IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Chief Judge Marcia S. Krieger

Civil Action No. 10-cv-02139-MSK-BNB

LENOX MACLAREN SURGICAL CORPORATION,

Plaintiff,

v.

MEDTRONIC, INC.;
MEDTRONIC SOFAMOR DANEK, INC.,
MEDTRONIC PS MEDICAL, INC. d/b/a Medtronic Neurologic Technologies, and
MEDTRONIC SOFAMOR DANEK CO., LTD.,

Defendants.

OPINION AND ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

THIS MATTER comes before the Court pursuant to the Defendants' Motion for Summary Judgment **(# 400)**, the Plaintiff's response **(# 408)**, and the Defendants' reply **(# 415)**. Also before the Court are: 1) the parties' Joint Motion **(# 288)** for determination of the admissibility of the expert opinions of Dr. Samuel Chewning, which the parties agreed **(# 367)** to have the Court resolve on the papers[1]; 2) the Defendants' Objections **(# 390)** to the Magistrate Judge's July 20, 2015 Recommendation **(# 378)** that the Plaintiff's Motion to Strike **(# 296)** the Defendants' Amended Answer **(# 87)** be granted and that the Defendants' Motion for Leave to Amend their Answer **(# 324)** be denied, and the Plaintiff's response to those Objections **(# 395)**;

[1] The parties tendered additional documents **(# 376, 377)** for the Court's consideration in addressing the motion.

3) the Defendants' Motion in Limine **(# 383)**, and the Plaintiff's response **(# 405)**[2]; 4) the Plaintiff's Motion To Strike Expert Reports and Exclude Trial Testimony of Three Spine Surgeon Witnesses **(# 389)**, the Defendants' response **(# 406)**, and the Plaintiff's reply **(# 413)**; and 5) the Defendants' Motion for Leave to Restrict Access **(# 399)** to certain exhibits attached to the Defendants' summary judgment motion and a corresponding motion **(# 409)** by the Plaintiffs relating to the Plaintiff's response thereto.

FACTS

This case presents a long and complex factual scenario, both substantively and procedurally. The following consists of only the most cursory summary, and the Court elaborates as necessary in its analysis of each motion.

1. The Parties

Plaintiff, Lenox-Maclaren Surgical Corporation ("Lenox"), is a manufacturer of surgical bone mills. In this action, it contends that the Defendants engaged in a lengthy, complex, and coordinated campaign to force Lenox out of the bone mill market, allowing the Defendants to successfully introduce and market a competing bone mill. According to Lenox, the campaign was ultimately successful, allowing the Defendants to monopolize the bone mill market for several years.

The four named Defendants here are each members of a complex corporate structure. Lenox elides the various corporate identities of the Defendants by routinely referring to them, individually or collectively, under the undifferentiated name "Medtronic." For reasons that will become clear below, the Court declines to follow that lead; instead, the Court will attempt to

[2] This motion raises the same issues as, and thus is largely supplanted by, the Defendants' summary judgment motion discussed herein. Accordingly, the Court denies it as moot.

scrupulously distinguish among the Defendants and identify with precision the role that each plays in the events at issue.

Defendant Medtronic, Inc. appears to be the overarching corporate parent, with Defendant Medtronic Sofamor Danek, Inc. ("MSD") as one of its subsidiaries. MSD, in turn, has at least two corporate subsidiaries of its own, Defendant Medtronic Sofamor Danek Co. Ltd. ("Med Japan") and non-party Medtronic Sofamor Danek USA ("Med USA"). Defendant Medtronic PS Medical, Inc.'s place in the corporate family tree is unclear, although it has some relationship to Medtronic, Inc. For the most part, neither party has come forward with any particularized evidence of the Defendant entities' stock ownership, corporate officers, membership of boards of directors, or decision-making practices.

2. The Alleged Campaign

In 2000, Lenox manufactured[3] and sold a hand-cranked "bone mill" (sometimes called a "bone fragmenter" or "grinder"), a tool used by surgeons performing bone fusion operations to grind a patient's bone material into fragments. Although the genesis of the arrangement is disputed, it is uncontroverted that in 2000, Lenox and Med USA entered into a multi-year contract (the "distribution agreement" or simply "the agreement"). The terms of the agreement granted Med USA an exclusive license to purchase bone mills from Lenox, re-brand them with Med USA's name (or, perhaps, with the name "Medtronic"), and distribute them. The agreement called for Med USA to make an initial purchase of 500 Lenox bone mills in the first year, followed by specific minimum purchase requirements in subsequent years. Med USA made the initial purchase of 500 mills in the first year of the agreement, but did not purchase any mills in

[3] The Court is cognizant that there is some evidence to suggest that Lenox actually contracted with a third party for manufacture of the bone mills. Precise identification of the manufacturer of the Lenox bone mill is irrelevant to the analysis herein, thus the Court will simply assume that Lenox manufactured its own bone mills.

subsequent years. The failure to make the minimum purchases entitled Lenox to terminate Med USA's exclusive license, although it is not clear when (or if) Lenox did so. Lenox contends that this was the first step in the alleged campaign.

Shortly after purchasing the initial batch of Lenox bone mills, Med USA distributed some of the mills to hospitals under a "loaner program." The loaner program allowed hospitals to use the bone mills without charge, rather than purchase them. Lenox contends that the loaner program was a calculated act (and the second step in the Defendants' overall scheme), designed by the Defendants to stimulate demand for bone mills among hospitals and surgeons who were previously using less-effective equipment and techniques, but to prevent the hospitals from obtaining permanent ownership of a durable tool that would not need immediate replacement. This, argues Lenox, allowed the Defendants to cultivate and preserve a customer base for the purchase of bone mills, but delay such purchases until such time as they introduced their own competing product.

