September 30, 2005. *Id.*, § 8.1. Exhibit D to the Distribution Agreement, entitled “Minimum Quarterly Order Quantities,” also recognized that the EuroStar I clinical trial might “reveal efficacy or safety levels materially less than that revealed, on average, in the published pivotal results for similar drug eluting stents.” *Id.*, Ex. D thereto at CON000127. In these circumstances, the parties agreed that, if Biotronik requested, the parties would negotiate in good faith to reduce the minimum quantities Biotronik was otherwise obliged to purchase. *Id.*

Article 7 of the Distribution Agreement is entitled “Assurance of Supply.” It provides that Conor must give 12 months advance notice of a decision to discontinue the manufacturing of CoStar, and that Biotronik would have the right to continue placing orders for CoStar for the ensuing 12 months. In addition, this article provides that “[w]here possible, the Parties shall agree on a replacement of such discontinued Product If no such replacement product is agreed, Biotronik shall have the right to terminate the Agreement”

Section 10.6 of the Distribution Agreement deals with the recall of products, and requires immediate notification to the other party if a recall “is desirable or required by law in the Territory or elsewhere.” The parties must then “discuss reasonably and in good faith whether such recall is appropriate or required and the manner in which any mutually agreed recall should be handled.” Defs. Ex. A, § 10.6. Despite this language, the following section provides that it is “Conor’s exclusive right and obligation to issue recalls, safety alerts, advisory notices or similar remedial actions on the Products.” *Id.*, § 10.7.

As part of the transaction, Conor Medsystems, Inc. (Conor US), a Delaware company and the parent of Conor, signed a written Guaranty guaranteeing all of Conor's obligations under the Distribution Agreement. Defs. Ex. A; Pl. Rule 19-a, ¶ 1.

Conor obtained European regulatory approval for CoStar in the form of the CE mark in February 2006 based upon results from EuroStar I and other clinical trials known as Pisces and CoStar I, which demonstrated that CoStar was safe and effective. Defs. Ex. H. Biotronik began selling CoStar in early 2006, and claims that the stent was well received by physicians and that its sales were growing rapidly. Am. Compl., ¶¶ 20-21; Pl. Ex. 58 at pp. 14-15.

In November 2006, Johnson & Johnson (J&J) announced its intention to acquire all of the stock of Conor US. Defs. Ex. L. The transaction closed on February 1, 2007. Defs. Ex. M. Cordis Corporation (Cordis), a subsidiary of J&J, markets a heart stent, called Cypher, that elutes a drug called Sirolimus. Defs. Ex. L; Pl. Rule 19-a, ¶ 25, at p. 7. Since the acquisition of Conor by J&J, Conor has remained a separate corporate entity, but has operated in conjunction with Cordis. *Id.*

Conor had enrolled CoStar patients in a clinical trial to support its application for FDA approval of the sale of CoStar in the United States. This clinical trial was called CoStar II. CoStar II was intended to compare the performance of CoStar against an FDA-approved drug-eluting stent known as Taxus, manufactured by Boston Scientific, at eighth-month follow-up with respect to major adverse cardiac events (MACE), defined to mean death, heart attack (myocardial infarction) and target vessel revascularization (the need for re-intervention of the artery). Defs. Ex. H, at CON0074294-95. On May 7, 2007, Conor issued

a press release regarding the results of the CoStar II trial, stating that CoStar “failed to meet its primary endpoint.” Defs. Ex. W. The press release goes on to explain that Costar did not “ demonstrate non-inferiority at eight month followup” against Taxus in the CoStar II trial, and that based upon those results, Conor was terminating its application for FDA approval and withdrawing CoStar from the markets where it had been approved for sale. *Id.* However, the press release also states that “[t]he trial did not identify safety issues, and the overall rates of death, myocardial infarction and stent thrombosis were consistent with those observed in other clinically relevant drug-eluting stent studies.” *Id.*

On May 9, 2007, Conor sent Biotronik a letter entitled “Urgent Field Advisory and Corrective Action.” Defs. Ex. BB. This letter advised Biotronik that Conor was “initiating remedial action” with respect to CoStar pursuant to Section 10.7 of the Distribution Agreement, “and initiating corrective action” to remove CoStar from the market. *Id.* On June 6, 2007, Conor notified Biotronik that it would not extend the term of the Distribution Agreement past December 31, 2007. Defs. Ex. FF. Biotronik alleges that this notice was given only after Conor had wrongfully breached the Distribution Agreement by ceasing to supply the CoStar stents to Biotronik and thus, the Distribution Agreement remained in full force and effect though December 31, 2008. Am. Compl., ¶¶ 36-37.

In an email dated May 9, 2007, Dr. Claus Martini, Biotronik’s then chief executive officer, was informed that Conor had no substitute paclitaxel or other drug-eluting stent to offer current CoStar customers. Defs. Ex. CC. Conor proposed supplying Cordis’ Cypher stent directly to Biotronik’s end-user customers to replace their CoStar inventories at Conor’s cost, citing Section 10.7 of the Distribution Agreement, or provide credit for returned CoStar

stents, at the customer's option. *Id.* Biotronik rejected this proposal. Martini Decl., ¶ 27.

