

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BROTECH CORPORATION and : CIVIL ACTION
PUROLITE INTERNATIONAL, LTD. :
 :
v. :
 :
WHITE EAGLE INTERNATIONAL :
TECHNOLOGIES GROUP, INC., :
ET AL. : NO. 03-232

MEMORANDUM

Padova, J.

June 21, 2004

Before the Court is Plaintiffs Brotech Corporation's and Purolite International, Ltd.'s Motion to Dismiss Defendant RenalTech International, LLC's Amended Counterclaim. For the reasons that follow, the Motion is granted and the Amended Counterclaim is dismissed in its entirety, without prejudice.

I. BACKGROUND

Plaintiffs have brought this action to correct the name of the inventor on patents relating to inventions of certain Russian scientists and for a declaration of joint co-ownership and joint equitable title to those patents. They have also brought claims for misappropriation of trade secrets, tortious interference with contract and other common law claims arising from Defendants' alleged interference with the relationship between Plaintiffs and those Russian scientists. The Second Amended Complaint alleges that, for the last ten years, Plaintiffs' employees have engaged in a cooperative research and development program with several Russian scientists led by Professor Vadim A. Davankov of the Russian

Academy of Science. (2d Am. Compl. ¶ 2.) As a result of that research, Plaintiffs' employees and the Russian scientists have developed unique macronet and micronet copolymer resins for a variety of adsorptive uses and methods to produce these resins in a commercially viable manner, including their use in renal dialysis. (Id. ¶ 4.) The Second Amended Complaint further alleges that Defendants procured eleven United States patents on these inventions, misrepresenting their ownership and failing to acknowledge Plaintiffs' property rights. (Id. ¶ 73-74.) The disputed patents are: U.S. Patent 5,773,384 issued June 30, 1998; U.S. Patent 5,904,663 issued May 18, 1999; U.S. Patent 6,087,300 issued July 11, 2000; U.S. Patent 6,114,466 issued September 5, 2000; U.S. Patent 6,127,311 issued October 3, 2000; U.S. Patent 6,133,393 issued October 17, 2000; U.S. Patent 6,136,424 issued October 24, 2000; U.S. Patent 6,153,707 issued November 28, 2000; U.S. Patent 6,156,851 issued December 5, 2000; U.S. Patent 6,159,377 issued December 12, 2000; U.S. Patent 6,303,702 issued October 16, 2001. (Id. ¶ 74.)

Defendant RenalTech International, LLC ("RenalTech") has asserted the instant Amended Counterclaim against both Plaintiffs asserting that Plaintiffs are using their superior economic resources and this litigation to gain control of Defendants' pioneering technology. The Amended Counterclaim alleges that RenalTech is developing new technology to assist chronic renal

failure patients by removing middle molecular weight toxins, which are not efficiently removed by renal dialysis, from the blood. (Am. Countercl. ¶¶ 15-16.) RenalTech's chemists have developed this technology, a biocompatible adsorbent polymer and a device incorporating this polymer, trademarked BetaSorb, which has been designed to be used in conjunction with hemodialysis. (Id. ¶ 16.) A human clinical trial of BetaSorb is currently underway in the United States. (Id.) RenalTech is also studying the use of its polymer technology to treat severe sepsis. (Id. ¶¶ 23-24.) RenalTech claims to be the only organization currently conducting human clinical trials for such products and the only organization at an advanced stage of seeking regulatory approval from the Food and Drug Administration ("FDA"). (Id. ¶ 32.) RenalTech acknowledges that such products cannot be sold or used in the treatment of individuals unless they have received FDA approval. (Id.)

The Amended Counterclaim alleges that Plaintiffs have brought this action in order to coerce RenalTech into ceding control of its intellectual property to Plaintiffs so that Plaintiffs can unlawfully monopolize the market for its products. (Id. ¶ 33.) The Amended Counterclaim alleges claims against Plaintiffs for attempted monopolization pursuant to Section 2 of the Sherman Act, 15 U.S.C. § 2; incipient conspiracy to monopolize pursuant to Section 2 of the Sherman Act; and conspiracy to restrain trade pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1.