It is at this juncture, that corporate identities among the Defendants become important. It appears to be undisputed that Med USA was the initial purchaser of the Lenox bone mills and made the decision to loan, rather than sell, the mills. But, as discussed below, Lenox's claims here are not (and cannot be) brought against Med USA. In this action, Lenox is attempting to show that the decision to create or implement the loaner program was made by all or some of the Defendants herein, either independently or in conjunction with Med USA. Unfortunately, Lenox never clearly explains which other Defendants jointly made these decisions with Med USA or otherwise. Instead, Lenox uses the undifferentiated label "Medtronic" to describe all of the Defendants (and occasionally Med USA), obscuring any contention as to the actions of any

particular Defendant(s). The only specific contention that the Court ascertains is Lenox's contention that Defendant Med Japan facilitated the loaner program alongside Med USA.

The third (and most pivotal) step in the alleged campaign occurred in or about 2006. Med USA claimed to receive complaints from three Japanese doctors using the Lenox bone mill. The complaints allegedly asserted that the bone mills malfunctioned during use, leaving metal shavings in the ground bone. Med USA contacted Lenox about the complaints and Lenox conducted an investigation. Lenox ultimately concluded that it could not substantiate the complaints and posited that the appearance of shavings resulted from misuse of the bone mill. (Lenox now contends that the complaints were simply fabricated[4] by, or at the direction of, the Defendants.) Med USA requested that Lenox initiate a recall of the bone mills, but Lenox refused. In October 2006, Med USA initiated its own recall[5] of the bone mills. Lenox contends this recall was improper, and intended to stigmatize Lenox and destroy its reputation in the market.

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[4] The crux of this contention is an alleged incongruity in the Defendants' statements about the complaints coming from Japan. The Defendants had generally maintained that the complaints were lodged with Med USA by the Japanese surgeons performing the operations. Lenox was ultimately able to contact those surgeons, each of whom denied ever having made complaints about the bone mills. The Defendants then clarified their assertions, explaining that the complaints came not from the surgeons themselves, but from Med Japan salespersons, third-party distributors, or operating room staff where were involved with or observed the incidents in question.

Lenox previously sought sanctions **(# 345)** against the Defendants for their misrepresentations as to the source of the complaints. The Court denied **(# 391)** that motion on procedural grounds without making any particular factual findings about the parties' contentions.

[5] Med USA contacted the U.S. Food and Drug Administration ("FDA") concerning the recall. Ultimately, the FDA "agree[d]" with the decision to recall the bone mills and gave guidance as to how the recall should be conducted. It is unclear from the record whether the FDA's agreement was a necessary predicate to Med USA initiating the recall (or whether Med USA was merely informing the FDA of a decision it had already made) or what consequences flowed from the FDA's "agreement" with the recall.

Once again, the Court pauses to differentiate between the Defendants. Lenox contends that the recall was a premeditated act by "Medtronic" as part of its campaign to eliminate Lenox as a competitor. However, in the arbitration action against Med USA, Lenox argued, and the arbitrators determined, that the recall was initiated by Med USA. In this action, Lenox must show that one or more specific Defendants here had culpable involvement with the decision to recall the bone mills, but, as noted earlier, Lenox generically alleges acts by the undifferentiated "Medtronic." As the discussion herein explains, the Court understands Lenox to assert that Med USA's corporate parents, MSD and Medtronic, Inc., participated in that decision.

Defendant PS Medical introduced its own bone mill product (sometimes called "the Midas Rex") in 2007. Lenox contends that, having tarnished Lenox's reputation via the recall and while preserving customer demand via the loaner program, the Defendants were able to quickly dominate the bone mill market, securing nearly 100% of that market by 2007 and retaining nearly 66% of the market through at least 2010.

3. Arbitration of Claims against Med USA

In 2007, Lenox brought claims against Med USA, alleging that Med USA entered into the distribution agreement, engaged in the loaner program, and initiated the recall, all for the purpose of dominating the bone mill market with Med USA's "own" bone mill. Specifically, Lenox asserted claims for patent infringement, violation of the Colorado Consumer Protection Act, and trade libel. Per the terms of the distribution agreement, Lenox's claims against Med USA were submitted to arbitration.

After a full arbitration hearing (on slightly different claims than those Lenox initially asserted), the arbitration panel found that: (i) Med USA's loaner program did not breach the parties' contract; (ii) Med USA's production of the Midas Rex bone mill did not breach the

parties' contract; (iii) Med USA's (allegedly inadequate) promotional efforts on behalf of the Lenox bone mill did not violate the covenant of good faith and fair dealing; (iv) the loaner program did not create "contributory infringement" of Lenox's patent because the "first sale" doctrine allowed Med USA to freely use the bone mills it had purchased; (v) Med USA's recall of the bone mills was improper and premature (given that Lenox was undertaking efforts to resolve the alleged defects), constituting an intentional interference with Lenox's prospective business relations; and (vi) Med USA was liable to Lenox for $246,000 in damages, plus prejudgment interest.

4. The Current Lawsuit

In 2010, Lenox revised its theories and commenced the instant suit. Lenox's new theory abandons its prior contentions that Med USA was the primary actor, and instead asserts that the various Defendants herein engaged in anticompetitive conduct that allowed "Medtronic" to attempt and subsequently create a monopoly in the bone mill market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.[6] Lenox's contentions in this action allege the same unlawful acts – a campaign to obtain the right to distribute Lenox bone mills, to suppress purchase demand via the loaner program, to harm Lenox's reputation by initiating the recall, and then to satisfy the now-cleared market with the Midas Rex bone mill– but Lenox now asserts those contentions against new Defendants.

Early in this litigation, Senior Judge Matsch granted summary judgment to the Defendants on Lenox's monopolization claims. He found that: (i) Lenox's narrow definition of the relevant product market, which covered only mechanical bone mills (of which Lenox was then the only provider), was improper, and that the proper market definition should include

[6] Lenox also asserts common-law claims for tortious interference with prospective business relations and fraud. The analysis herein applies with equal force to those common law claims.

surgical hand tools such as rongeurs, scissors, and forceps; (ii) Lenox could not show that the Defendants obtained monopoly power in the market for a sufficient period of time, as competitors such as Stryker and DePuy quickly entered the market with their own bone mills; and (iii) Lenox demonstrated only injury to itself, not to competition generally, and that the exclusionary effect caused by the recall was neutralized by April 2007, when the FDA terminated the recall.