Thereafter, Conor paid Biotronik 8,320,000 Euros, plus a 20% handling charge, to satisfy its financial obligations relating to the withdrawal of CoStar from the market, pursuant to its obligations under Section 10.7 of the Distribution Agreement to "bear all direct costs and expenses of any recall." Martini Tr. at 261; Defs. Exs. EE & A, § 10.7.

Biotronik commenced this action on November 13, 2007, alleging that Conor breached the Distribution Agreement. The Amended Complaint, filed in August 2009, asserts two causes of action against Conor for breach of contract and one claim against Conor US for breach of the Guaranty.

Biotronik contends that there were no safety or health concerns underlying the decision to cease manufacture of CoStar, and that Conor's purported "corrective action" and/or "recall" of the CoStar stent was a "sham," intended to bolster J&J's own coronary stent products "by temporarily removing the Costar stent from the market with the intent of re-introducing it in some modified form in the future." Am. Compl., ¶¶ 41-43. Biotronik alleges that the stent has been and is safe and effective for treatment of human cardiovascular disease. *Id.*, ¶ 31. Biotronik's first cause of action alleges that Conor breached Article 10 of the Distribution Agreement as well as the implied covenant of good faith and fair dealing. *Id.*, ¶¶ 39-47. Biotronik also alleges that Conor acted unilaterally without consulting Biotronik as required by Section 10.6 of the Distribution Agreement. *Id.*, ¶ 30.

Biotronik's second cause of action alleges that Conor's actions constituted a breach of Article 7 of the Distribution Agreement, because Conor discontinued manufacturing CoStar without affording Biotronik the rights set forth in that article. Am. Compl., ¶¶ 48-49.

Biotronik claims that, as a result of these breaches, it has sustained damages in excess of \$100 million, and that, pursuant to the Guaranty, Conor US is jointly and severally liable for these damages.

Defendants move for summary dismissal of the Amended Complaint, arguing that the unambiguous language of Section 10.7 of the Distribution Agreement gave Conor the “exclusive right and obligation to issue recalls . . . or similar corrective remedial actions” for CoStar. Defendants further maintain that, faced with the results of the CoStar II clinical trial showing that CoStar had nearly double the failure rate of the Taxus stent, Conor properly exercised its rights pursuant to Section 10.7 and recalled CoStar.² In defendants’ view, Biotronik’s rights to advance notice, a final 12-month supply, and a replacement product under Article 7 of the Distribution Agreement if Conor decides to discontinue manufacturing CoStar simply do not exist, because CoStar was recalled under Section 10.7. While Conor claims that the recall was a “sham” and that Conor was not truly motivated by concerns for patients in recalling CoStar, defendants claim that extensive discovery in this case has failed to support this claim.

Defendants also claim entitlement to summary judgment on Biotronik’s claim that Conor breached Section 10.6 of Distribution Agreement by failing to adequately consult with Biotronik before recalling CoStar on the ground that it is not actionable. Finally, even if Biotronik had a viable claim for breach of contract, the damages it seeks, i.e., the lost

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Defendants use the term “recall” in their motion papers, although Conor called the withdrawal of CoStar a “remedial action” or “corrective” action in correspondence with Biotronik (Defs. Ex. BB) and none of the publically-released documents refers to the action taken as a recall.

profits resulting from its ability to sell CoStar for the remaining term of the Distribution Agreement, are allegedly barred by Section 14.5's bar against claims for "any indirect, special, consequential, incidental or punitive damages."

Breach of the Distribution Agreement

A contract is unambiguous if "on its face [it] is reasonably susceptible of only one meaning." *Greenfield v Philles Records, Inc.*, 98 NY2d 562, 570 (2002); *see also Breed v Insurance Co. of N. Am.*, 46 NY2d 351, 355 (1978). Conversely, "[a] contract is ambiguous if the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings." *Feldman v National Westminster Bank*, 303 AD2d 271, 271 (1st Dept 2003) (internal quotation marks and citations omitted). "Whether an agreement is ambiguous is a question of law for the courts" and is to be "determined by looking within the four corners of the document, not to outside sources." *Kass v Kass*, 91 NY2d 554, 566 (1998) (citation omitted). The goal of the court is to determine the intent of the parties, "giving a practical interpretation to the language employed and the parties' reasonable expectations." *Slamow v Del Col*, 174 AD2d 725, 726 (2d Dept 1991), *aff'd* 79 NY2d 1016 (1992); *see also Goldman Sachs Group, Inc. v Almah LLC*, 85 AD3d 424, 427 (1st Dept 2011).