This is not RenalTech's first attempt to assert antitrust claims against Plaintiffs in this action. RenalTech previously asserted a Counterclaim against Plaintiffs asserting causes of action for attempted monopolization pursuant to Section 2 of the Sherman Act; conspiracy to restrain trade pursuant to Section 1 of the Sherman Act; and for tortious interference with existing and prospective business relations. Plaintiffs filed a motion to dismiss. On November 18, 2003, the Court granted the motion to dismiss RenalTech's counterclaim for attempted monopolization pursuant to 15 U.S.C. § 2 because the market proposed in the Counterclaim did not "encompass any interchangeable substitute products and [did] not allege that there are no substitute products." (Nov. 18, 2003 Memorandum and Order at 11.) The Court granted the Motion to Dismiss RenalTech's counterclaim for conspiracy to restrain trade pursuant to 15 U.S.C. § 1 because the Counterclaim did not allege an antitrust injury and did not sufficiently allege the relevant product market. (Id. at 16.) The Motion to Dismiss was also granted with respect to RenalTech's claims for tortious interference with existing and prospective business relations. The Order dismissed the Counterclaim without prejudice and with leave to file an amended counterclaim. Defendants subsequently filed the instant Amended Counterclaim.

The Amended Counterclaim attempts to correct the deficiencies in the original Counterclaim by adding allegations relating to the

relevant markets and antitrust injury. The Amended Counterclaim alleges that there are two markets relevant to Plaintiffs' anticompetitive conduct. (Am. Countercl. ¶ 33.) The first is the "supplier market in the United States for the manufacture and supply of RenalTech's proprietary polymeric resin to RenalTech." (Id. ¶ 33.) The Amended Counterclaim alleges that Plaintiffs' anticompetitive conduct is intended to coerce RenalTech into an exclusive manufacturing agreement, which would foreclose competition in the supplier market. (Id.) The second market is "the market in the United States for the finished product incorporating RenalTech's patented, proprietary hemocompatible or biocompatible polymeric resins designed to remove middle molecular weight compounds or toxins from physiological fluids, including human blood." (Id. ¶ 34.) RenalTech states that it is "unaware of any existing or development stage product or service targeted toward or capable of removing the middle molecular weight toxins from physiological fluids as RenalTech's polymeric resin does" and that "there is no known substitute at any price for RenalTech's polymeric resin for the removal of middle molecular weight toxins." (Id.) The Amended Counterclaim further alleges that if Plaintiffs' anticompetitive conduct is successful, they will be able to control the price and output of this polymeric resin and consumers will "have no practical or available substitute for a product or service that removes middle molecular weight toxins." (Id.)

The Amended Counterclaim also alleges that Plaintiffs' anticompetitive litigation tactics have damaged RenalTech in two ways. RenalTech claims to have suffered recognizable antitrust injury in the form of "the costs and expenses that RenalTech has incurred and will incur in defending this predatory, anticompetitive sham litigation." (Id. ¶ 39.) It further alleges that Plaintiffs' "coercion of an anticompetitive supply agreement will increase RenalTech's costs in producing finished products incorporating its patented polymeric resin, thereby increasing the price which will ultimately be charged to the consumer." (Id. ¶ 40.) In addition, the increased cost will reduce demand for the product, limiting sales and injuring RenalTech. (Id.)

II. LEGAL STANDARD

When deciding a Motion to Dismiss pursuant to Rule 12(b)(6), the court must accept as true all well pleaded facts in the complaint, or counterclaim, and any reasonable inferences derived from those facts, and view them in the light most favorable to the Plaintiff. FTC v. Commonwealth Marketing Group, Inc., 72 F. Supp. 2d 530, 535 (W.D. Pa. 1999) (citations omitted). However, the Court need not accept "bald assertions or legal conclusions." Morse v. Lower Merion School District, 132 F.3d 902, 906 (3d Cir. 1997). The dismissal standard is higher in antitrust cases than generally. Rolite, Inc. v. Wheelabrator Envir. Systems, Inc., 958 F. Supp. 992, 995 (E.D. Pa. 1997). The facts underlying the elements of an

antitrust claim must be pled with specificity. Syncsort Incorporated v. Sequential Software, Inc., 50 F. Supp. 2d 318, 328 (D.N.J. 1999) (dismissing antitrust counterclaim brought pursuant to Section 2 of the Sherman Act for failure to allege specific facts setting forth the elements of a claim for monopolization or attempted monopolization); see also Com. of Pennsylvania ex. rel. Zimmerman v. PepsiCo., Inc., 836 F.2d 173, 182 (3d Cir. 1988) ("When the requisite elements are lacking, the costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint.") (quoting Car Carriers, Inc. v. Ford Motor Co., 734 F.2d 1101, 1106 (7th Cir. 1984)).