Lenox appealed that order, and the Tenth Circuit reversed, addressing the following: (i) as to the Defendants' newly-raised argument that the arbitration proceeding precluded Lenox from litigating the current claims on *res judicata* grounds, the Tenth Circuit found that whether the Defendants were in privity with Med USA for preclusion purposes is a factual issue and the Defendants' failure to raise that argument at summary judgment prevented Lenox from coming forward with evidence on that point; (ii) as to the relevant product market, there was a factual question of whether inexpensive hand tools and expensive bone mills are part of the same market; (iii) that the Defendants' possession of 97% of the bone mill market in 2007 and 62% of that market as late as 2010, coupled with evidence of various barriers to enter that market, was sufficient to permit a finding that the Defendants had monopoly power; (iv) that Lenox adduced sufficient evidence that the Defendants' efforts during the recall constituted a type of trade disparagement sufficient to amount to exclusionary conduct for monopolization purposes; (v) although the Defendants challenged Lenox's ability to rely on the recall without naming Med USA as a party herein (and on the grounds that none of the named Defendants participated in initiating the recall), the Tenth Circuit found that this issue fell outside the scope of the discovery permitted by the District Court prior to the summary judgment proceedings, and thus, declined to

reach it; (vi) that a prior ruling by the Tenth Circuit,[7] affirming the District Court's denial of a motion by the Defendants seeking to compel Lenox to arbitrate the monopolization claims did not operate to require proof of cooperation between non-party Med USA and the Defendants to sustain Lenox's current claims; (vii) that Lenox came forward with adequate evidence of harm to competition by showing that, from 2007 to 2010, the Defendants were able to charge "supracompetitive prices" and that sales of bone mills from competitors (other than Stryker) remained insubstantial; and (viii) that by showing sufficient evidence to support an actual monopolization claim, Lenox adduced sufficient evidence to support its attempted monopolization claim as well. *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114 (10th Cir. 2014).

5. Pending issues

The Tenth Circuit remanded the case and it was reassigned to the undersigned. The parties engaged in additional discovery and the Court granted the Defendants leave to file a second summary judgment motion directed at then-unaddressed aspects of the case. In that motion **(# 400)**, the Defendants raise the following arguments: (i) that Lenox cannot prove anticompetitive conduct by any individual Defendant and that all of the conduct forming the basis of Lenox's monopoly claims are actions taken solely by non-party Med USA; (ii) that Lenox's monopolization claims are untimely, as the claims accrued at the time the alleged anticompetitive acts began, namely, the signing of the distribution agreement in 2000, and the four-year statute of limitations thus expired in 2004, long before commencement of this case in 2010; (iii) that the Defendants are entitled to judgment in their favor on their affirmative defense under the *Noerr-Pennington* doctrine, as the alleged anticompetitive conduct – most

[7] *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 449 Fed.App'x 704 (10th[h] Cir. 2011).

significantly, initiating the recall – was action directed at petitioning the Government (via the FDA) to take action; (iv) that the Defendants are entitled to judgment in their favor on their affirmative defense of *res judicata*, insofar as Lenox's claims against these Defendants necessarily require Lenox to take the position that the Defendants are in privity with Med USA, and thus, the Defendants are entitled to claim *res judicata* effect for claims that Lenox could, but did not, bring against Med USA during the prior arbitration proceedings; and (v) for similar reasons, the Defendants are entitled to summary judgment in their favor on their affirmative defense of arbitration and award.

Also pending are several additional motions that the Court will not summarize here but will briefly address in its analysis.

ANALYSIS

A. Motion for Summary Judgment

1. Standard of review

Rule 56 of the Federal Rules of Civil Procedure facilitates the entry of a judgment only if no trial is necessary. *See White v. York Intern. Corp*., 45 F.3d 357, 360 (10th Cir. 1995). Summary adjudication is authorized when there is no genuine dispute as to any material fact and a party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Substantive law governs which facts are material and what issues must be determined. It also specifies the elements that must be proved for a given claim or defense, sets the standard of proof, and identifies the party with the burden of proof. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Kaiser Francis Oil Co. v. Producer's Gas Co*., 870 F.2d 563, 565 (10th Cir. 1989). A factual dispute is genuine and summary judgment is precluded if the evidence presented in support of and opposition to the motion is so contradictory that, if presented at trial, a judgment could enter for

either party. *See Anderson*, 477 U.S. at 248. When considering a summary judgment motion, a court views all evidence in the light most favorable to the non-moving party, thereby favoring the right to a trial. *See Garrett v. Hewlett Packard Co.*, 305 F.3d 1210, 1213 (10th Cir. 2002).

If the movant has the burden of proof on a claim or defense, the movant must establish every element of its claim or defense by sufficient, competent evidence. *See* Fed. R. Civ. P. 56(c)(1)(A). Once the moving party has met its burden, to avoid summary judgment the responding party must present sufficient, competent, contradictory evidence to establish a genuine factual dispute. *See Perry v. Woodward*, 199 F.3d 1126, 1131 (10th Cir. 1999); *Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887, 891 (10th Cir. 1991). If there is a genuine dispute as to a material fact, a trial is required. If there is no genuine dispute as to any material fact, no trial is required and the court enters judgment.

If the moving party does not have the burden of proof at trial, it must point to an absence of sufficient evidence to establish the claim or defense that the non-movant is obligated to prove. If the respondent comes forward with sufficient competent evidence to establish a prima facie claim or defense, a trial is required. If the respondent fails to produce sufficient competent evidence to establish its claim or defense, then the movant is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

2. Individual liability of the named Defendants

To establish a claim for monopolization under Section 2 of the Sherman Act, Lenox must show a specific Defendant: (i) obtained monopoly power in the relevant market; (ii) willfully acquired or maintained this power through exclusionary conduct; and (iii) that the conduct caused harm to competition. *Lenox*, 762 F.3d at 1119. To establish a claim for attempted monopolization, Lenox must show a specific Defendant: (i) intended to control prices or destroy

competition; (ii) engaged in anticompetitive conduct directed at accomplishing that goal; and (iii) enjoyed a dangerous probability of achieving a monopoly. *Id.* at 1129.