The contention that Article 7 and Section 10.7 are mutually exclusive, and that the provisions of Article 7 are irrelevant and do not apply to a recall that involves a permanent withdrawal of the product from the market, is rejected. "Courts are obliged to interpret a contract so as to give meaning to all of its terms." *Mionis v Bank Julius Baer & Co.*, 301

AD2d 104, 109 (1st Dept 2002), citing *Corhill Corp. v S.D. Plants, Inc.*, 9 NY2d 595, 599 (1961) (a cardinal rule of construction is not to adopt an interpretation that leaves a contractual provision without force and effect). As Biotronik points out, a recall and a discontinuance of manufacturing are not necessarily mutually exclusive of one another. It is indeed the case that there are all types of recalls, and the typical recall occurs when there is a problem with a manufacturing lot, and the manufacturer recalls that lot, but does not discontinue manufacturing the product. Here, Conor's corrective action involved both recalling current CoStar inventories and a complete cessation of all future CoStar production, and thus Article 7 is triggered.

Defendants rely on the testimony of Dr. Martini and Marlou Janssen, Conor's former vice president of sales and marketing, to establish that the provisions of Article 7 do not apply to a recall. There is no doubt that Dr. Martini and Ms. Janssen testified as such. See Martini Tr. at 182; Janssen Tr. at 83. However, their testimony is taken out of context. Dr. Martini also testified that he did not believe that this was a legitimate recall (*id.* at 183), and that Conor could only invoke Section 10.7 based on a "legitimate health or safety reason." *Id.* at 244-245. Ms. Janssen also testified that "[i]t is appropriate for the manufacturer to have the right of recall after serious safety issues have been identified." Janssen Tr. at 63-64. Thus, both testified that the provisions of Article 7 do not apply in the event of a recall for the protection of the health and safety of patients, not a product recall for business reasons.

Defendants argue that the protections afforded the distributor under Article 7 cannot be given in the event of a recall or other type of remedial action under Section 10.7. Defendants further maintain that Conor's "exclusive right" to issue recalls was not limited

to recalls mandated by law or a regulatory authority or to recalls justified by safety concerns, because the language of Section 10.6 refers to recalls either party believes is "desirous" or "appropriate."

Biotronik agrees that if the withdrawal of CoStar from the market was announced based on the fact that it was found to be a danger to patients, that this would certainly interfere with Biotronik's right to receive 12 months prior notice and the opportunity to continue placing orders for the product for one more year. However, Biotronik contends that the CoStar withdrawal was not a true recall, because the CoStar II trial results did not demonstrate that CoStar was an unsafe product and Conor was not mandated by European law or a regulatory authority to recall CoStar.

Here, the parties have articulated different interpretations of the word "recall" as used in Sections 10.6 and 10.7 of the Distribution Agreement. The term is not defined. Section 10.7 uses the phrase "recalls, safety alerts, advisory notices or similar remedial actions," which suggest that patient safety is the motivating factor for taking these actions. The next sentence states: "In such case BIOTRONIK will support and fully cooperate with CONOR to comply with the applicable laws and regulations." Defs. Ex. A, § 10.7. This sentence suggests that the remedial action is being dictated by a government authority, which is consistent with the provisions of Section 10.6, about giving notification of and discussing the details of a recall either party believes "is desirous or required by law." As Biotronik points out, if Conor could order a recall in the absence of any safety issue, then they have, in effect, a right to terminate the Distribution Agreement at any time. *See Cross v Frezza*, 161 AD2d 927, 928-29 (3d Dept 1990) (exercise of contingency required objective standard

of reasonableness; otherwise, one party would have a unilateral right to terminate the contract).

In addition, the Distribution Agreement specifically recognizes that, while the Eurostar I trial might yield results sufficiently positive to enable CoStar to be approved for sale in Europe, it could show that CoStar was less effective “than that revealed, on average, in the published pivotal results for similar drug-eluting stents.” Defs. Ex. A, Ex. D. In these circumstances, the parties provided that, if Biotronik requested, the parties would negotiate in good faith to reduce the minimum quantities it was otherwise obligated to purchase. Thus, in Biotronik’s view, the Distribution Agreement would continue even if CoStar were less efficacious than other stents.

Defendants admit that their voluntary withdrawal of CoStar from the market was based on efficacy concerns. The May 7, 2007 press release quotes a J&J executive’s statement that: “While the safety data from this trial are consistent with other drug-eluting stent studies, it was disappointing that this product did not meet the high standards for efficacy that our product portfolio represents.” Defs. Ex. W. However, in moving for summary judgment, defendants insist that the deposition testimony of their witnesses, Dr. Martini of Biotronik, and Biotronik’s own expert witness, establishes that efficacy translates to patient safety in two ways.

Nicholas Valeriani, J&J’s worldwide chairman of medical device and diagnostic business, and the individual who had final authority over the decision to withdraw CoStar from the market, testified that CoStar performed “no better than a bare metal stent. And patients would be exposed to the risk of anticoagulation therapy, i.e, having to take Plavix

with this product.” Valeriani Tr. at 12, 28. Dr. Campbell Rogers, Cordis’ chief scientific officer, testified that patients with drug-eluting stents are prescribed anti-platelet drugs like Plavix for 12 months, as contrasted with one month for bare metal stents, and those drugs pose risks of bleeding and allergic reaction and may require delaying other medical procedures. Rogers Tr. at 32-35. The second way in which CoStar’s lack of performance translated to patient safety was the fact that patients receiving CoStar had higher rates of restenosis than Taxus, and the need for re-intervention always exposes the patients to risks of anesthesia and bleeding. Valeriani Tr. at 39. One of Biotronik’s experts, Dr. Sigmund Silber, agreed that aspirin and Plavix inhibit clot formation and thus both have a risk of bleeding. Silber Tr. at 18.

