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claims. Regarding the first fraud claim, that Collagen committed fraud through its representations to the FDA during the PMA process, the court upheld its decision finding that its original decision was unaffected by *Medtronic*. Also, the MDA preempted the claim that Collagen had committed fraud through misrepresentations about the product for the same reasons that the misbranding and mislabeling claims were preempted. Furthermore, even though the Mitchells' claimed fraud in advertising and promotional materials, the court held that the claims must fail because an FDA regulation controlled Collagen's promotional materials as part of the PMA process and was preemptive in the absence of an allegation that the material was non-conforming.

Finally, the court granted summary judgment on the Mitchells' warranty claim even though the vagueness of the warranty precluded the court from determining whether an expressed or implied warranty was alleged. If an implied warranty claim had been intended, the MDA preempted it because of the warranty's interference with the standards set by the FDA during the PMA process. If the Mitchells had intended to submit an express warranty claim, the claim would still fail. Since warranties arise from the parties themselves as part of their bargain, the court stated that an express warranty claim would not necessarily interfere with the PMA and warrant preemption. However, since the Mitchells failed to assert a proper express warranty claim earlier in the litigation, they were estopped from doing so now. Therefore, the court found summary judgment was proper.

After reconsidering the Mitchells' claims in light of *Medtronic*, the Seventh Circuit reaffirmed the district court's granting of summary judgment to Collagen on all of the Mitchells' claims. Specifically, the court held that the MDA preempts common law causes of action unless the claims merely allege non-compliance with PMA requirements because they would impose a requirement "different from, or in addition to" the PMA process. In arriving at this conclusion, the court distinguished *Medtronic*, holding that it applied only to products that went through the "substantially equivalent" process, as opposed to the PMA process, which is more specific and thus within the preemptive scope of the MDA.

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Telemarketing Company Lacked Standing in Antitrust Suit

By James Saranteas

In ***Barton & Pittinos, Inc. v. Smithkline Beecham Corp.*, 118 F.3d 178 (3rd Cir. 1997)**, the United States Court of Appeals for the Third Circuit affirmed a district court decision holding that an injury alleged by a pharmaceutical marketing company bringing suit was not the type of injury the antitrust laws were intended to prevent. Since the marketing company bringing suit was not a competitor in the market in which trade was allegedly restrained, the marketing company lacked standing under the antitrust laws. The Third Circuit affirmed the district court's grant of summary judgment dismissing Barton's antitrust claims for lack of standing and dismissing Barton's other claims for lack of supplemental jurisdiction.

Marketing Plan Led to Litigation

The litigation sprung from the broken pieces of a novel plan that Barton & Pittinos, Inc. ("Barton"), a pharmaceutical marketing company, developed to market Smithkline Beecham Corporation's ("Smithkline") Hepatitis-B vaccine ("the vaccine") to nursing homes. Barton developed the marketing plan in response to an Occupational Safety and Health Administration ("OSHA") mandate that was directed at certain employers, such as nursing homes, whose employees could be exposed to the Hepatitis-B virus. The mandate required nursing homes to educate their employees about the Hepatitis-B vaccine and make the vaccine available to their employees. In response to OSHA's regulatory mandate, Barton developed a two-part plan for marketing the vaccine to nursing homes and presented this plan to Smithkline, which was one of only two manufacturers of the vaccine. Barton and Smithkline then entered into an agreement to put the marketing program in action.

In the first part of the program, Barton was to provide nursing homes with educational and regulatory material about the vaccine and Smithkline would pay Barton a flat fee. Then, Barton was to phone nursing homes and solicit orders for the vaccine. Since Barton lacked the requisite federal licensing to sell the vaccine, Barton was to give vaccine orders that it solicited to General Injectables and Vaccines, Inc.

("General"), a licensed medical supply house. General would then fill the orders Barton solicited from the nursing homes with the vaccine from Smithkline. Barton contended that Smithkline was to pay it a commission on the sales under this second part of the program.

Before Barton made any sales, however, Smithkline discontinued the marketing program. Nursing homes traditionally have received medications and vaccines from consultant pharmacists. These pharmacists and their trade associations complained to Smithkline that Barton's marketing program bypassed them and undercut the vaccine prices the pharmacists could provide to the nursing homes. Pharmacists complained to Smithkline and threatened to boycott Smithkline's products. In reaction to these complaints, Smithkline discontinued the marketing program and reverted to using the pharmacists to distribute the vaccine.

Barton Alleged Federal Antitrust Violations and State Law Claims

After Smithkline terminated its relationship with Barton, Barton brought suit in federal district court for breach of contract and unjust enrichment. Barton also alleged that Smithkline conspired with the pharmacists to restrain competition in the nursing home market for the vaccine and that this restrained trade in violation of § 1 of the Sherman Act, 15 U.S.C. § 1. Thus, Barton claimed it was entitled to treble damages under § 4 of the Clayton Act, 15 U.S.C. § 15, for damages arising under its restraint of trade claim.

In district court, Smithkline moved for summary judgment on the restraint of trade issue. Smithkline argued that Barton lacked standing on this claim because Barton was neither a competitor nor a consumer in the nursing home vaccine market. The district court granted Smithkline's motion, citing Barton's failure to show an "antitrust injury." The district court also ruled that under the antitrust laws, there existed other, more direct, victims of the alleged conspiracy to restrain trade and that the apportionment of damages among those injured would be so complex that it weighted against finding that Barton had standing on the antitrust issue. Therefore, the district court dismissed Barton's only federal claim and declined to use its supplemental jurisdiction over the state law breach of contract and unjust enrichment claims.

