UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TWIN CITIES BAKERY WORKERS HEALTH AND WELFARE FUND,	:	
Plaintiff,	:	
v.	:	Civil Action No. 01-2197 (JR)
BIOVAIL CORPORATION,	:	
Defendant.	:	
MEIJER, INC. and MEIJER DISTRIBUTION, INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 03-2075 (JR)
BIOVAIL CORPORATION,	:	
Defendant.	:	

MEMORANDUM

In these consolidated actions, purchasers of Tiazac, a brand-name drug, have sued its manufacturer, Biovail Corporation, for damages they claim to have suffered because of Biovail's unlawful interference with the attempts of another drug manufacturer (not a party to this action) to bring a cheaper, generic version to market. Biovail has filed a single-issue motion for summary judgment, asserting that none of the plaintiffs can prove that its unlawful acts caused them to be damaged. The motion is well taken and will be granted.

Background

Plaintiffs Twin Cities Bakery Workers Health and Welfare Fund and Meijer, Inc. are, and for all relevant periods have been, purchasers of Tiazac, an extended-release form of diltiazem hydrochloride prescribed for chronic hypertension and angina which has been on the market since September 1995.[1] On June 22, 1998, Andrx Pharmaceuticals, Inc. filed an abbreviated new drug application (ANDA) seeking FDA approval to manufacture and distribute Tatzia, which it claimed to be bioequivalent to Tiazac. The Andrx ANDA was not approved until April 10, 2003, nearly five years later, but these plaintiffs allege that, if Biovail had not unlawfully interfered with the approval of Andrx's ANDA, it would have been approved and Tatzia would have been on the market by around February 14, 2001. The compensation plaintiffs seek is for the difference between what they paid for Tiazac and the lower price they would have paid for the generic Tatzia during the period of Biovail's unlawful interference.

The ANDA process was created in 1984 by the Hatch-Waxman Amendments to the Food, Drug and Cosmetics Act, Pub. L. No. 98-417, both to expedite the approval of generic drugs and to protect the rights of pioneer drug manufacturers. Under the Hatch-Waxman Amendments, a manufacturer seeking approval of a

[1] The Twin Cities Bakery Workers Health and Welfare Fund amended complaint adds other plaintiffs, all of whom allege that they are and have been Tiazac purchasers.

generic drug using the ANDA process is not required to prove the safety and efficacy of its drug, but it must demonstrate bioequivalency with the pioneer drug.

The process designed by Hatch-Waxman for protecting the patent rights of pioneer drug manufacturers is quite complex. Patents claimed for pioneer drugs by their manufacturers are listed in an FDA publication titled "Approved Drug Products With Therapeutic Equivalence," commonly referred to as the Orange Book. When a generic manufacturer submits an ANDA, it must deal with the patents listed in the Orange Book. One of the generic manufacturer's options is the so-called Paragraph IV certification, 21 U.S.C. § 355(b)(2)(A)(iv), which is an assertion that the patent claimed by the brand name drug manufacturer is invalid or that the generic version will not infringe it. The pioneer manufacturer has 45 days after the filing of a Paragraph IV certification to sue the ANDA applicant for patent infringement. 21 U.S.C. § 355(j)(5)(iii). If the pioneer manufacturer sues, the FDA must stay its approval of the ANDA for 30 months, or until the issuance of a final-court decision, whichever is sooner. 21 U.S.C. § 355(j)(5)(iii).

On July 3, 1996, some two years before Andrx submitted its ANDA for Tatzia, Biovail certified to the FDA that Tiazac claimed U.S. Patent No. 5,529,791 (the '791 patent). The '791 patent was duly listed in the Orange Book. When Andrx submitted

its ANDA for Tatzia on June 22, 1998, it made a Paragraph IV certification that Tatzia did not infringe the '791 patent. On October 7, 1998, Biovail sued Andrx for infringement of the '791 patent, thus triggering the 30-month statutory stay of Andrx's ANDA. A federal district court later found no infringement of the '791 patent, Biovail Corp. Int'l v. Andrx Pharm. Inc., 158 F. Supp. 2d 1318 (S.D. Fla. 2000). That decision was affirmed on February 13, 2001, Andrx Pharm. Inc. v. Biovail Corp. Int'l, 239 F.3d 1297 (Fed. Cir. 2001).