Although this evidence is compelling, it is not entirely consistent with the public stance taken by Conor and J&J back in May of 2007.³ After the Costar II trial results became available and were analyzed by J&J/Cordis and Conor, they proclaimed CoStar's safety to the doctors who used it, European regulators, the FDA, Conor's customers, Biotronik and other distributors, the public, and the analysts following J&J's stock. *See, e.g.*, Pl. Exs. 22, 23 and 31 (CoStar II trial “did not identify safety issues.”); *see also* Pl. Ex. 20 (“no significant differences in major safety events”); Pl. Ex. 40 (“voluntary market withdrawal” was “not based on any specific safety concerns”); Pl. Ex. 44 (withdrawal not based on safety concerns). Patients who participated in the CoStar II trial were told “there are no precautions

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The deposition testimony of Dr. Martini that defendants rely on is less compelling. After clearly stating that “[a] recall is always safety-related,” he merely acknowledged that efficacy could be “one of the parameters that’s considered” in deciding whether to order a recall. Martini Tr. at 22.

or actions you need to take after CoStar stent implantation” and to “continue [your] usual care as for other patients with heart disease.” Pl. Ex. 40 at CON0008953-8954. Other patients implanted with CoStar were told that the “need for repeat procedures still occurred in less than 1 in 10 of all patients;” “[t]he complications expected would be the same as with any implanting drug-eluting stent;” and “[t]here are no additional safety risks related to the Costar® stent you received.” Pl. Ex. 40 at CON0008953.

Dr. Azin Parhizgar of Conor wrote on May 7, 2007 that Conor's action should not be called a recall, but a “voluntary stock removal,” because “the MDD [referring to European medical device directives] language” for what constitutes a recall is “risk of death and serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.” Pl. Ex. 25; *see also* Caparra Tr. at 59. In an email dated May 7, 2007, Conor is reported as saying that it “[did] not consider this a recall situation.” Pl. Ex. 26. On May 8, 2007, Conor drafted a document called a Health Hazard Analysis (HHA) in which the action is described as a “voluntary market withdrawal of the product from all markets where currently distributed due to competitive commercial viability assessment and standard of efficacy that is [held by J&J for Cypher].” Pl. Ex. 33 at CON0050781. This initial draft of the HHA concluded that “no potential hazards and harms or immediate and/or long range health consequences exist,” and classified the likelihood of “potential or actual harm to patients” as “negligible.” *Id.*, at CON0050778. When the HHA was finalized on May 10, 2007, this language was removed. Defs. Ex. NN. On January 25, 2008, in a memo to files Conor stated: “In May 2007, a business decision was made to discontinue commercialization of the CoStar product.” Pl. Ex. 51 at CON0104210.

Biotronik's expert, Dr. Sigmund Silber, opines that, based on his personal experience with the CoStar stent and his understanding of the clinical studies in which it has been used, that the CoStar II trial showed that "Costar was just as safe as Taxus; that CoStar "had many unique features," and that "patients would have fared better if physicians had been allowed the choice to use Costar." Defs. Ex. KK. Biotronik also offers the expert report of Maria E. Donawa, M.D., a consultant on European regulation of medical devices, who opines that the recall of CoStar was not mandated by European law or regulations or by any governmental or regulatory authority. Defs. Ex. LL.

Finally, Biotronik offers the expert opinion of Frank Vandeputte, an international sales and marketing executive. Mr. Vandeputte contends that a stent manufactured by Medtronic also failed to meet its primary endpoint in a clinical trial comparing it to J&J's Cypher stent. The results of that trial were announced in October 2005, but, unlike CoStar, the stent is still on the market and has commanded a "very healthy market share" due to a successful marketing strategy. Pl. Ex. 58 at p.11.

Biotronik argues that the testimony of Mr. Valeriani and Dr. Rogers is an "after-the-fact" attempt to tie patient safety to the decision to withdraw CoStar. That decision is described as a "commercial decision by J&J--and not by Conor--concerning J&J's short-term business strategy to avoid competition with its own Cypher stent and its long-term business strategy for developing and marketing heart stents." Am. Compl., ¶ 38. The short-term strategy was that J&J saw no reason to supply a competitor, Biotronik, with the means to compete with Cypher in important European markets. As support for this claim, Biotronik offers evidence that, once J&J acquired Conor, according to Richard Dakers, Cordis' vice

president of franchise development, J&J planned to “fire all the distributors” to get “control of the margin on the product and product pricing.” Dakers Tr. at 40-41; *see also* Martini Tr. at 100-101 (J&J sought early termination of the Distribution Agreement so J&J could “start commercialization of the CoStar stent themselves”).

