IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Senior District Judge Richard P. Matsch

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

LENOX MACLAREN SURGICAL CORPORATION,
a Colorado Corporation,

Plaintiff,
vs.

MEDTRONIC, INCORPORATED,
a Minnesota corporation;
MEDTRONIC SOFAMOR DANEK, INCORPORATED,
an Indiana corporation;
MEDTRONIC PS MEDICAL, INCORPORATED, d/b/a
MEDTRONIC NEUROLOGIC TECHNOLOGIES,
a California corporation; and
MEDTRONIC SOFAMOR DANEK CO., LTD.,
a Japanese corporation,

Defendants.

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Lenox MacLaren Surgical Corporation (Lenox) is a surgical instruments supplier in Louisville, Colorado. In 1999, its president, Linda Lenox, developed a prototype of a hand cranked mill to morselize bone for use in spinal fusion surgery. At a demonstration of it in a surgery performed by consulting surgeons in Vail, Colorado, Michael DeMane of Medtronic suggested that Lenox market this new product through a Medtronic company.

Recognizing that Medtronic was a well established provider of medical devices world-wide, Linda Lenox agreed to an Exclusive Supply and License Agreement with

Medtronic Sofamor Danek USA, Inc. (MSD-USA) as of April 16, 2000 ("the License Agreement," Defs.' Ex. 13). That was an unfortunate decision. In consideration of a cash payment and an agreement to buy 500 units of what was described as the Lenox-MacLaren Bone Fragmenter Unit, MSD-USA obtained the exclusive right to market the product for one year on its terms and under its trademark.

Medtronic met the purchase obligation for the first year but made no additional purchases during the remainder of the five year term of the agreement. Most of the units purchased were loaned out rather than resold to hospitals, clinics and surgeons. The mutual exclusivity in the agreement expired after the first year and, in approximately 2003, another Medtronic company began selling a pneumatic bone mill attachment to a Medtronic power source in competition with the Lenox mills that were in use during the remaining four years. In early 2007, Medtronic PS Medical, Inc. began selling a newly developed electric bone mill, the Midas Rex.

In an arbitration proceeding, Lenox claimed a breach of the License Agreement by MSD-USA's use of the loaner program and the production of the pneumatic bone mill by another Medtronic company. Those claims were denied by the arbitration panel. (*See* Defs.' Ex. 36). As to the production of the pneumatic mill, the panel found that it was not generally similar in design because they look different; have different power sources; one cut and the other crushed bone; one was sterilized for reuse while the other was disposable; they were of different weights and placement of the bone into each device was different.

In October 2006, over a year after the License Agreement had expired, MSD-USA initiated a voluntary recall of the Lenox mills, sending a notice to all who had received the Lenox mills distributed by MSD-USA. (Pl.'s Ex. O).

That recall was the basis for a claim of intentional interference with prospective business relations which the arbitration panel found to have been proven because there was insufficient evidentiary support for claims of any product defect and the panel found that the recall was motivated by an intent to clear the Lenox bone mills out of the market. Concluding that the recall had some effect on Lenox sales and reputation, the panel awarded damages of $246,000 plus interest, based on Medtronic profits from sales to customers with recalled Lenox bone mills. (Defs.' Ex. 36).

Disappointed with the arbitration award of March 11, 2010, Lenox filed this civil action on September 1, 2010, naming the parent company (Medtronic, Inc.) and three other subsidiaries, excluding MSD-USA, as defendants, alleging violations of Sections 1 and 2 of the Sherman Act.[1]

The defendants moved to dismiss pursuant to Rule 12(b)(6) and(b)(7), contending that these antitrust claims were simply an effort to remodel the claims that were adjudicated in the arbitration proceeding or, alternatively, that joinder of MSD-USA was required. That motion was denied after hearing, upon the court's acceptance of assurance from plaintiff's counsel that the actions of MSD-USA were not claimed to be in concert with these named defendants and that the License Agreement litigation was "utterly collateral" to this case.

This lawsuit progressed with extensive and expensive discovery which, by this court's direction, was to focus on the questions of liability, reserving damages issues. At a hearing on a discovery dispute on November 14, 2012, the court directed the plaintiff to submit a summary of

[1]The defendants and MSD-USA are considered companies controlled by Medtronic, Inc. for purposes of this motion. That relationship is denied by the defendants.

its evidence and contentions concerning (1) the relevant market; (2) market share and (3) injury to competition. That submission was received on January 4, 2013.

The defendants moved for summary judgment on February 4, 2013, the plaintiff responded, the defendants replied, and a hearing was held on May 29, 2013.

Much of what has been submitted in the papers received from the parties has been sealed pursuant to protective orders and in this memorandum order that confidentiality has been respected as much as possible, consistent with this court's obligation to summarize the facts underlying the legal conclusions stated herein.