On appeal, Barton argued that the evidence on record showed that Smithkline, General, and the pharmacists all considered Barton to be a competitor with the pharmacists. Additionally, Barton argued that case law supported a finding that it was a competitor. Thus, Barton contended, it had standing under antitrust laws.

Antitrust Injury Did Not Create Antitrust Standing

Section 4 of the Clayton Act, 15 U.S.C. §15, contains broad language in favor of finding a cause of action under federal antitrust laws. In deciding whether Barton had standing to bring its antitrust claim, the Third Circuit considered *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519 (1983). In *Associated*, the Court interpreted the statute under its narrower, common-law background which focused on the *injury* a plaintiff suffered, and that Court considered whether antitrust law was intended to prevent that type of injury. The Court concluded that antitrust laws were designed to redress only those injuries suffered by a competitor or a consumer in the market in which trade was allegedly restrained. The Third Circuit reasoned that the relevant market in this case was the nursing home market for the vaccine and if Barton was not a competitor in that market, then Barton did not have antitrust standing under *Associated*. The court reasoned that since Barton neither sold, nor distributed, nor sought to sell the vaccine, Barton was not a competitor in this market and therefore did not have standing in this case.

Marketer of Vaccine Program Was Not a Competitor

Barton argued that the court defined the "market" incorrectly. In Barton's view, Barton and its program competed with the pharmacists in the nursing home vaccine business. The Third Circuit remained unconvinced. The court reasoned that although "its program" — including Barton's marketing, General's supply, and Smithkline's development of the vaccine — did, indeed, compete with the pharmacists in the nursing home vaccine market, Barton alone was not a competitor. In fact, the court noted that the pharmacists' efforts to terminate the Barton program was evidence of the fact that the pharmacists considered the program a competitive threat. Furthermore, evidence of the nursing homes' favorable reaction to Barton's program showed that the program was reasonably interchangeable with the pharmacists' offerings. However, the court found that this evidence only showed that the entire program, not Barton's vaccine marketing alone, competed with the pharmacists.

To hold for Barton, the court would need to find that what Barton

alone offered — and not what Smithkline, Barton, and General offered in combination — was interchangeable with the pharmacists' offerings. The court reasoned that since Barton only marketed the vaccine, nursing homes could not switch to Barton without dealing with General because Barton could not provide the vaccine. Thus, Barton's services were not interchangeable with the pharmacists' offerings of both information about the vaccine and the vaccine itself. Based on this reasoning, the court concluded that Barton was not a competitor in the market for sales of the vaccine.

Vaccine Was Not Merely an "Additional Input"

Alternatively, Barton argued that even though Barton needed to work with General to provide the vaccine to the nursing homes, Barton was not a competitor of the pharmacists. In other words, Barton argued that it should not be excluded as a competitor simply because it needed an "additional input," the vaccine, to compete. The Third Circuit acknowledged that other courts have held that a product that required an "additional input" should not be excluded from the relevant market. However, the court here reasoned that since Barton was legally barred from providing the vaccine on its own, the vaccine could not be described as merely an additional input. The court, therefore, concluded that nursing homes could not have switched from the pharmacists to Barton alone, and as such, Barton was not a competitor in the relevant market.

Court Rejected Plaintiff's Case Law Arguments

Barton argued that case law supported a finding that it was a competitor in the vaccine market to nursing homes. For example, Barton looked to *Bhan v. NME Hospitals, Inc.*, 772 F.2d 1467 (9th Cir. 1985), which favors finding that a party is a competitor even though it requires additional input in order for its product or service to be interchangeable with other products in the market. In *Bhan*, the Ninth Circuit held that nurse anesthetists and M.D. anesthesiologists competed in the same market even though the nurses required the "input" of a supervising physician. The Ninth Circuit came to this conclusion because the supervision was easily available and common practice. Unlike the nurses in *Bhan,* however, the Third Circuit found that Barton could not easily obtain the additional input required. Barton lacked the requisite prescription drug license and was thus legally prohibited from distributing the vaccine.

Barton also cited *Yellow Page Cost Consultants, Inc. v. GTE Directories Corp.*, 951 F.2d 1158 (9th Cir. 1991), as persuasive case law supporting its argument that it could compete with the pharmacists in the vaccine market without providing the vaccine itself. In *Yellow,* GTE produced phone directories and sold advertisements in the directories. Customers could buy advertisements and consulting services or simply consulting services either from advertising companies ("advertisers") or GTE. After GTE discontinued the practice of allowing the advertisers to place ads in GTE's telephone directories, customers began placing their ads directly with GTE, thereby circumventing the advertisers and their services. Even though the advertisers could still sell consulting services, they were no longer allowed to place ads. They, in turn, lost business due to the inconvenience customers faced by not being able to take care of all their business with one company. The advertisers brought suit alleging antitrust violations against GTE.

The Ninth Circuit granted the advertisers antitrust standing because the court found that the advertisers and GTE competed in the market for yellow-pages advertising consulting services, however, the court did not determine whether the advertisers competed with GTE in the sales of advertising despite the fact that the advertisers did not actually sell the ads, but only information about the ads. Since the plaintiff in *Yellow* actually competed with the defendant to some degree, the Third Circuit refused to find that *Yellow* supported Barton's argument on appeal. Therefore, the Third Circuit could not rely on *Yellow* to hold that Barton was a competitor in the nursing home vaccine market because it had merely marketed the vaccine.

In sum, the Third Circuit concluded that Barton was not a competitor in the nursing home market for the vaccine. Since Barton was not a competitor in the market in which trade was allegedly restrained, Barton lacked antitrust standing. Accordingly, the court affirmed the district court's grant of summary judgment dismissing Barton's antitrust claims for treble damages and dismissing Barton's state law claims for lack of supplemental jurisdiction.

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