5-30-2000

In Re: Warfarin Sodium Anti-trust Case

Filed May 30, 2000

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 99-5034

IN RE: WARFARIN SODIUM ANTITRUST LITIGATION

JOHN KUSNERIK; SARA ALTMAN; SAMUEL GORDON
TISCHLER; MARIE A. STECKEL; ROBERT BAREISS;
JOHN CIVATTE, JR.; MARY BANTEN,
Appellants

Appeal from the United States District Court
for the District of Delaware
(D.C. Civ. No. 98-cv-01232)
District Judge: Honorable Sue L. Robinson

Argued
March 24, 2000

Before: MANSMANN, GREENBERG and BARRY,
Circuit Judges.

(Filed: May 30, 2000)

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OPINION OF THE COURT

MANSMANN, Circuit Judge.

Consumers of the prescription drug Coumadin, anxious to purchase its generic equivalent, ask us to determine if complaints filed by them sufficiently state a claim for injunctive relief under section 16 of the Clayton Act against Coumadin's manufacturer. We find that in dismissing the complaints under Fed. R. Civ. P. 12(b)(6), the District Court improperly referred to matters beyond the complaints and did not correctly analyze the legal standard for antitrust standing. For these reasons, we will reverse and remand.

I.

Coumadin, known generically as warfarin sodium, is the brand name of a blood-thinning drug prescribed for the prevention and treatment of blood clots.1 Treating physicians carefully monitor patients taking the drug because, as the parties stipulated, too little a dose can lead to a stroke or cardiac arrest and too much can cause internal bleeding.

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1. We accept as true the facts as alleged in the complaint. Bald Eagle School District v. Keystone Financial, Inc., 189 F.3d 321, 327 n.7 (3d Cir.
1999).

The defendant, DuPont Pharmaceuticals Company, manufactures Coumadin. Although the patent protection for Coumadin expired in April 1962, DuPont has dominated the oral anti-coagulant market for over 30 years. Until one of the plaintiffs to this action, Barr Laboratories, Inc., introduced its generic tablets, no equivalent product competed with DuPont's Coumadin.

Barr Laboratories and the present plaintiffs filed lawsuits alleging that DuPont, anticipating a loss of market share resulting from the introduction of a cheaper generic substitute for Coumadin, orchestrated a campaign disparaging generic substitutes generally, and Barr Laboratories' warfarin sodium particularly. The cumulative effect of these attacks was to raise Barr Laboratories' cost to enter the anti-coagulant market and to disable its market penetration. The by-product claim brought by the individual plaintiffs is that, due to DuPont's effort to derail generic competition, they have paid inflated prices for Coumadin.

The specific allegations of DuPont's anti-competitive activity in the relevant market concern DuPont's attempt to prevent and/or delay Food and Drug Administration approval of warfarin sodium in a generic form, publication and dissemination of false and misleading information to the public regarding generic warfarin sodium, undertaking aggressive public relations efforts involving the circulation of deceptive information and increasing Coumadin's marketing efforts by feeding misinformation to doctors and other medical professionals.

Citing these unlawful attempts to monopolize, Barr Laboratories filed suit against DuPont, alleging various antitrust law violations. Barr Laboratories also asserted claims under the Lanham Act, New York state law and common law. Four named individuals, each claiming to represent a nationwide class of 1.8 million Coumadin users, filed separate complaints for monetary damages and injunctive relief, alleging that DuPont violated section 2 of the Sherman Act and various state laws. These class plaintiffs also sought treble damages under section 4 of the Clayton Act and injunctive relief under section 16 of the Clayton Act.

DuPont filed a motion to dismiss both Barr Laboratories' and the class plaintiffs' claims for failure to state a claim upon which relief could be granted under Fed. R. Civ. P. 12(b)(6).

The District Court granted in part and denied in part DuPont's motion to dismiss Barr Laboratories' lawsuit.2 The class complaints were dismissed in their entirety.

The only issue relevant to this appeal is the District Court's decision that the class plaintiffs lack standing to seek injunctive relief under section 16 of the Clayton Act. The District Court summarily concluded that because the class had not sufficiently alleged either antitrust injury or a causal connection between DuPont's alleged unlawful activity and the supposed injury of Coumadin users, it failed to assert injury of the type the Sherman Act was designed to prevent. As such, the class did not have standing to request injunctive relief.

Our jurisdiction to review this dismissal is authorized by 28 U.S.C. S 1291.

II.

Rule 12(b)(6)

We first explore whether the District Court erroneously considered matters beyond the scope of the complaints in rendering its antitrust standing determination. Our review of a District Court's decision to dismiss a lawsuit for failure to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6) is plenary. Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d 305, 311 (3d Cir. 1999). The motion to dismiss should be granted only if "after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff 's favor, no relief could be granted under any set of facts consistent with the allegations in the complaint."

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2. The Barr Laboratories' case was subsequently remanded to the Southern District of New York. At oral argument, counsel represented that this portion of the litigation has settled.

Trump Hotels and Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998).

Although the District Court recited this Rule 12(b)(6) standard in making its decision, the court impermissibly cited and relied on facts beyond the corners of the complaints. Excerpts from the District Court opinion illustrate this point:

> Although class plaintiffs do not discuss third party payor arrangements, it is almost certain that most of the 1.8 million class members had some sort of health insurance.
>
> * * *
>
> If defendants' monopolization of the oral anticoagulant market resulted in supracompetitive prices for Coumadin, the insurance and third party payor organizations most likely absorb some or all of that overcharge.
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> * * *
>
> Moreover, the sheer variety of third party payor plans would render the apportionment of damages among the class plaintiffs incredibly complex.