Lenox has essentially two alternatives for seeking to hold the named Defendants here liable under a monopoly theory. First, it could invoke some doctrine that would render these Defendants automatically liable for Med USA's conduct. For example, Lenox might attempt to pierce the corporate veil of Med USA, demonstrating that it is nothing more than the alter ego of one or more of the named Defendants, or show that the named Defendants here are liable for Med USA's conduct under doctrines of vicarious liability, *respondeat superior*, or the like. Second, Lenox might respect the corporate independence of the various Defendants, instead attempting to show that each of the individual Defendants engaged in monopolistic conduct of their own accord, either individually or in concert with Med USA. Both approaches pose difficulties.

First, Lenox already alleged (with partial success) that the anticompetitive actions at issue here – entry into the distribution agreement, the loaner program, the recall – were performed by Med USA. This raises the possibility that the claims against the Defendants here could be barred by the doctrines of *res judicata* or collateral estoppel. The doctrine of *res judicata* precludes a party from litigating claims that were (or could have been) previously presented and finally determined in a prior proceeding; the doctrine of collateral estoppel precludes a party from challenging factual or legal determinations that were resolved against that party in a prior proceeding. These preclusion doctrines require four elements: (i) entry of a final judgment in an earlier proceeding; (ii) identical parties in both suits, or, at a minimum, a privity between parties in the current suit and parties in the prior suit; (iii) identical claims or issues in both suits; and

(iv) that the party to be precluded had a full and fair opportunity to litigate in the prior suit. *Johnson v. Dept. of Veterans Affairs*, 611 Fed.App'x 496, 497 (10thCir. 2015).

Lenox does not appear to dispute that its claims against Med USA were resolved in the arbitration that ended in a final award. Arbitration proceedings resulting in a final award can be given preclusive effect. *See MACTEC, Inc. v. Goerlick*, 427 F.3d 821, 831 (10th Cir. 2005). Moreover, the preclusion analysis examines claims on a "transactional approach," looking to whether the claims asserted in the prior action arose from "the same event" asserted in the instant action. *Id.* at 832. Thus, although Lenox asserted different claims against Med USA (breach of contract, patent infringement, etc.) than those asserted against the Defendants here (monopolization, fraud), its claims against Med USA in the arbitration sprang from exactly the same events – entry into the distribution agreement, the loaner program, the recall – as those on which Lenox bases its monopoly claims in this lawsuit. Finally, Lenox does not dispute that it had a full and fair opportunity to litigate its claims in the prior arbitration. Thus, the doctrines of *res judicata* and collateral estoppel preclude Lenox's claims against the Defendants if those Defendants were in "privity" with Med USA. Privity is a somewhat elusive concept that, at bottom, seeks to determine whether two persons or entities "are really and substantially in interest the same." *Pelt v. Utah*, 539 F.3d 1271, 1281 (10th Cir. 2008).

Attempts by Lenox to demonstrate that the Defendants here are somehow vicariously or automatically liable for anticompetitive behavior by Med USA pose a dire risk of placing them in privity, thus bringing Lenox under the *res judicata* or collateral estoppel umbrella. Thus, Lenox's briefing wisely attempts to (mostly) steer clear of such arguments, expressly disclaiming, for example, any assertion that the Defendants are alter egos of Med USA. Instead, Lenox primarily follows the second path; that is, asserting anticompetitive conduct by each

named Defendant on their own, often in conjunction with Med USA, but nevertheless conduct would expose the Defendants to individual liability.

This is, in essence, a contention that the named Defendants conspired, among themselves and with Med USA, to secure a monopoly for the benefit of PS Medical. Although Lenox has not denominated its monopoly claims as arising under a conspiracy theory, liability for conspiracy to monopolize may arise if Lenox can show that the named Defendants: (i) entered into an agreement; (ii) with the specific intent to gain or retain monopoly power; (iii) that one or more participants in that agreement took overt acts in furtherance of it; and (iv) that the agreement had an appreciable effect on interstate commerce.[8] *See TV Communications Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1026 (10th Cir. 1992).

Assuming that Lenox is proceeding on a theory that the Defendants conspired with each other (and with Med USA) to create a monopoly, the Court finds that Lenox has failed to come forward with adequate evidence of any agreement among them. Lenox offers no evidence of an express agreement between any two Defendants, or between any Defendant and Med USA. The record contains no written documents, memoranda or inter-Defendant e-mails referring to monopolistic plans or strategies. Likewise, it is devoid of any evidence from which such an

[8] In *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 777 (1984), the Supreme Court held that a corporate parent could not "conspire" with its wholly-owned subsidiaries for purposes of a claim of conspiracy to restrain trade under Section 1 of the Sherman Act, because the parent and subsidiaries operate with unitary economic interests. Some courts have suggested that the reasoning of *Copperweld* could be extended to monopolization claims under Section 2. *See e.g. Ritz Camera & Image, LLC v. SanDisk Corp*, 772 F.Supp. 1100, 1110 (N.D.Ca. 2011); *Carpenter Technology v. Allegheny Technologies*, 646 F.Supp.2d 726, 734-35 (E.D.Pa. 2009). This Court is not persuaded that *Copperweld*'s reasoning can be extended into the monopoly context and thus, the Court assumes that, as a matter of law, the various Defendants could be liable for conspiring amongst themselves to obtain monopoly power for one of them. *See also Growers 1-7 v. Ocean Spray Cranberries, Inc.*, 2014 WL 1764533 at n. 11 (D.Ma. May 2, 2014) (rejecting argument that First Circuit has extended *Copperweld* to monopoly cases).

agreement can be inferred, such as that the same decisionmakers owned or controlled one or more Defendants and Med USA, or acted in concert with regard to business decisions. Lenox offers only the generalized conclusion that all of the Defendants acted in concert to exclude Lenox and monopolize the bone mill market without meaningful evidence to support that theory.