III. DISCUSSION

Plaintiffs argue that the Amended Counterclaims should be dismissed because RenalTech has failed to cure the defects in its original Counterclaim. Plaintiffs maintain that the Amended Counterclaim's allegations of product market and antitrust injury remain insufficient to support claims under the antitrust laws.

A. Product Market

Plaintiffs argue that the Amended Counterclaim should be dismissed because the allegations describing the relevant product market do not establish the reasonable interchangeability of use or

the cross-elasticity of demand between the product and substitutes for it.¹ The United States Court of Appeals for the Third Circuit ("Third Circuit") has recognized that the failure to plead the relevant product market is a sufficient basis for dismissal of an antitrust claim. Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir. 1997); see also, Syncsort, 50 F. Supp. 2d at 331. The Third Circuit has explained that "[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." Id. (quoting Brown Shoe Co. v. U.S., 370 U.S. 294, 325 (1962); Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991)). In Queen City Pizza, the Third Circuit defined cross-elasticity as "a measure of the substitutability of products from the point of view of buyers," i.e., the measure of "the responsiveness of the demand for one product to changes in the price of a different product." Id. at 438 n.6 (citation omitted). A complaint which fails to define the relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or which alleges a proposed relevant market that clearly does not encompass all

¹In order to state a claim for attempted monopolization, conspiracy to monopolize, or conspiracy to restrain trade pursuant to the Sherman Act, the Amended Counterclaim must allege the relevant product market. See Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993); Farr v. HealthEast, Inc., Civ.A.No. 91-6960, 1993 WL 220680, at *11 (E.D. Pa. 1993); Petruzzi's IGA v. Darling-Delaware, 998 F.2d 1224, 1229 (3d Cir. 1993).

interchangeable substitute products, is legally insufficient. Id.
at 436.

The Amended Counterclaim defines the relevant product market
as follows:

the market in the United States for the finished product incorporating RenalTech's patented, proprietary hemocompatible or biocompatible polymeric resins designed to remove middle molecular weight compounds or toxins from physiological fluids, including human blood. RenalTech is unaware of any existing or development stage product or service targeted toward or capable of removing the middle molecular weight toxins from physiological fluids as RenalTech's polymeric resin does. Thus, there is no known substitute at any price for RenalTech's polymeric resin for the removal of middle molecular weight toxins. If BroTech and RenalTech succeed in their anticompetitive conduct through this sham litigation, they will be able to control the price and output of the polymeric resin, and consumers will have no practical or available substitute for a product or service that removes middle molecular weight toxins.

(Am. Countercl. ¶ 34.) Although the Amended Counterclaim fails to allege the cross-elasticity of demand for interchangeable substitute products, that failure is not fatal in this case because the Amended Counterclaim alleges that RenalTech's polymeric resin is unique and does not have any substitutes. See Mitel Corporation v. A&A Connections, Inc., No. Civ. A. 97-cv-4205, 1998 WL 136529, at *4 (E.D. Pa. Mar. 20, 1998) (recognizing that "in circumstances where the product or service is unique and therefore not interchangeable with other products or services, the single brand

can constitute the relevant market") (citing Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451, 482 (1992); Queen City Pizza, 124 F.3d at 439). Accordingly, the Court finds that the Amended Counterclaim's allegation that RenalTech's polymeric resin does not have any substitutes is sufficient to allege a unique product and that the Amended Counterclaim sufficiently alleges a product market made up of just that unique product.

B. Antitrust Injury

Plaintiffs also argue that the Amended Counterclaim should be dismissed because RenalTech has failed to cure the deficiency in the Counterclaim's allegation of antitrust injury. Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26 respectively, provide a private right of action for violations of Sections 1 and 2 of the Sherman Act. See 15 U.S.C. §§ 15, 26. In order to recover damages or seek injunctive relief in an antitrust suit brought pursuant to Sections 4 or 16 of the Clayton Act, a private plaintiff must prove the existence of an antitrust injury, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) (citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)). The Third Circuit has recognized that, because the purpose of the antitrust laws is to protect competition, the court must examine "the antitrust injury question from the viewpoint of the consumer. 'An

antitrust plaintiff must prove that challenged conduct affected the prices, quantity or quality of goods or services, 'not just his own welfare.'" Mathews v. Lancaster General Hosp., 87 F.3d 624, 641 (3d Cir. 1996) (quoting Tunis Bros., 952 F.2d at 728). The Amended Counterclaim contains the following allegations of antitrust injury:

39. And although they have not yet succeeded, BroTech's and Purolite International's predatory litigation tactics are having their intended effect, and RenalTech has suffered antitrust injury. RenalTech has suffered and will suffer antitrust injury in at least two ways. First, the costs and expenses that RenalTech has incurred and will incur in defending this predatory, anticompetitive sham litigation are themselves a recognized form of antitrust injury, such costs and expenses reflecting the anticompetitive effect of the wrongful acts undertaken with an anticompetitive intent.