The Federal Circuit's decision would have ended the statutory stay of Andrx's ANDA after about 28 months. Shortly before the Federal Circuit ruled, however, Biovail acquired U.S. Patent No. 6,162,463 (the '463 patent) and certified to the FDA that Tiazac claimed that patent as well. When the '463 patent was listed in the Orange Book, Andrx complained to the FDA that Biovail had listed it unlawfully. Then, on February 16, 2001, Andrx filed a Paragraph IV certification. On April 5, 2001, Biovail sued Andrx again, this time for infringing the '463 patent, thereby triggering a second 30-month stay of Andrx's ANDA.

Throughout this process, Andrx continued to move forward as best it could with its ANDA, particularly during the brief period from February 13, 2001 until April 5, 2001 during which no stay clouded its application. Indeed, the FDA had

tentatively approved Andrx's ANDA on September 29, 2000, and it did so again on May 14, 2001. Beginning in May 2001, however, Andrx's generic product experienced stability testing and dissolution failures. Andrx had produced 15 batches for commercial distribution in January 2001, but in May it learned that two of those batches had not met specifications. Ultimately, six of the 15 production lots failed dissolution tests. Andrx produced new batches in September 2001, and, in December 2001, informed the FDA that it was rejecting all 15 of the January 2001 batches. On March 12, 2002, the FDA Division of Bioequivalence informed Andrx that it must perform new bioequivalency studies. On March 22, 2002, having withdrawn the data it had submitted in the fall of 2001, and having filed both a major and a minor amendment to its ANDA, Andrx submitted the required new studies. Further data, amendments, and requests for data were exchanged between Andrx and the FDA over the following months.

On April 23, 2002, the Federal Trade Commission filed a complaint against Biovail for antitrust violations in connection with its listing of the '463 patent. Biovail subsequently entered into a consent decree pursuant to which it withdrew the infringement suit it had filed against Andrx. The second stay of Andrx's ANDA thus expired on August 20, 2002, but the FDA did not approve Andrx's ANDA for Tatzia until April 10, 2003.

Analysis

Causation as an element of antitrust damages

Plaintiffs seek treble damages under § 4 of the Clayton Act, 15 U.S.C. § 15. A § 4 plaintiff "must show both an injury-in-fact to his 'business or property' and a causal connection between that injury and the defendant's allegedly illegal acts." Hecht v. Pro-Football, Inc., 570 F.2d 982, 987 (D.C. Cir. 1977). The legislative history of the Clayton Act shows Congress's concern to provide "an effective remedy for consumers who were forced to pay excessive prices," Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 530 (1983), but an antitrust plaintiff is fully subject to common law requirements of proximate cause and certainty of damages. Associated Gen. Contractors, 459 U.S. at 532-33. As stated by one court:

> Causation in fact is, of course, a necessary element of any claim for relief under Section 4 of the Clayton Act, 15 U.S.C. § 15 . . . . Discussions of the causal nexus between economic injury and an antitrust violation may also implicate issues such as standing or proximate cause . . . . However, lack of causation in fact is fatal to the merits of any antitrust claim. Consequently, an essential element of the plaintiffs' claim is that the injuries alleged would not have occurred *but for* [the defendant's] antitrust violation.

Argus Inc. v. Eastman Kodak Co., 801 F.2d 38, 41 (2d Cir. 1986) (emphasis in original). In order to recover damages in this case, the plaintiffs must show that, but for Biovail's unlawful conduct, Andrx would have entered the market with Tatzia before

August 20, 2002, and that they -- the plaintiffs -- would have had the benefit of lower prices due to competition.

What would the FDA have done?

Biovail's submission is that plaintiffs cannot possibly sustain their burden of proving "but for" causation, because the FDA did not approve Andrx's ANDA until April 10, 2003, nearly eight months after the effects of its allegedly unlawful conduct had ceased. Opposing the motion for summary judgment, the plaintiffs respond that the FDA would have approved Andrx's ANDA around February 13, 2001 were it not for the stay that Biovail triggered with its improper certification of the '463 patent; that Andrx would have brought Tatzia to market immediately thereafter; that, despite the testing failures and manufacturing problems it experienced starting in May 2001, Andrx would not have recalled all the batches of its drug; and that the FDA would not have required Andrx to institute a total recall of its product but would have sanctioned a limited recall. That theory of causation has a number of moving parts, but plaintiffs insist that genuine issues of material fact are disclosed by the record and that they are entitled to try their damages before a jury. They proffer (by affidavit) the opinion testimony of Jeffrey Gibbs, an attorney, and Dr. Nicholas Fleischer, a former employee of the FDA. They also proffer the affidavit of Diane Servello, an Andrx employee. Mr. Gibbs and Dr. Fleischer would testify to