As for the long-term strategy, Biotronik points out that J&J acquired Conor primarily to acquire what it called Conor’s “novel reservoir technology” (*see* Defs. Ex. M; Dakers Tr. at 34, 40), and that J&J planned to use, and is currently developing, this technology to dispense the drug Sirolimus, the drug J&J used with its Cypher stent. Pl. Exs. 50 and 53. J&J’s documents refer to “platform protection” as a reason for the withdrawal of CoStar. Pl. Ex. 18. Michael Boennighausen, Conor’s former general manager, testified that, in discussing whether CoStar should remain on the market between April 18 and May 7, 2007,

“one of the issues was to ensure that the technology platform was not negatively affected by the results of the COSTAR trial. So one of the issues to consider with respect to keeping the product on the market is what the effect would be on the platform since J&J had plans for additional products to follow on CoStar.

Q. And was there concern that if the product remained on the market, competitors might make negative comments specifically about the delivery system or platform?

A. Right. The concern was that one would not be able to separate the effect of the drug from the platform itself.”

Boennighausen Tr. at 103-104.⁴ Thus, Biotronik argues that the European sales forces of

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The court notes that Mr. Boennighausen was not part of the group of J&J personnel who actually made the decision to withdraw CoStar from the market (Valeriani Tr. at 12, 18), and Mr. Boennighausen testified that he could not recall with whom he had these discussions. Boennighausen Tr. at 103.

every other stent competitor, including J&J's own Cypher sales force, would be motivated to attack CoStar, and only Biotronik would be motivated to defend it -- a scenario unacceptable to J&J.

The circumstances surrounding the decision to recall CoStar lend support to plaintiff's theory that J&J was motivated solely based on competitive business concerns. After the results of the CoStar II trial was released, Mr. Valeriani put together an ad hoc group of ten people consisting solely of J&J and Cordis employees to consider what the "next steps" would be. Valeriani Tr. at 12-20. Surprisingly, no Conor personnel were included in these meetings (*id.*; *see also* Boennighausen Tr. at 73; Parhizgar Tr. at 141), and there are no contemporaneous documents recording the discussions or Mr. Valeriani's acceptance of the group's recommendation such as emails, notes or memoranda. *Id.* at 17-22, 62-63.

Since the meaning of the word recall as used in Section 10.6 and 10.7 is ambiguous, it cannot be concluded as a matter of law, that what defendants now call a recall of CoStar could be based on concerns other than patient safety. If a jury concludes that Conor had the right to issue a recall or corrective action based on efficacy concerns, then the question remains whether the results of the CoStar II clinical trial mandated an immediate withdrawal of CoStar from all markets and a complete cessation on future production such that the protections afforded Biotronik under Article 7 of the Distribution Agreement could not be given. If a jury concludes that a recall or corrective action under Section 10.6 must be related to patient safety, there is a disputed issue of fact as to the motivation for recalling CoStar -- whether, as defendants' claim, CoStar's failure to demonstrate non-inferiority to Taxus in

the CoStar II trial translates to patient safety in the manner in which their witnesses testified or it was a business decision motivated by J&J's desire to protect Cypher and its plans for future stents using the CoStar reservoir technology, as Biotronik claims.

There is also a question of fact regarding whether Conor supplied Biotronik with stents that were materially different from the stents that Conor promised to deliver to Biotronik in 2004. Biotronik alleges that, after entering into the Distribution Agreement and after completing the manufacture of all the stents needed to conduct the EuroStar I trial for European approval, Conor changed both the process it used to manufacture CoStar and the design and functioning of CoStar. Conor was apparently concerned that Paclitaxel could be toxic in dosages that were too large, and reduced the initial burst of Paclitaxel released upon the stent's implantation. Boennighausen Tr. at 100. This fact is admitted by defendants (*see* Defs. Mem. at p. 15; Def. Ex. GG at CON0016728, CON0016731; *see also* Pl. Ex. 46, 47, 48).

A party may not defeat summary judgment on the basis of a new theory advanced for the first time in opposing the motion and not pleaded in its complaint. *Hassan v Bellmarc Prop. Mgt. Servs., Inc.*, 12 AD3d 197, 198 (1st Dept 2004); *Pinn v Baker's Variety*, 32 AD3d 463, 464 (2d Dept 2006). The theory of "altered CoStar" is not, however, new and appears to have extensively explored by both parties in discovery. The Amended Complaint alleged that the stents were changed by Conor after the Distribution Agreement was signed. Specifically, Biotronik alleged that "Conor decided to use, and did use, Costar stents in the [CoStar II] Trial that were materially different from the Costar stents that Conor was supplying to Biotronik for sale in the Territory." Am. Compl., ¶ 23. At oral argument,

Biotronik's counsel explained that the allegation in paragraph 23 was made in error:

“We assumed, we believed and we alleged on information and belief that the stent to which -- with which we were supplied, the stent that we sold in Europe was in fact the same stent that had been tested in the EuroStar test and that the change was made only for purposes of the CoStar [II] test.

What we learned in discovery is that they made the change even earlier. . . . and so although the original CoStar was used for the EuroStar test, once European approval was achieved and they began to supply us with stents for distribution, they supplied us with the altered version of the stent.”