The defendants submitted a Statement of Undisputed Facts (SUF) in their motion for summary judgment. In its response, Lenox challenges only statements concerning the sale and use of other bone mills by alleging that Medtronic's own documents acknowledge only one substantial competitor – Stryker's electric bone mill; the date when Medtronic began developing the Midas Rex electric bone mill; the testimony of Linda Lenox concerning ability to manufacture; the complaints of defects; the make-up of the executive committee deciding on the recall; the manufacturing capacity of Lenox and the testimony alleged to be a concession of no lost sales. (Pl's resp. at 53-55).

Accordingly, many facts in the defendants' statement have not been disputed and are relied on in this ruling.

THE RELEVANT MARKET

Central to a claim of antitrust law violations is the definition of the relevant product market in which businesses compete.

In the complaint, the plaintiff defined the geographic market as world-wide. (Compl. ¶¶ 107- 108). The plaintiff now says that the geographic market is "no smaller than the United States" and that is the market that the defendants address in their motion and supporting exhibits.

In the complaint, the plaintiff identified the relevant product market as "the surgical bone mill market," stating that such market includes "bone mills that function to mill bone for use during spinal fusion surgeries." (Compl. ¶¶ 102-03). At oral argument, plaintiff's counsel identified the product market as "mechanical bone mills for spinal fusion surgery." That narrow definition is essential to the scenario that Lenox attempts to present. It claims that the Lenox bone mill was a technical breakthrough permitting surgeons to avoid the disadvantages of hand morselizing bones for implants in fusions of vertebra; that Medtronic used MSD-USA to introduce the Lenox mill to surgeons and develop a market for it through the loaner program; that the defendants trumped up complaints of product defects to initiate a recall after developing the Medtronic electric bone mill to eliminate the Lenox mill as the only competing product and thereby established a single product monopoly enabling Medtronic to charge supracompetitive prices to the detriment of the public.

In essence, Lenox says that it had the only mechanical bone mill being used in spinal fusion surgeries until Medtronic began sales of the Midas Rex electric bone mill to those who had been using the Lenox mills which Medtronic recalled on spurious grounds. The plaintiff claims that the recall has so disparaged its mill that it is no longer acceptable by surgeons, hospitals and clinics. In considering the plaintiff's contention that it could not recover from the stigma of the recall, it is noteworthy that the mills recalled bore the Medtronic trademark.

The evidence in the developed record shows that the plaintiff's definition of the relevant product market is an artifice constructed to support its scenario.

There is no disagreement that most spinal fusion surgeries require some bone implant in the target area and that a key element of the procedure is the grinding of bone to a size and consistency enabling the implant to fuse with vertebral bone making a stable structure. Before the development of bone mills, morselizing of bone was done by the use of surgical hand tools – rongeurs, scissors and forceps. To support its contention that these tools should be excluded from the relevant product market, Lenox relies on two declarations from an experienced spinal surgeon, Dr. Samuel Chewning, Jr., M.D., MBA. (Pl.s' Ex. 1, #154-4; Pl.'s Ex. 3, #194-15). He proclaimed that after bone mills came to market, the use of hand tools became an obsolete practice. To counter Medtronic's statistical data showing that during the relevant time period most of the spinal fusion surgeries performed in the United States did not use powered bone mills, Dr. Chewning observed that powered bone mills are a relatively recent innovation and they have not replaced hand tools completely because it takes time for the latest technology to disseminate.

The statistical data show there has been a continuing evolution in spinal surgical devices and that powered grinding mills are replacing hand tools and manual methods for milling bone where there is a sufficient volume of spinal surgeries to justify the larger cost. There are also substantial differences between the plaintiff's manually operated product and the electric mills sold by Medtronic and its competitor, Stryker. The Lenox mill is reusable but between uses it must be disassembled and the parts sterilized. The electric mills have a power base with disposable cups for the grinding.

The relevant product market is defined by reasonable interchangeability. Dr. Chewning's declarations do not contradict Medtronic's evidence about the number of spinal fusion surgeries performed without bone mills. According to Dr. Chewning, technical superiority and physician preference are factors showing that hand tools should be excluded from the relevant product market.

The plaintiff also submitted the declaration of an economist, Dr. Robert S. Maness, PhD, who opines that the option of hand morselizing is not a competitive constraint on bone mills. (Pl.'s Ex. 2, #146-5). His opinions are premised on Dr. Chewning's statements about the obsolescence of hand tools. Dr. Maness offers no economic analysis to support his conclusion.

The evidence offered by Lenox is insufficient to support a finding that it has properly defined the relevant product market.