their opinions that the FDA would have approved Andrx's application in mid-February 2001 if Biovail had not listed the '463 patent in the Orange Book and that the FDA would not have required a total recall of Tatzia if it had already been placed on the market before Andrx's testing and manufacturing problems arose. Ms. Servello's affidavit states that, if Tatzia had already been on the market, Andrx would not of its own volition have recalled all the January 2001 batches of Tatzia when the dissolution failures and problems with its manufacturing process came to light in May, but instead would have instituted only a limited recall. Thus, some batches of Tatzia would have remained on the market and would have been available for purchase by the plaintiffs. Pls.' Opp'n 3.

Biovail moved to strike the Gibbs and Fleischer declarations on Daubert/Kumho Tire grounds. On January 7, 2005, I denied that motion, observing that the gatekeeper needs to see what is being presented at the gate, but I now find both declarations to be inadmissible, and I find plaintiffs' proof of causation too speculative as a matter of law to present to a jury.

The "gatekeeping" obligation assigned to trial judges by Daubert v. Merrell Dow Pharm., Inc. applies to non-scientific expert testimony. Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 141 (1999). The Gibbs and Fleischer opinions are not

readily susceptible to Daubert analysis. They are based upon the witnesses' experience in the field of FDA regulation of generic drugs and cannot be tested, or verified, or subjected to peer review. Both witnesses have extensive experience in or before the FDA, and the opinions of both make reference to the record before the court. See Merit Motors v. Chrysler Corp., 569 F.2d 666, 672 (D.C. Cir. 1977). Nevertheless, I find that their declarations are not -- and cannot be -- sufficiently reliable to "assist the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702, and that in any event their value is substantially outweighed by the danger of unfair prejudice or misleading the jury. Fed. R. Evid. 403. According to the Advisory Committee Notes accompanying the 2000 Amendments to Rule 702:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." [] The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable.

The subject matter of the Fleischer and Gibbs declarations is whether or not, and when, the Food and Drug Administration would have made complex, discretionary, multi-layered, case-specific decisions relating to the initial approval and subsequent need to recall a prescription drug.

Dr. Fleischer's opinion is that the FDA would have approved Andrx's ANDA on or about February 14, 2001 if Biovail had not listed the '463 patent in the Orange Book in January 2001, and that the FDA would have permitted Andrx's generic drug to remain on the market "continuing through the present," despite the dissolution failures and manufacturing problems Andrx's generic drug experienced beginning in May 2001. These opinions are unaccompanied by data that demonstrate their reliability -- no examples of the time lines by which the FDA has approved the ANDAs of other drug manufacturers, no personal experience of predicting what the FDA might do that proved to be correct. The opinions are little more than Dr. Fleischer's ipse dixit, prepared, incidentally, especially for this litigation (not his regular line of work). Mr. Gibbs's declaration, prepared for a prior litigation between Andrx and Biovail, states that "in practice [the Office of Generic Drugs] generally issues a final approval within a very brief period, unless there is a significant outstanding issue to be resolved." Pl. Ex. 25, Gibbs Decl. ¶ 17. He opines that "Andrx would have received final ANDA approval shortly after February 14, 2001. Had approval been issued, Andrx could have immediately marketed the Taztia it had made earlier." Id. at ¶ 18. He echoes Dr. Fleischer's testimony that technical issues are more easily dealt with after approval than before, that Andrx's recall would have been limited to the

six lots that failed dissolution testing, and that the FDA would not have withdrawn its approval of Andrx's ANDA based on these test results. Id. at 25-26.

Both experts give examples of limited recalls sanctioned by the FDA upon limited dissolution failures experienced at various time intervals in other cases. Pl. Ex. 35, Gibbs Decl. ¶ 27; Fleischer Decl. ¶ 30 . These examples add incrementally to the reliability of the Gibbs and Fleischer opinions about a limited recall, but not enough to cure the fundamentally speculative nature of their opinions. The experts' declarations are too speculative to forge the chain of causation plaintiffs' proof of damages requires. See Merit Motors, Inc., 569 F.2d 666 (D.C. Cir. 1977); Williams v. Ford Motor. Co., 187 F.3d 533 (6th Cir. 1999).

What would Andrx have done?