7/12/11 Tr. at 29-30. Plaintiff is also not contending that Conor's supply of altered CoStar is an independent breach of the Distribution Agreement, only that Conor's failure to comply with its supply obligations under the Distribution Agreement is being justified by the results of the CoStar II trial -- a trial which tested the safety and efficacy of a stent that was materially different from the stent that Conor agreed to supply to Biotronik. While the Distribution Agreement gives Conor the right, in its sole discretion, to make changes to CoStar (Defs. Ex. A, § 6.2), that right is subject to certain qualifications, one of which being that Conor has to inform Biotronik at least three months ahead of "any design change that changes form, fit or function of the Product." *Id.*

Defendants contend that the changes were within the specifications submitted in connection with the CE mark, but at the low end of those specifications (*see* Pl. Ex. 47 at CON0058249; Pl. Ex. 48 at CON0016731), and that this change was implemented to reduce tissue toxicity. Pl. Ex. 48 at CON0016731. Biotronik's own damages expert admits that “[t]he release kinetic specifications submitted by Conor for CE-mark approval were broad, and Conor had the ability to lower the elution rate for Paclitaxel and still remain within the approved specifications.” Pl. Ex. 58 at p.7. Defense counsel characterizes the changes as

a “minor” or “slight” variation in the amount of Paclitaxel released in the stent. *See* Defs. Reply Mem. at p. 6; 7/12/11 Tr. at 5-7. However, this so-called minor or slight change apparently caused the product to perform poorly in the CoStar II trial so much so that J&J believed it should be completely withdrawn from all markets where it was being sold.

There is also a question of fact whether Conor breached Article 7 of the Distribution Agreement by failing to offer Biotronik a replacement stent for CoStar. Article 7 provides that “[w]here possible, the parties shall agree on a replacement of such discontinued Product . . .” In an email dated May 9, 2007, Dr. Martini was informed that Conor had no substitute Paclitaxel or other drug-eluting stent to offer current CoStar customers. Defs. Ex. CC. However, at this point in time, Conor was a subsidiary of J&J, and Cordis, another J&J subsidiary, manufactured the Cypher drug-eluting stent. Indeed, the email referred to above was written by Richard Dakers of Cordis, and in it, he, speaking on behalf of Conor, proposed supplying the Cordis Cypher stent directly to Biotronik’s end-user customers to replace their CoStar inventories at Conor’s cost, or provide credit for returned CoStar stents, at the customer’s option. *Id.* Biotronik rejected this proposal, not because, as defendants claim, it did not regard Cypher as a suitable replacement, but because Conor was not offering to supply Biotronik with Cypher on an exclusive basis and because Conor wanted to deliver directly to Biotronik’s customers thereby bypassing Biotronik. Martini Tr. at 178; Martini Decl., ¶ 26. What Conor offered to do, and what Dr. Martini testified was unacceptable, was to supply the Cypher stent directly to Biotronik’s customers to fill open orders for some unspecified period of time. Pl. Ex. 43; Martini Decl., ¶ 27.

Citing CPLR 4547, defendants argue that any offer to supply Cypher was an attempt to resolve potential issues between the parties, and thus is not admissible evidence. While the offer cannot be used to show that Conor breached the Distribution Agreement by withdrawing CoStar from the market, it is direct evidence as to whether it was “possible” for Conor, through its sister corporation, Cordis, to supply Biotronik with a replacement product. And while the rest of Article 7 gives Biotronik the right to terminate the Distribution Agreement “[i]f no such replacement product is agreed [upon],” nothing provides that this is Biotronik’s sole or exclusive remedy in the event of a breach of Article 7 by Conor.

Defendants also seek to dismiss, as non-actionable, the claim that Conor breached Section 10.6 of the Distribution Agreement by unilaterally initiating a recall of CoStar without consulting Biotronik. *See* Am. Compl., ¶¶ 30, 41. While it is correct that a party’s breach of an obligation to consult the counter-party before taking action absolutely permitted under the contract has been held not to give rise to a cognizable claim for damages (*see Inside Out Prods. Inc. v Scholastic Inc.*, 1995 WL 375927, at *2 [SD NY 1995]), there is a question of fact as to whether the Distribution Agreement gave Conor the exclusive right to withdraw CoStar from the market in the absence of patient safety concerns.

For these reasons, defendants’ motion for summary judgment dismissing the first and second causes of action of the Amended Complaint is denied. The disputed issues of fact presented on this application forecloses me from ruling, as a matter of law, that Conor did not breach the Distribution Agreement when it withdrew CoStar from the market in May 2007 and discontinued manufacturing the product.