MONOPOLY POWER

Defendant Medtronic PS Medical began selling the Midas Rex electric bone mill in January 2007. It was the first electric bone mill on the market. Stryker began selling an electric bone mill in May 2008. Lenox contends that at least between the recall in late 2006 and Stryker's entry, Medtronic had a 100% share of the bone mill market through sales of its pneumatic and electric mills. That contention is defeated by the facts that Lenox itself sold some of its mills in 2007 and there were other hand cranked mills and a pneumatic mill by DePuy also available. (Defs.' SUF ¶¶ 11-14; 19 & 25; Defs.' Exs. 8-10, 16 & 21). The plaintiff contends that some of these other mills were not used for spinal surgeries and the sales of the others were not significant enough to be meaningful. The argument of plaintiff's counsel ignores undisputed evidence showing that several bone mills, including Stryker's manually-operated TOM mill, the

Biomet mill, and the Tracer mill, were being sold for spinal surgery. Sales records provided for the Biomet mill and the Tracer mill show that Lenox was not Medtronic's only competitor before Stryker began selling its electric mill in 2008. In addition, comparison of the number of spinal surgeries performed in the United States during that period with Medtronic's sales leads to the inference that hand tools were still in extensive use. (*See* Defs.' SUF ¶ 33).

Support for a finding of such a transitory monopoly requires a showing of barriers to entry. Lenox relies on the declaration of Scott Hay, a designer and engineer of medical devices. (Pl.'s Ex. 4, #194-16). He asserts that there are barriers to entry at five stages of the process of introducing a medical device to the market: (1) design and development; (2) manufacturing (3) development of name recognition; (4) distribution, and (5) pricing.

Lenox had no difficulty in the first two stages. It is undisputed that Linda Lenox spent approximately three months developing her bone mill, and her out-of-pocket costs were approximately $9,000 to develop a prototype and $20,000 in patent-related costs. FDA approval was not required – only registration. Lenox recovered her out-of-pocket costs through the License Agreement with MSD-USA. (Defs.' SUF ¶ 16). She was able to enter into an agreement with MSD-USA, which had established name recognition, a distribution network and pricing expertise.

With respect to distribution, Hay states that medical devices are typically sold to hospitals by sales representatives, who generally work either for an independent distributor or for a major market participant like Medtronic, Stryker or DePuy. Hay states than an entrant must decide whether to hire an independent distributor, or affiliate with a large company.

With respect to pricing, Hay states entrants must compete with established companies that have advantages because they sell in greater volumes, allowing them to capture economies of scale in manufacturing. He also states that established companies often sell related products and can engage in bundling tactics or offer discounts on one product in return for purchases of other products.

Dr. Maness, the economist, also opines that barriers to entry are sufficiently large in the market for mechanical bone mills that entry would not be timely or sufficient to prevent an exercise of monopoly power. In support of that opinion, Dr. Maness references documents and testimony that are not included in the plaintiff's submissions. It appears he relies primarily on Hay's statements.

While there is no doubt that there are obstacles to new entrants, the argument that Medtronic could exclude competitors is defeated by the fact that Stryker entered the market in 2008 and captured a larger share than Medtronic, based on revenues, as early as 2011. In contrast, during the same time period, Lenox made little or no competitive efforts. Lenox did not actively market or promote its bone mill, other than maintaining a website. It relied on word-of-mouth to sell its products. Lenox did not seek another distributor or to obtain any other assistance in attempting to compete with Medtronic after the one-year period of exclusivity in the License Agreement expired or after the agreement ended in April, 2005. (Defs.' SUF ¶¶ 66-68).

Monopoly power must be sufficiently durable to enable the monopolist to maintain a supracompetitive price for such a significant period as to injure consumers. The duration of such power is meaningful only if there are such barriers to a new entry that there is harm to

competition. The one and one half years between the recall and Stryker's entry is not meaningful. Medtronic did not have the ability to maintain its pricing and did lower its prices when Stryker's electric bone mills were sold. (Defs.' SUF ¶ 27 & Ex. 24).

Lenox contends that Medtronic's market power is shown by Medtronic's profit margin on the disposable bowls it sells individually for use with its electric bone mill. Contrary to the plaintiff's argument, that evidence does not support an inference that such pricing results from illegal monopoly power. The disposable bowl is a feature of powered mills that differentiates them from other methods.

EXCLUSIONARY CONDUCT

To support a Section 2 claim, the plaintiff must show that Medtronic engaged in exclusionary conduct. In this case Lenox relies on the same conduct that was the factual basis for its claims against MSD-USA in the arbitration proceeding. That was an injury to Lenox as a market participant but it is not an injury to the competitive market for devices for morselizing bone for use in spinal fusion surgeries.