Plaintiffs' chain of causation also requires probative evidence of what Andrx would have done when six of 15 batches failed dissolution tests at the three-month mark.[2] The record on that point contains damaging deposition testimony by Diane

[2] Plaintiffs would also have to prove that Andrx had promotional and sales materials ready, had a distribution chain in place, and would actually have sold Tatzia at a price less than Tiazac. See Andrx Pharm. v. Biovail Corp., 256 F.3d 799, 806-07 (D.C. Cir. 2001) (plaintiff must demonstrate intention to enter a market and preparedness to do so). These elements of proof are not challenged on the instant motion for summary judgment.

Servello, who was designated to testify for Andrx under Rule 30(b)(6), to the effect that Andrx chose to reject all 15 batches, Def. Ex. 13., Servello Dep. 267, and that, if Andrx had brought Tatzia to market before learning of the dissolution failures, the situation would have "require[d] a recall." Id. at 267-68. Later in the same deposition, when asked about a document noting that Andrx's manufacturing process could not produce a product that consistently met specifications, Ms. Servello agreed that "all of those batches had they been distributed would have to have been recalled." Id. at 286.

On the other hand, plaintiffs argue, is Diane Servello's declaration, prepared after her deposition and as support for plaintiffs' opposition to the instant motion. In her declaration, Ms. Servello states that the decision to reject all 15 lots of Tatzia was made in the "context" of Andrx's litigation with Biovail and the statutory stay on Andrx's ANDA. In that "context," once Andrx had optimized its processes and manufactured new lots of Tatzia, "there was no longer any reason to seek to market the lots manufactured" in January 2001. Pl. Ex. 27, Servello Decl. ¶ 7. Her declaration (as opposed to her deposition) asserts that "if Andrx already had obtained final approval in February 2001, [and if Andrx had] commenced marketing of its product shortly thereafter, and [if Andrx had] subsequently learned that certain limited lots of product were

failing on stability at the tree-month interval" then "Andrx would have limited any recall to those lots of product that had failed stability testing." Id. at ¶ 8 (emphasis added).

The plaintiffs' burden to show what Andrx would or would not have done had it received earlier approval of its ANDA is a weighty one. See Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 670 (D.C. Cir. 1996) (difficult to show likelihood of a result that depends on predicting action of an unrepresented third party). It is also central to the plaintiffs' proof of damages. See id. at 672 (court need not accept alleged causal chain if each link is not supported by competent evidence). A proffer of Ms. Servello's affidavit as trial testimony would be subject to the objection that it is speculative. If the objection were sustained, another link in plaintiffs' chain of causation would be broken. If it were overruled, the jury would have to decide which of Ms. Servello's statements to believe. Thus, what plaintiffs have offered on the critical question of what Andrx would have done is either a broken link in the chain of causation, or a very weak one. It takes more than a scintilla of evidence to survive summary judgment. Pyramid Securities Ltd. v. IB Resolution Inc., 924 F.2d 1114, 1116 (D.C. Cir. 1991). "The greater number of uncertain links in a causal chain, the less likely it is that the entire chain will hold true." Bentsen, 94 F.3d at 670.

* * * * *

The City of Pittsburgh sued an electric utility claiming that the defendant's pre-merger agreement with another electric utility had violated the Sherman Act, denying the City the opportunity to pay lower rates for electric service. The district court's dismissal of the suit was affirmed because plaintiff had not established a causal connection between the unlawful act alleged and its injury: the Public Utility Commission had not approved the entry of a second provider into the relevant market. "[T]he fact that no competition existed was the result of the regulatory structure." City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 262 (3rd Cir. 1998). Because "the realization of competition is in the hands of regulators there is no way that the City can show that competition would have occurred absent the concerted activity between the two utilities," id. at 267 (emphasis added). The court continued

> Allegheny Power was not legally able to provide power in the Redevelopment Zones and we do not know whether the PUC would ever have granted the permission for it to do so. Thus, as a matter of law, the court cannot conclude that the loss of potential competition was causally related to the decision of the two power companies to merge. The City is really claiming that it would have benefitted from competition it *hoped would occur* . . . . The presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise.

Id. at 267-8 (emphasis in original).