40. Second, BroTech's and Purolite International's ability to control the price of the polymeric resin supplied by them to RenalTech (if their anticompetitive scheme succeeds) will cause further antitrust injury directly to RenalTech and to consumers. BroTech's and Purolite International's coercion of an anticompetitive supply agreement will increase RenalTech's costs in producing finished products incorporating its patented polymeric resin, thereby increasing the price which will ultimately be charged to the consumer. Moreover, the excessive price charged to the consumer as a result of BroTech's and Purolite International's anticompetitive conduct is likely to reduce demand for the product, thereby limiting RenalTech's sales and injuring RenalTech. BroTech and Purolite International still profit, even with reduced sales, because their anticompetitive conduct allows them to charge

excessive prices to RenalTech, whereas RenalTech is faced both with excessive prices charged by BroTech and Purolite International and with reduced demand from consumers.

(Am. Countercl. ¶¶ 39-40.)

Plaintiffs have moved to dismiss the Amended Counterclaim on the grounds that these allegations are insufficient to allege an antitrust injury. Plaintiffs maintain that these paragraphs are insufficient to allege antitrust injury for two reasons: (1) the potential effect on consumers and RenalTech of Plaintiffs' future behavior, as alleged in paragraph 40 of the Amended Counterclaim, is too hypothetical to state an injury under the antitrust laws because RenalTech's polymeric resin products have not been approved by the FDA and (2) the costs of defending this litigation, as alleged in paragraph 39 of the Amended Counterclaim, do not constitute an antitrust injury.

1. Future antitrust injury

Plaintiffs argue that the Amended Counterclaim should be dismissed because the potential injury to competition alleged in paragraph 40 of the Amended Counterclaim is insufficient to state an antitrust injury where unsurmounted statutory or regulatory hurdles preclude the antitrust plaintiff from entering the market. (Pls.' Supp. Mem. at 3.) RenalTech has not yet entered the market for its polymeric resin. "When competitors violate the antitrust laws and another competitor is forced from a market, the latter

suffers an injury-in-fact." Andrx Pharmaceuticals, Inc. v. Biovail Corp. International, 256 F.3d 799, 806 (D.C. Cir. 2001). A competitor such as RenalTech "that has not yet entered the market may also suffer injury but courts require a 'potential' competitor to demonstrate both its intention to enter the market and its preparedness to do so." Id. (citing Hecht v. Pro-Football, Inc., 570 F.2d 982, 994 (D.C. Cir. 1977)). The following factors are considered to be sufficient indicia of preparedness to enter the market: "adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, 'such as the consummation of relevant contracts and procurement of necessary facilities and equipment.'" Hecht, 570 F.2d at 994 (footnote and citation omitted); see also Out Front Productions v. Magid, 748 F.2d 166, 170 (3d Cir. 1984) ("a company . . . beginning business . . . must show not only that it had the background, experience, and financial ability to make a viable entrance, but even more important, that it took affirmative actions to pursue the new line of business.") (citations omitted). Consequently, in determining whether RenalTech has sufficiently pled an injury, or threatened injury, resulting from the filing of the instant lawsuit, the Court must examine its intent and preparedness to enter the market for its polymeric resin. Andrx, 256 F.3d at 807.

The Amended Counterclaim acknowledges that RenalTech must

obtain FDA approval for products utilizing its polymeric resin before these products can be "sold or used in the treatment of individuals." (Am. Countercl. ¶ 32.) Regulation of medical devices² is governed by the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended by the Medical Device Amendments of 1976, 90 Stat. 39, 21 U.S.C. § 301 (West 1999). See Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341, 343 (2001). The degree of regulation by the FDA depends upon whether the medical device in question is a Class I, II or III device. Id.; see also 21 U.S.C. § 360c(a). Class I devices are subject only to general manufacturing controls, Class II devices are subject to more stringent controls, and Class III devices must complete a premarket approval (PMA) process before they may be marketed. Id. at 343-44.