In an effort to avoid generality, the Court has carefully combed Lenox's briefing to identify where Lenox has articulated facts showing agreement between the Defendants or involvement by any individual Defendant in the alleged anticompetitive acts. The Court proceeds to specifically examine each such instance.

a. Distribution agreement

Lenox does not appear to dispute that only Med USA, not any of the Defendants, entered into the distribution agreement. The Court does not understand Lenox to argue that any other Defendants were involved in that agreement, for example by negotiating, incurring obligations, or performing the agreement on Med USA's behalf. To the extent Lenox alleges that entering into the distribution agreement was part of a coordinated scheme, the record reflects otherwise: that Med USA alone entered into the agreement. Nor does Lenox offer any evidence to establish that any of the named Defendants here directed Med USA to enter into the distribution agreement or controlled how Med USA performed under that agreement.

b. Loaner program

The Defendants have come forward with evidence that the loaner program was devised and implemented solely by Med USA. They point to a March 18, 2003 e-mail to Lenox from Karl Dahlquist. That e-mail – which appears to be written on behalf of Med USA[9] - discusses a

[9] The signature block on Mr. Dahlquist's e-mail identifies him as Senior Legal Counsel for "Medtronic Sofamor Danek," without indicating whether this is Defendant MSD, or whether it is Med USA, both of whom use the words "Medtronic Sofamor Danek" in their names. The

dispute between the parties concerning their contractual arrangement and offers to return MSD's remaining inventory of bone mills to Lenox, with the exception of "a small inventory to support its loaner surgery program" and the need to obtain "a small stock of replacement parts for its loaner inventory needs." Mention of the loaner program is somewhat oblique to the subject of the e-mail, comprising an insubstantial reference ina lengthy, five-paragraph e-mail. Other record evidence, however, clearly points to Med USA as the source of the loaner program. One of Lenox's tendered experts, David Duncan, testified in a deposition that "my understanding . . . is that [Med USA] were the ones directly loaning it as a subsidiary of one of the other defendants." Lenox's Complaint in the litigation against Med USA alleged that Med USA initiated the loaner program, and the arbitration panel found as much, stating "Respondent [Med USA] put a number of the bone mills it had purchased into its 'loaner program.' The evidence at the hearing showed that [Med USA] loaned out Lenox bone mills for in excess of 2800 procedures."

Lenox now "disputes that [Med USA] conducted the loaner program." Instead, it contends that Med Japan "loaned the Lenox bone mill in Japan after receiving the mills from MSD." The sole evidence Lenox cites to in support of this contention is the deposition testimony of Hirotsugu Saito. But close review of that deposition transcript reveals that the fact Lenox asserts – that Med Japan loaned bone mills – is found only in the predicate of a question asserted by Lenox's counsel, and that Mr. Saito never addressed the issue:

> Q [referring to an unidentified witness]: The witness was from the United States, but he interviewed you and several of your colleagues prior to his deposition; and then he testified on behalf of [Med Japan], even though he was in Minneapolis. I just want you to know that.

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content of the e-mail, which refers to "the contractual agreement between Medtronic Sofamor Danek and Lenox MacLaren" suggests that Mr. Dahlquist is referring to Med USA, as it was the only party to that agreement.

> And in that deposition – I'm reading from a document that he gave us in which he prepared answers to questions, and he testified that [Med Japan] imported a total of 88 units from [Med USA] of the Lenox bone mill, known as the Bone Fragmenter, beginning on June 5, 2001.
>
> Do you have any reason to disagree with that?
>
> A: Well, like I mentioned earlier, I do not have a precise recollection of when this product began to be imported. So if you say it was 2001, it may have been the case.
>
> Q: Thank you.
>
> A: I don't have a precise recollection.
>
> Q: Okay. He also provided us with a chart telling us how many bone mills were sold in each year and how many various loans there were in each year.
>
> A: Okay.
>
> . . .
>
> Q: So in 2001, he told us that there was one bone mill sold in Japan and 36 times, a bone mill was loaned in Japan.
>
> A: To the hospitals?
>
> Q: Yes.
>
> A: You mean the bone mills were rented out?
>
> Q: Yes. And 2002, he said that three were sold; 223 times, the bone mill – the Lenox bone mill was loaned. Do you have any reason to disagree with that?
>
> A: Well, since I do not have a precise recollection of the exact number of units sold or loaned, I cannot agree or disagree.

(Emphasis added.) Lenox offers no other evidence of Med Japan's role in the loaner program.[10]

[10] Notably, Lenox did not tender the document containing the "prepared answers" or the testimony from the unidentified Med Japan representative that address the loaner program but offers only the quoted excerpt.

Even if the Court were to accept all of the factual predicates contained in counsel's queries as substantive evidence, however, there is still not support for Lenox's proposition that Med Japan was involved in the conception, design, or implementation of the loaner program. At best, it establishes only that Med Japan "imported" the bone mills from Med USA and loaned them to hospitals in Japan. The excerpt does not indicate whether this loaning was done of Med Japan's own initiative, whether it was acting pursuant to a request or instructions from Med USA or some other entity, or, given Mr. Saito's inquiry as to whether "loaned" meant "rented out," whether any actual gratuitous "loaning" occurred in Japan at all. To the extent that Lenox is alleging that Med Japan conspired with Med USA to monopolize the bone mill market by engaging in the loaner program, Lenox must do more than show that Med Japan lent bone mills; rather, it must show that Med Japan did so with "a specific intent to monopolize." *Lantec, Inc. v. Novell, Inc.*, 306 F.3d 1003, 1028 (10th Cir. 2002). Given the nebulous content of the deposition excerpt, the Court finds that Lenox has not come forward with evidence to demonstrate a genuine dispute as to whether Med Japan had any culpable involvement in devising or implementing the loaner program.

At her deposition, Linda Lenox, Lenox's principal, presented a different position. When asked "what company do you believe loaned your bone grinder to customers?", she replied "Medtronic Sofamor Danek," without specifying whether this was a reference to Med USA or to MSD. She was then asked "do you have any reason to believe that any of the four defendants in this lawsuit had any involvement with loaning your bone grinder to customers?" to which she responded "I don't know." This, too, suggests that Ms. Lenox believed that the entity behind the loaner program was Med USA.