Recovery of Biotronik's Lost Profits

Biotronik seeks to recover lost profits resulting from its inability to sell CoStar for the remaining term of the Distribution Agreement and Conor's failure to provide a replacement product. Biotronik claims, through the report of its damages expert, that CoStar's 2006 and first quarter 2007 sales were steady, and that, despite the results of the CoStar II clinical trial, CoStar's market share would increase in the remainder of 2007, 2008 and the first quarter of 2009. Pl. Ex. 58, at 14-18. Biotronik's expert opines that the company's lost margin on the sale of CoStar through the end of April 2009 is approximately \$85 million. *Id.*, at 20-21.⁵

Section 14.5 of the Distribution Agreement provides that "neither party shall be liable to the other for any indirect, special, consequential, incidental or punitive damage with respect to any claim arising out of this agreement (including without limitation its performance or breach of this agreement) for any reason." Because the lost profits Biotronik seeks are consequential damages under New York law, defendants contend they are barred by Section 14.5 of the Distribution Agreement. Biotronik argues that, in the context of an exclusive distribution agreement, its lost profits on the sale of CoStar are general damages, because they are the direct, natural, and probable consequence of defendants' breach.

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The parties dispute whether the remaining term of the Distribution Agreement is December 31, 2007 or December 31, 2008. Biotronik's claim for lost profits for the first quarter of 2009 is based on the provision in the agreement for a four-month, non-exclusive, sell off of inventory period upon termination or expiration of the Distribution Agreement. *See* Defs. Ex. A, § 16.5. Conor always had the right, which it exercised, not to extend into 2008, meaning that, but for the alleged breach, the Distribution Agreement would have terminated on December 31, 2007. Thus, at most, Biotronik would have had the right to sell CoStar through the first quarter of 2008.

“The distinction between general and special contract damages is well defined but its application to specific contracts and controversies is usually more elusive.” *American List Corp. v U.S. News & World Report*, 75 NY2d 38, 42 (1989). General damages are those “which are the natural and probable consequence of the breach.” *Kenford Co. v County of Erie*, 73 NY2d 312, 319 (1989). Consequential damages, on the other hand, are “indirect and compensate for additional losses incurred as a result of the breach.” *Appliance Giant, Inc. v Columbia 90 Assoc., LLC*, 8 AD3d 932, 934 (3d Dept 2004). “A claim for lost profits is generally [considered to be] a claim for special or extraordinary damages.” *Yenrab, Inc. v 794 Linden Realty, LLC*, 68 AD3d 755, 759 (2d Dept 2009); *see, e.g., Rose Lee Mfg. v Chemical Bank*, 186 AD2d 548, 551 (2d Dept 1992); *Schonfeld v Hilliard*, 218 F3d 164, 176 (2d Cir 2000).

Because Biotronik was appointed Conor's exclusive distributor and was required to buy the CoStar stents from Conor and pay Conor a fixed percentage of Biotronik's sales pursuant to the Distribution Agreement, Biotronik argues that its mark-up, or gross profits, are incorporated into the very terms of the parties' agreement. The loss of those profits, in Biotronik's view, is the direct result of Conor's refusal to meet its supply obligations.

Biotronik purports to rely on a very old Supreme Court case, *Masterton & Smith v City of Brooklyn* (7 Hill 61, 69 [1845]), in which the court stated that “profits or advantages which are the direct and immediate fruits of the contract entered into between the parties” are recoverable. In *Masterton*, the plaintiff contracted with City of Brooklyn to furnish, cut, fit, and deliver marble, dressed in a certain manner, to be used in the construction of a building; the defendant agreeing to pay in installments. Part of the marble was duly

delivered and paid for, and then the City stopped building and refused to receive and pay for any more marble; that being the breach complained of. The Supreme Court said, in substance, that the measure of damages, under such circumstances, was the difference between the cost of procuring the marble and what the plaintiff was to receive for it under the parties' agreement.

Biotronik also relies on *American List Corp. v U.S. News & World Report* (75 NY2d 38, *supra*), as support for its claim that its lost profits for sales of CoStar can be awarded as general damages. However, in that case, the defendant magazine agreed to rent, over a 10-year period, mailing lists of names of college students to be compiled by the plaintiff. The magazine agreed to finance the plaintiff's start-up costs by paying a larger fee per name in the first five years. A schedule of the estimated number of names to be provided and the fees to be paid by the defendant was appended to the contract. The magazine repudiated the contract after about a year and a half. The trial court awarded the plaintiff the balance due on the contract for the remaining 10-year term, reduced to its present value. The Court of Appeals rejected the magazine's argument that the trial court improperly awarded the plaintiff "lost future profits," holding that the plaintiff only sought to recover "moneys which defendant undertook to pay under the contract." 75 NY2d at 43.