²Device is defined by the Food, Drug and Cosmetic Act as:
an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).

The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both safe and effective. Id. at 344 (citing 21 U.S.C. §§ 360e(d)(2)(A),(B)). The FDA's process for review of a Class III device requires "an average of 1200 hours [for] each submission." Id. at 344-45 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996)).

The Amended Counterclaim contains no allegations with respect to the classification of products incorporating RenalTech's polymeric resin, or the degree of FDA review which must be completed before those products may be marketed. The Amended Counterclaim similarly fails to include any allegations regarding how far RenalTech has gone in the process of obtaining FDA approval of products incorporating its polymeric resin, when such approval may be anticipated, or whether it will be prepared to enter the product market as soon as such approval has been received. The Amended Complaint simply alleges that such approval must be obtained and that RenalTech is seeking such regulatory approval from the FDA. (Am. Countercl. ¶ 32.) As the Amended Complaint does not allege facts establishing RenalTech's intent and preparedness to enter the market for its polymeric resin product, that it would be prepared to enter the market for said product in the absence of the instant lawsuit, or that FDA approval of said products is probable, the Court finds that paragraph 40 of the Amended Counterclaim is insufficient to state an antitrust injury.

See Andrx 256 F.3d at 807-08 (determining that district court correctly dismissed generic drug manufacturer's antitrust counterclaim in patent infringement action where the generic drug manufacturer failed to allege that it was prepared to enter the market or that it anticipated FDA approval for its generic drug; also finding that district court erred in dismissing said counterclaim with prejudice where the generic drug manufacturer might be able to cure its pleading deficiency).

C. Defense Costs

Plaintiffs argue that the Amended Complaint should be dismissed because RenalTech's payment of costs and expenses of litigation in defense of the instant litigation does not constitute an antitrust injury. RenalTech maintains, however, that legal fees and other costs and expenses incurred in defending sham, anticompetitive litigation are recognized elements of antitrust injury. RenalTech relies on a line of cases originating with the opinion of the United States Court of Appeals for the Ninth Circuit ("Ninth Circuit") in Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979). In Handgards, the Ninth Circuit found that the costs of defending a patent infringement suit which had been brought in bad faith constituted an antitrust injury: "In a suit alleging antitrust injury based upon a bad faith prosecution theory it is obvious that the costs incurred in defense of the prior patent infringement suit are an injury which 'flows' from the

antitrust wrong." 601 F.2d at 997. However, the Third Circuit has not adopted the Handgards determination that litigation costs alone qualify as antitrust injury.

The Third Circuit requires that an allegation of antitrust injury reflect the challenged activity's "anti-competitive effect on the competitive market." Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001). An antitrust plaintiff must show that the allegedly anticompetitive conduct harmed "the competitive landscape." Tunis Bros., 952 F.2d at 728 (citation omitted). While the Amended Counterclaim alleges that RenalTech's payment of defense costs in this litigation flows from Plaintiffs' allegedly anticompetitive conduct, there is no allegation that said payment had any effect on competition, on the price, quantity or quality of RenalTech's products, or prevented RenalTech from pursuing its entry into the market for its polymeric resin. See Mathews, 87 F.3d at 641; Eichorn, 248 F.3d at 140 ("we have consistently held an individual plaintiff personally aggrieved by an alleged anti-competitive agreement has not suffered injury unless the activity has a wider impact on the competitive market.") (citation omitted).

Accordingly, the Court finds that the Amended Counterclaim fails to allege antitrust injury arising from the filing of this action and Plaintiffs' Motion to Dismiss is, therefore, granted. Since RenalTech may be able to amend its counterclaim to cure the remaining deficiencies in its allegation of antitrust injury, the

dismissal is without prejudice.

An appropriate order follows.

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O R D E R

AND NOW, this 21st day of June, 2004, upon consideration of Plaintiffs' Motion to Dismiss Defendant RenalTech's Amended Counterclaim (Docket No. 45), Defendant RenalTech's response thereto, the argument held in open court on February 26, 2004, and the parties' supplemental memoranda, **IT IS HEREBY ORDERED** that the Motion is **GRANTED** without prejudice and with leave to file an amended counterclaim within twenty (20) days of the date of this Order.

BY THE COURT:

John R. Padova, J.