Thus, taking all of the evidence in the record together, even in the light most favorable to Lenox, the Court finds that Lenox has not come forward with evidence to dispute that Med USA alone created and implemented the loaner program, nor has Lenox shown that any of the named Defendants participated in designing, creating, or administering that program, much less that they did so with a monopolistic intent.

c. Recall

Next, the Court turns to the question of the recall. Again the he Defendants contend that Med USA unilaterally recalled the Lenox bone mills. They point to, among other things, the deposition testimony of Angel Lopez, who described a meeting at which the recall decision was made, and testified that all of the attendees at that meeting were Med USA employees. The Defendants also point to Exhibit 13, an October 10, 2006 memo from Peter Ganavazos, Director of Product Quality Assurance of Medtronic Spinal and Biologics (which appears to be affiliated with Med USA), discussing an "Executive Committee review meeting" at which Med USA decided to initiate the recall.

Lenox appears to argue that Medtronic, Inc., not Med USA, initiated the recall. It argues that "Medtronic, Inc. set forth the policies for recalls and instructs its subsidiaries on how and when to recall products." In support, Lenox cites to the deposition testimony of Greg Anglin, an employee of an unspecified Medtronic-related entity he refers to as "Medtronic Spine" or the "Spine Business Unit" (although his testimony expressly distinguishes it from "Medtronic Corporate," but does not otherwise elaborate). He states that he has contact with Medtronic's corporate headquarters "because of our complaint system is a global system, and it is basically created by corporate. They train us. They – we meet to discuss issues and provide future enhancements, things like that." The fact that Medtronic, Inc. shares a "complaint system" with

other Medtronic entities, "trains" employees of other corporate entities (in some unspecified regard), or that members of those entities sometimes have meetings and discussions with officials at Medtronic, Inc. does not demonstrate that Medtronic, Inc. "instructs its subsidiaries on how and when to recall products," much less that Medtronic, Inc. was particularly involved with the recalling of the Lenox bone mill.

Lenox also asserts that "three executives of Medtronic, Inc. were required to sign the official recall form before any action could be taken." In support of this, it cites to Docket # **192-4**, submitted as an exhibit in Lenox's response to a prior summary judgment motion. The exhibit is identified only as "a document produced by the defendant in a separate litigation." *Docket* # 194, ¶ 13. It appears to consist of a "Field Notification/Corrective Action Plan," listing various tasks and information that Med USA employees would use when implementing the recall, and a series of signature pages for eight individuals.[11] Lenox eventually identifies the Medtronic, Inc. executives signing the document as being Pete Wherly, Ken Kopesky, and Michael DeMane.[12] Assuming that representatives of Medtronic, Inc. signed the recall plan, the evidence cited by Lenox does not establish the proposition that such signatures "were required . . . before any action could be taken," or that Medtronic, Inc. had input into or control over the recall. At best, the signatures establish only that Medtronic, Inc. executives knew of the recall

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[11] The individuals and their positions are identified as: (i) Pete Ganavazos, Director, Product Quality; (ii) Paul Elliott, Group Director, Global Quality; (iii) Brad Coats, Vice President of Regulatory, Quality and Clinical Advancement; (iv) Pete Wherly, Senior Vice President, Spinal & Navigation; (v) Ken Kopesky, Vice President, Corporate Compliance; (vi) Michael DeMane, President, Europe, Canada, Latin America and Emerging Markets; (vii) Jean-Luc Butel, Senior Vice President and President, Asia-Pacific; (viii) Jill Serbosek, Vice President, Business and Marketing Strategy.

[12] Lenox does not point to any evidence establishing that these three are indeed affiliated with Medtronic, Inc. and not some other entity, but the Defendants do not challenge this assertion in their reply and the Court will assume, for purposes of this motion, that Mr. Wherly, Mr. Kopesky, and Mr. DeMane are indeed executives of Medtronic, Inc.

plan. Nothing in the document itself represents that the signatures of the Medtronic, Inc. executives reflected control over the recall decision, or even that Medtronic, Inc. necessarily agreed with it. In the absence of concrete evidence demonstrating Medtronic, Inc.'s control over the decision to initiate the recall, Lenox only speculates about what purposes the Medtronic, Inc.'s executives' signatures on the recall plan demonstrate.

Lenox further contends that Paul Elliott, a member of the Med USA Executive Committee that approved the recall, testified that "other people attended the executive committee meeting who were not listed [in the minutes] (including potentially the executives of Medtronic, Inc., such as Pete Wherly and Ken Kopesky)." Mr. Elliott's actual deposition testimony is that "most of the attendees that are listed [in the minutes of the meeting where the recall was approved by Med USA] would have been the executive committee, but not all of them. I would have represented quality, and then there was an operations representative, an R and D representative. I can't remember who else was required to attend." The Court understands this testimony to suggest that fewer than the seven people listed in the memo memorializing the decision to initiate the recall actually comprised the Executive Committee that made that decision.

When asked "[w]ould Pete Wherly have been part of this executive committee," Mr. Elliott replied "I don't remember." Again, this statement lends no support to Lenox's contention that Mr. Wherly "potentially" attended the meeting (much less suggest that Mr. Wherly, on behalf of Medtronic, Inc., was involved in the decision to initiate the recall). Counsel then inquired of Mr. Elliott whether certain individuals, including Mr. Wherly, Mr. Kopesky, or "corporate Medtronic" would have been "notified or consulted about" the decision to initiate a recall. Mr. Elliott responded that "definitely if it was to take a recall[,] Pete Wherly would have

been notified, yes," and agreed that Mr. Kopesky would "have the opportunity to review that file and make a different decision." But testimony that Med USA would have "notified" Medtronic, Inc. about a decision to initiate a recall, or testimony establishing that Medtronic, Inc. could have overridden that decision, is not proof that Medtronic, Inc. did participate in the decision to initiate the recall or that it did anything more than accept Med USA's decision. This certainly does not establish the existence of any conspiratorial "agreement" between Med USA and Medtronic, Inc., or an agreement manifesting Medtronic, Inc.'s specific intent to assist other entities to obtain monopoly power in the bone mill market.