Tractebel Energy Mktg., Inc. v. AEP Power Mktg., Inc. (487 F3d 89, 109 [2d Cir 2007]), also relied upon by Biotronik, involved the breach, by the buyer, of a long-term energy contract. The buyer promised to take a minimum amount of energy products and make payments at prices stipulated in the contract. After the buyer repudiated the contract, litigation ensued, and the seller sought damages for, inter alia, "the profits it expected to

make had the contract been performed.” 487 F2d at 93. The district court ruled that these profits were not determinable with a sufficient degree of certainty. The Second Circuit reversed, finding that this was not a claim for lost profits on collateral business arrangements, but, rather, that the seller was only trying to “recover money that the breaching party agreed to pay under the contract” and thus were “general damages.” *Id.* at 109. “The profits are precisely what the non-breaching party bargained for, and only an award of damages equal to lost profits will put the non-breaching party in the same position he would have occupied had the contract been performed.” *Id.* at 109-110.⁶

All three of these case do not involve the lost profits on future sales of a product to third parties. They merely stand for the proposition that a party to a contract may recover the money that the breaching party agreed to pay under the contract, the price of the marble in *Masterton*, the cost of renting the lists of college students in *American List*, and the energy products in *Tractebel Energy*. In the present case, Biotronik is not merely seeking to recover moneys that Conor agreed to pay under the Distribution Agreement, rather it seeks to recover the amount of profits it believes it would have made on the re-sale of CoStar stents to its sub-distributors and end-user customers. Section 14.5 of the Distribution Agreement is clear -- the parties did not contemplate that consequential damages in the form of lost profits could be awarded for any breach. *International Gateway Exch., LLC v Western Union Fin. Servs., Inc.*, 333 F Supp 2d 131, 150 (SD NY 2004). The fact that Conor would receive a fixed

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Other cases Biotronik cites are equally distinguishable. *Inacom Corp. v Sears, Roebuck & Co.* (254 F3d 683 [2d Cir 2001]), did not involve a claim for lost profits. There the plaintiff was seeking mitigation costs (*id.* at 691-92), and the case was decided under Illinois law.

percentage of Biotronik's sales does not change the fact that Biotronik is claiming damages in the form of lost profits on collateral business arrangements, and that these are consequential damages the parties expressly agreed would not have to be paid in the event of a breach.

Biovail Pharms., Inc. v Eli Lilly & Co. (2003 WL 25901513 [ED NC 2003]), is only one of two cases that Biotronik cites that is analogous to the facts of this case. Indeed, the facts of *Biovail* are extremely similar -- an exclusive distributor of a drug sued the manufacturer after the drug is recalled from the market. There, too, the parties' agreement excluded "incidental and consequential damages." *Id.* at *2. The plaintiff argued that its lost and future profits on the sale of the drug were general and not special damages. The district court agreed, holding that lost profits could be awarded as general damages for breach of "a contract for the right to re-sell a product where the buyer suffered damages due to the sellers complete inability or failure to supply the product which it was buying to re-sell." *Id.* Likewise, in *D.P. Serv., Inc. v AM Intl.* (508 F Supp 162, 167 [ND Ill 1981]), another distributorship case, the court held that a contractual exclusion of consequential damages did not preclude recovery of lost profits because a distribution agreement "[u]nquestionably ... contemplated [plaintiff]'s selling of [defendant]'s machines for a profit."

Neither of these federal district court decisions are persuasive authority. *Biovail* was decided under Indiana law and *DP Service* was governed by California law. *Biovail* misconstrues the meaning of Section 2-715 (2) (a) of the Uniform Commercial Code, which states that "[c]onsequential damages resulting from a seller's breach include" "any loss resulting from general or particular requirements and needs of which the seller at the time

of contracting had reason to know and which could not reasonably be prevented by cover or otherwise.” The Official Comments to this section squarely places a buyer’s lost profits from a seller’s breach of an agreement to supply those goods within the realm of consequential damages. UCC 2-715, Comment 6.

Biotronik also claims that the issue of whether the lost profits it seeks are general or consequential damages is a factual issue that must be addressed by the jury, citing two federal district court cases. *Long Is. Light. Co. v Transamerica Deleval, Inc.*, 646 F Supp 1442, 1459 n 30 (SD NY 1986) (*LILCO*); *American Elec. Power Co. v Westinghouse Elec. Corp.*, 418 F Supp 435, 459-60 (SD NY 1976). The plaintiff in *LILCO* did not seek lost profits as an element of damages for its claim that the defendant manufacturer sold defective emergency diesel generators. 646 F Supp at 1459, n 30. *LILCO* also relies on *American Power Corp.*, where the district court refused to issue a definitive ruling that lost profits were not recoverable when the parties’ contract precluded the recovery of consequential damages, and that term was specifically defined to include lost profits. Not only do I not agree with the district court’s ruling in *American Power Corp.*, the sole support for this ruling is a federal case from the District of Connecticut decided under Michigan law.⁷

Accordingly, I conclude that the lost profits that Biotronik seeks to recover for Conor’s alleged breach of the Distribution Agreement are consequential damages under New York law, and thus barred by Section 14.5 of the Distribution Agreement. Biotronik may still pursue a claim for nominal damages and any other damages it is entitled by law or agreement resulting from the claimed breaches of the Distribution Agreement.

⁷*Applied Data Processing, Inc. v Burroughs Corp.*, 394 F Supp 504, 509 (D Conn 1975).

CONCLUSION AND ORDER

For the foregoing reasons, it is hereby

ORDERED that defendants' motion for summary judgment is denied.

DATED: October 19, 2011

ENTER:

A handwritten signature in black ink, appearing to read "Bernard J. Fried", is written above a horizontal line.

J.S.C.

HON. BERNARD J. FRIED