The City of Pittsburgh decision was rooted in antitrust standing theory. Biovail does not assert lack of standing here (perhaps because it successfully resisted the standing argument made by Andrx in Andrx Pharm. v. Biovail Corp. Intern., 256 F.3d 799 (D.C. Cir. 2001)). In a sense, this case picks up where Andrx Pharmaceuticals left off: the plaintiffs have properly alleged injury-in-fact and causation, see id. at 806-12, and the injury they complain of would be antitrust injury if they could prove causation, see id. at 812-815. When challenged by Biovail's motion for summary judgment, however, plaintiffs have failed to adduce proof of causation. Without the testimony of Mr. Gibbs and Dr. Fleischer, which I have ruled inadmissible, they cannot prove that the FDA would have approved Tatzia before Biovail's settlement with the FTC removed the Hatch-Waxman stay of Andrx's ANDA, or that the FDA would have permitted only a partial recall of Tatzia after its testing failures. And their proof of what Andrx might have done after the testing failures is either another broken link or a very weak link in an already compromised chain. Plaintiff's proof that Biovail's acts caused them damages is thus insufficient and cannot go to a jury. Foremost-McKesson, Inc. v. Instrumentation Lab. Inc., 527 F.2d 417, 418 (5th Cir. 1976) (failure to introduce sufficient

evidence of causation in private antitrust suit prevents court from sending case to jury).[3]

Injunctive Relief

The FTC's 2002 complaint against Biovail was settled pursuant to a consent decree under which Biovail divested itself of its exclusive rights in the '463 patent; agreed not to bring any legal action to enforce the '463 patent; dismissed with prejudice any legal claims relating to enforcement of the '463 patent including the litigation in the Southern District of Florida that triggered the second 30-month stay of Andrx's ANDA; agreed to take no action to cause a 30-month stay of Andrx's ANDA; and agreed not to list patents in the Orange Book in violation of applicable law. The consent Decree expires in 2012. Pls.' Ex. 2.

Claims for injunctive relief under § 16 may be granted only if a party shows "the threat of irreparable injury to the plaintiff in the absence of injunctive relief." Found. on Economic Trends v. Heckler, 756 F.2d 143, 151 (D.C. Cir. 1985); see Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 127 (1986) (§ 16 differs from § 4 because it requires only

[3] I have carefully noted the panel's observation in Andrx Pharmaceuticals, 256 F.3d at 815 n.18, that "[d]ifficulty of ascertainment [should not be] confused with right of recovery," quoting Bigelow v. RKO Radio Pictures, 327 U.S. 251, 265 (1946). A broken chain of causation, however, means that there is no right of recovery.

demonstration of threatened loss and not actual injury). "[A]n injunction issues only if there is a showing that the defendant has violated, or imminently will violate, some provision of statutory or common law, and that there is a 'cognizable danger of recurrent violation.'" Madsen v. Women's Health Ctr. Inc., 512 U.S. 753, 766 (1994) (citing United States v. W.T. Grant Co., 345 U.S. 629, 633,(1953)).

The limits upon Biovail for the next seven years under the FTC consent decree leave no room for "threatened conduct that will cause loss or damage," and plaintiffs have made no showing of a "cognizable danger of recurrent violation." The plaintiffs' suit for injunctive relief has been challenged by a motion for summary judgment, and they have not responded with evidence of a concrete threat of irreparable injury. Their claim for injunctive relief under § 16 will be dismissed.[4]

[4] In seeking injunctive relief the plaintiffs assert, inter alia, that prices for Tatzia remain artificially inflated by royalty payments that Andrx must make to Biovail and that Andrx passes on to consumers pursuant to their settlement agreement. That assertion is too remote from the injunctive relief plaintiffs seek and too complicated by other factors to be sorted out in the context of this suit, if, indeed, these plaintiffs even have standing to complain about it. Note that in exchange for agreeing to pay royalties to Biovail on its sales of Tatzia, Andrx received certain consideration wholly unrelated to Tiazac, including dismissal of unrelated litigation Biovail had brought against Andrx as well as Biovail's agreement not to sue Andrx over its generic version of Cardizem CD. Def. Combined Reply, Ex. 3 at §§ 1.20,2.1, Schedule A.

Conclusion

For the reasons set forth above, the claims for damages and injunctive relief under the Clayton Act will be dismissed in both of these consolidated cases. In No. 01-2197, the Twin Cities plaintiffs have set forth claims under state antitrust and consumer statutes. The parties have not identified, nor have I found, legal differences between those statutes and the Clayton Act that would require a different result as to those claims, and accordingly they will be dismissed as well. Appropriate orders accompany this memorandum.

JAMES ROBERTSON
United States District Judge