Lenox lastly makes an abbreviated argument that MSD, as the corporate parent of both Med USA and Med Japan, was involved in the recall. Lenox suggests that MSD "was a part of the complaint process" for the allegedly-fabricated complaints that led to the recall. Once again, Lenox's evidentiary support for this proposition is dubious. Lenox points to the deposition testimony of Minako Matsuda, an otherwise unidentified individual who completed a complaint form regarding a Lenox bone mill in Japan. The very last question posed to Mr./Ms. Matsuda in the deposition transcript excerpt is "Right here, at the very top [of the complaint form], it says 'Please complete and return to 'MSD Global.' Who is MSD Global?" Matsuda responds "I don't know." Lenox characterizes this exchange as demonstrating "the return of the false complaints forms to 'MSD Global,' presumably the parent company of the MSD family of companies including [Med] Japan and [Med] USA, which is MSD, Inc." Lenox has done no more than extract a factual assertion contained in the predicate of a question (that the top of the complaint form states 'return to MSD Global'), presented it as substantive proof of that fact (that the form does indeed state as much), proceed to "presum[e]" a fact for which no evidentiary support is provided (that "MSD Global" is the same as MSD, Inc.), and then concluds that these

"facts" demonstrate MSD's involvement in the complaint process. The scant evidence supplied by Lenox in support of the assertion that MSD, Inc. was actively involved with the complaint process is insufficient to carry that weight.

Having canvassed the entirety of Lenox's summary judgment response, the Court finds that the Defendants adequately demonstrated that the actions giving rise to Lenox's monopoly claims – entry into the distribution agreement, initiation of the loaner program, and declaring the recall of the Lenox bone mills – were each conducted by Med USA. Lenox fails to present any evidence creating a genuine dispute of fact as to whether any of the named Defendants here were meaningfully involved, be it individually or in concert with Med USA, with any of these actions, much less that they entered into any conspiratorial agreement with Med USA to take such actions with the specific intent of one of the Defendants obtaining monopoly power. This precludes Lenox from maintaining, as a factual matter, a contention that the individual Defendants are liable under a monopoly theory for their own individual actions or for having acted in concert with Med USA.

3. Legal arguments for the Defendants' liability

Although the bulk of Lenox's briefing focuses on arguments that the Defendants here are culpable for their own conduct, Lenox does offer a handful of arguments that could nevertheless be understood to assert that, as a matter of law, the Defendants here are somehow liable for any anticompetitive acts undertaken solely by Med USA. First, it cites to cases like *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 777 (1984) and *Climax Molybdenum Co. v. Molychem, LLC*, 414 F.Supp.2d 1007, 1012 (D. Colo. 2005). The Court need not discuss these cases in detail, as even Lenox admits that they stand for the limited proposition that a corporate parent may be held liable for the anticompetitive actions of a subsidiary only where they are alter

egos (an argument Lenox expressly declines to make) or "when the parent controls, dictates or encourages the subsidiary's anticompetitive conduct" such that "the parent engages in sufficient independent conduct to be held directly liable." *Climax*, 414 F.Supp.2d at 1012 (emphasis added). As the preceding discussion establishes, Lenox has not come forward with evidence that any of the named Defendants here "controlled, dictated, or encouraged" anticompetitive conduct by Med USA.

Lenox also makes what can be construed as *respondeat superior* arguments: that Defendants such as MSD and Medtronic, Inc. are liable for Med USA's actions simply because they are parent corporations. It is well-established that there is no automatic vicarious corporate liability. Rather, Lenox is obligated to show some independent anticompetitive conduct by the named Defendants themselves, whether individually or in concert with Med USA. *See generally Nobody In Particular Presents, Inc. v. Clear Channel Communications, Inc*, 311 F.Supp.2d 1048, 1068-69 (D. Colo. 2004). It has not done so.

Finally, Lenox appears to argue that the Tenth Circuit's prior decision in this action forecloses the Defendants' contention that Lenox lacks evidence of monopolistic behavior by them. Such an argument misreads that decision. The Circuit noted that the Defendants "appear[ ] to assume that [they] had no role in the recall," but found that, at that point in time, the District Court limited the parties to conducting discovery on the question of the relevant market. 762 F.3d at 1128. It held that "[t]he district court could not have required evidence regarding the role of the affiliated companies in the recall when Medtronic lacked an opportunity to conduct discovery on the issue." *Id.* In short, the prior appeal considered only the question of the scope of the proper comparison market, and the Tenth Circuit refused to consider whether the named Defendants individually participated in monopolistic conduct. The parties have now had a full

opportunity to conduct discovery on that latter point, and Lenox is nevertheless unable to demonstrate culpable conduct by any of the named Defendants. Therefore, summary judgment in favor of the Defendants is warranted.

3. Remaining issues

Because the foregoing discussion addresses Lenox's claims in their entirety, the Court need not reach the remaining arguments in the Defendants' motion, or the other substantive motions pending in this action. Nevertheless, for purposes of completeness of the record, the Court has reviewed those issues and briefly addresses the remaining issues.

a. Statute of limitations

The Defendants argue that Lenox's monopolization claims are barred by the statute of limitation which, the Defendants allege, began running at the time Med USA entered into the distribution agreement with Lenox in 2000 and expired four years later. 15 U.S.C. § 15b. The Court disagrees. The limitation period in a monopoly claim runs from the most recent injury caused by the Defendants' activities, not from the violation's inception. *See Xechem, Inc. v. Bristol-Meyers Squibb, Co.*, 372 F.3d 899, 902 (7th Cir. 2004). Here, the decision to recall the Lenox bone mills in October 2006 was an action (indeed, perhaps the only action) that, at least in theory, caused Lenox to suffer an injury. This action, commenced in September 2010, was thus brought within the four-year limitations period.

b. *Noerr-Pennington*

The Defendants argue that they are immune from claims arising out of the decision to recall the Lenox bone mills because such conduct is protected by the *Noerr-Pennington* doctrine. Under that doctrine, "defendants are immune from antitrust liability for engaging in conduct (including litigation) aimed at influencing decisionmaking by the government." *Octane Fitness,*

LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749, 1757 (2014). The Defendants' theory is that they "sought the approval of [the FDA] with the decision to recall the bone mill." However, the Court finds that the record is unclear as to whether Med USA was required to obtain the FDA's approval prior to initiating a recall, or whether Med USA was able to effectuate the recall regardless of whether the FDA agreed with it or not. The record reflects that Med USA decided to initiate the recall in October 2006, but did not receive the FDA's approval of the recall until November 2006. Under such circumstances, there is at least a triable question as to whether Med USA's recall was an attempt to influence FDA decision-making or an action Med USA undertook regardless of government involvement. Accordingly, the Court would deny the Defendants' request for summary judgment on this defense.

c. *Res judicata* and arbitration and award

The Court has already addressed, to some extent, the principles of *res judicata* that underlie the Defendants' invocation of these defenses. Generally speaking, the Court would agree with Lenox that these defenses are without merit so long as Lenox's theory of liability turns on the alleged culpable actions of the named Defendants, or upon actions performed by Med USA as part of a conspiratorial agreement between it and the Defendants. To the extent that Lenox presents an alternative theory that the Defendants here have some sort of automatic or vicarious liability for actions taken solely by Med USA, the Defendants' *res judicata* defense might have some merit.

B. Admissibility of Dr. Chewning's opinions under Fed. R. Evid. 702

For the same reasons discussed above, the Court offers only an abbreviated analysis of the remaining substantive motions. The parties' Joint Rule 702 motion **(# 288)** identifies two opinions by Dr. Samuel J. Chewning, proffered by Lenox: (i) "The FDA recall initiated by

Medtronic was unwarranted and improper," and (ii) "The FDA recall had led to Lenox MacLaren experiencing extreme difficulty in selling its Bone Mill to hospitals." Medtronic challenges both opinions on two grounds: (i) that Dr. Chewning lacks sufficient qualifications to express those opinions, Fed. R. Evid. 702(a), and (ii) that Dr. Chewning's opinions are based on insufficient facts and data, Fed. R. Evid. 702(b).

The Court finds that Dr. Chewning's knowledge and experience as a spine surgeon is insufficient to permit him to offer the two opinions, at least as they are presented and stated. The first opinion requires expertise in the FDA standards used for determining whether to initiate a recall or analyzing whether a recall was appropriate, and Dr. Chewning does not purport to have experience or knowledge in FDA decision-making concerning recalls. That is, he does not purport to have worked for the FDA or participated in any FDA recall decisions. The second opinion is a causal one, and Dr. Chewning lacks the experience or knowledge to opine as to the circumstances under which a recall causes hospitals to cease buying certain products. Such causal decision-making is the province of economists, or perhaps marketers or sales people. At best, Dr. Chewning might be able to offer percipient testimony regarding the reasons given by hospitals for purchasing decisions in which he was involved, but he may not opine broadly and abstractly on that issue.

C. Objections to Recommendation

The Magistrate Judge recommended **(# 378)** that the Defendants' Second Amended Answer **(# 269)**, filed without leave of court and after the deadline for amendment of pleadings, be stricken and that the Defendants' subsequent motion for leave to amend **(# 324)** be granted. Having reviewed the Magistrate Judge's reasoning and the Defendants' objections, the Court would overrule those objections and adopt the Recommendation, in part. The Court agrees with

the Magistrate Judge that the scope of Lenox's claims were sufficiently apparent from the outset of this action, such that the Defendants have not shown good cause for failing to timely raise the new affirmative defenses they seek to assert in the Second Amended Answer. Any amendment at this juncture is thus untimely, and thus, the Motion to Amend would be denied.

D. Plaintiff's Motion to Strike

Lenox moves **(# 389)**, essentially *in limine*, to exclude the testimony of three of the Defendants' tendered expert witnesses, claiming that the proffered testimony of each witness is nearly identical and thus, presentation of all three witnesses would be needlessly redundant and cumulative in violation of Fed. R. Evid. 403. Without considering whether Lenox's contention that the various witnesses' testimonies would be cumulative, the Court finds that determinations under Rule 403 are particularly unsuited for resolution prior to trial and would deny this motion as premature.

E. Motions to Restrict Access

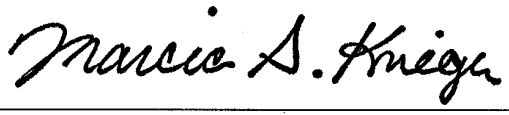
Both sides seek **(# 399, 409)** to restrict access to certain material contained in their summary judgment filings. With regard to most of the material, the party making the request states that its opponent designated the material in question as confidential pursuant to a protective order. As D.C. Colo. L. Civ. R. 7.2(c)(2) makes clear, such a showing is inadequate. In all other respects, the movant has made nothing more than a purely conclusory showing under Rule 7.2(c). The Court, having independently reviewed each of the filings made under provisional restriction, finds nothing therein warranting restriction or overcoming the public interest in access to judicial records. Accordingly, both motions are denied and the Clerk of the Court shall restore public access to the items.

CONCLUSION

For the foregoing reasons, the Defendants' Motion for Summary Judgment **(# 400)** is **GRANTED**, and the Clerk of the Court shall enter judgment in favor of the Defendants on all claims herein and shall close the case. The parties' Joint Motion **(# 288)** for determination of the admissibility of the opinions of Dr. Samuel Chewning, the Defendants' Objections **(# 390)** to the Magistrate Judge's July 20, 2015 Recommendation **(# 378)**, the Defendants' Motion in Limine **(# 383)**, and the Plaintiff's Motion To Strike Expert Reports and Exclude Trial Testimony of Three Spine Surgeon Witnesses **(# 389)** are each **DENIED AS MOOT**. The Defendants' Motion for Leave to Restrict Access **(# 399)** to certain exhibits attached to the Defendants' summary judgment motion and a corresponding motion **(# 409)** by the Plaintiffs relating to the Plaintiff's response thereto are both **DENIED**, and the Clerk of the Court shall restore public access to all portions of Docket # 401 and 409.

Dated this 3rd day of December, 2015.

BY THE COURT:



Marcia S. Krieger
Chief United States District Judge