Dr. Maness's declaration includes his opinion that Medtronic's actions harmed competition by eliminating the Lenox mill from the market and thereby depriving hospitals of a lower-price alternative to the Medtronic electric bone mill. Dr. Maness's conclusions are premised on the faulty assumption that consumers had only two choices before the recall and the recall left them with no choice other than Medtronic's bone mill. As factual support for his assumption that Medtronic's voluntary recall of the Lenox bone mill effectively eliminated all competition from the market, Dr. Maness references the complaint and the Rule 30(b)(6) deposition testimony of Linda Lenox. In that deposition, Lenox testified that Dr. Chewning and

other doctors told her that hospitals would not allow them to use the Lenox bone mill after the recall. (Pl.'s Ex. D, Lenox dep. (Sept. 12, 2013) at 17:3 – 24:15). That testimony is inadmissible hearsay and Dr. Maness's reliance on it is misplaced. Dr. Maness does not address the undisputed evidence showing the availability of other bone mills both before and after the recall and the continued availability of the Lenox mill after the recall.[2]

The plaintiff now complains that Medtronic's purported harm to competition includes "price discrimination." In support of that claim, the plaintiff points out that frequent users of the Midas Rex pay more than those who perform fewer procedures because, over time, frequent users pay more for the individually priced disposable bowls. (Pl.'s submission at pp. 14-15; Pl.'s resp. at pp. 31-32). Assuming the truth of the plaintiff's descriptions of Medtronic's pricing, the accusation of "price discrimination" provides no basis for going forward with this antitrust action. Lenox does not claim to have been victimized by Medtronic's pricing scheme or by an illegal tying arrangement.

The alleged harm to competition is trade disparagement. Disparaging comments by competitors are presumptively *de minimis* for antitrust purposes. *See Nat'l Ass'n of Pharm. Mfrs. v. Ayerst Labs*., 850 F.2d 904, 916 (2d Cir. 1988); *see also Am. Prof. Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof. Publ'ns, Inc*., 108 F.3d 1147, 1151 (9th Cir. 1997)("While the disparagement of a rival . . . may be unethical and even impair the opportunities of a rival, its harmful effects on competitors are ordinarily not significant enough

[2]With respect to the availability of the Lenox mill after the recall, the plaintiff's counsel represented during oral argument that Dr. Chewning's affidavit contains the statement that "Dr. Chewning [would] prefer to use the Lenox bone mill, but he can't because of the recall. His hospital won't let him order it because of potential liability." (Hr'g Tr. (May 29, 2013) at 26:11-15). That specific statement does not appear in either of Dr. Chewning's declarations.

to warrant recognition under § 2 of the Sherman Act."). To overcome this presumption, a plaintiff claiming an antitrust violation premised on trade disparagement must show that the disparaging statements were "(1) clearly false; (2) clearly material; (3) clearly likely to induce reasonable reliance; (4) made to buyers without knowledge of the subject matter; (5) continued for prolonged periods; and (6) not readily susceptible of neutralization or other offset by rivals." *Nat'l Ass'n of Pharm. Mfrs*., 850 F.2d at 916.

Based on the findings of the arbitration panel, it may be assumed that the recall was false, material, and induced reliance by at least some consumers. Dr. Chewning stated in his declaration that "in the medical-devices industry, a product recall is viewed as an extremely significant event that can obliterate a device's commercial prospects, even when the recall is later shown to have been warranted." That general observation is not sufficient to establish that the effects of this recall continued for a prolonged period or that Lenox could not have offset them. Undisputed evidence shows that the FDA investigated and cleared the Lenox bone mill by late 2006, and by April 4, 2007, the FDA considered the recall terminated. (Pl.'s Ex. R; Defs.' Ex. 53). In the relevant market, the buyers are hospitals and hospital purchasing groups whose choices are influenced by doctors who use their facilities. They are sophisticated consumers. Reasonable jurors could not conclude that the effects of this recall were not susceptible to neutralization. In addition, the arbitration panel already denied Lenox's claim of business disparagement/trade libel arising from the recall. (*See* Defs.' Exs. 2 & 36).

In sum, the plaintiff's submissions do not establish genuine issues of material fact as to relevant market, the defendants' monopoly power, or antitrust injury. The plaintiff's claims of monopolization and attempted monopolization fail because they are premised on an overly

narrow definition of the relevant product market and inaccurate portrayal of the competitive landscape. With respect to antitrust injury, the plaintiff's evidence, viewed in a light most favorable to it, shows injury only to itself.

Accordingly, it is

ORDERED that Defendants Medtronic, Inc., Medtronic Sofamor Danek, Inc., Medtronic Sofamor Danek Co., Ltd. and Medtronic PS Medical Inc.'s motion for summary judgment [#177] is granted.

The clerk shall enter a final judgment dismissing all of the plaintiff's claims and this civil action with an award of defendants' costs.

Dated: June 21, 2013

BY THE COURT:

s/Richard P. Matsch

Richard P. Matsch, Senior District Judge