(Emphasis added.)

While these factors loomed large in the District Court's conclusion regarding the absence of a significant nexus between DuPont's activity and the classes' injury, the complaints are notably silent regarding the impact of third party payor and prescription drug insurance plans on the price paid for Coumadin. The complaints instead alleged that the class members paid inflated prices for Coumadin because DuPont thwarted the generic's market entry. The District Court should have accepted this as true, analyzed if DuPont's preclusive conduct was violative of antitrust laws, and then decided whether to dismiss the complaints. Instead, in granting the motion, the District Court considered facts gleaned from counsel's argument and from its own experience, factors not contemplated by the dictates of Rule 12(b)(6).

DuPont submits a number of reasons why the District Court's consideration of factual assumptions de hors the complaints were properly considered. DuPont urges that the allegations concerning third party payors are within everyday knowledge and that the District Court could easily infer the presence of such entities from the pleadings. Alternatively, DuPont asserts that the District Court could take judicial notice of such facts. These contentions are not persuasive. First, Rule 12(b)(6) instructs that the District Court draw inferences in favor of plaintiffs, not the proponent of the motion. Second, the types of facts of which courts take judicial notice are of a different nature than those relied upon by the District Court here-- that the class members are most likely being reimbursed to some extent for the amount spent to purchase Coumadin. A judicially noticed fact is "one not subject to reasonable dispute in that it is either (1) generally known . .. . or (2) capable of accurate and ready determination" through unquestionably reliable sources. See Fed. R. Evid. 201(b); United States v. Carr, 25 F.3d 1194, 1202 n.3 (3d Cir. 1994). The facts cited by the District Court concerning third party payors not contained in the complaints do notfit the criteria of Rule 201(b).

Because these findings were integral to the District Court's standing decision, we must now determine whether the District Court's erroneous application of Rule 12(b)(6) caused a misinterpretation of the substantive standing issue.

III.

Section 16 Antitrust Standing

Section 16 of the Clayton Act, authorizing suits for injunctive relief, provides in part:

> Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, . . . when and under the same conditions and principles as injunctive relief

> against threatened conduct that will cause loss or damage is granted by courts of equity.

15 U.S.C. S 26 (1976).

Recovery under section 16 is best understood in how it differs from recovery under section 4 of the Clayton Act. While relief sought pursuant to section 4 of the Clayton Act requires proof of loss and any damages proven are trebled, injunctive relief under section 16 only requires a threat of loss. See Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 109-111 (1986). An antitrust plaintiff proceeding under section 16 must, however, still demonstrate that the injury in question is "injury of the type the antitrust laws were intended to prevent." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). A section 4 plaintiff 's standing is tested by an application of a number of factors designed to determine if the asserted damage goes beyond speculation and, that if there is cognizable damage, the plaintiff is the appropriate person to assert it for antitrust purposes. Associated General Contractors, Inc. v. California State Council of Carpenters, 459 U.S. 519, 538 (1983), ("Associated General"). Section 16 is not as demanding, but it does require a showing that there is "a significant threat of injury from [a] . . . violation of the antitrust laws . . . ." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 130 (1969).

In dissecting the Coumadin classes' section 4 claim, the District Court conducted a standing test under thefive Associated General factors: (1) the causal connection between the antitrust violation and the harm to the plaintiff; (2) whether the plaintiff 's alleged injury is of the type that the antitrust laws were intended to redress; i.e., did the plaintiff suffer antitrust injuries; (3) the directness of the injury; (4) the existence of more direct victims of the violation; and (5) the potential for duplicative recovery or complex apportionment of damages. 459 U.S. at 535-46.

Regarding factors one and three, which required the class to show that DuPont's monopolization of the anticoagulant market directly caused their injuries, the District Court identified the consumers' "third" position in the chain of distribution from DuPont to user and the influence of

managed care on what consumers pay for prescription drugs as reasons for holding that the class plaintiffs' alleged injury and DuPont's alleged conduct was too attenuated to justify antitrust standing. Specifically, the District Court opined that the class plaintiffs' ability to trace their overpayment to the alleged anticompetitive conduct " `traverses several somewhat vaguely defined links.' AGC, 456 U.S. at 540." The District Court thus concluded that the case described a "typical indirect purchaser scenario" and that, from the complaints, "it was unclear whether the class suffered any antitrust injury at all."

As to the class plaintiffs' request for injunctive relief under section 16, the District Court summarily concluded, by relying upon its section 4 discussion, that the class had not sufficiently alleged the required antitrust injury or the causal connection between DuPont's alleged unlawful activity and their purported injury. Thus, the District Court decided that the class failed to allege injury of the type the Sherman Act was designed to prevent; the class, therefore, did not have standing to request injunctive relief.

The Coumadin class fits the stereotypical indirect purchaser mold. Indirect purchaser status, however, is not fatal to a plaintiff 's request for injunctive relief under section 16 of the Clayton Act.

In Mid-West Paper Products Co. v. Continental Group, Inc., 596 F.2d 573 (3d Cir. 1979), we explained how the difference between sections 4 and 16 claims influences the question of standing as it relates to indirect purchaser status:

> in contrast to the treble damage action, a claim for injunctive relief does not present the countervailing considerations -- such as the risk of duplicative or ruinous recoveries and the spectre of a trial burdened with complex and conjectural economic analyses -- that the Supreme Court emphasized when limiting the availability of treble damages.

Id. at 590. Accordingly, we held that the plaintiffs did not have to satisfy the direct purchaser requirement as a condition of seeking injunctive relief. Id. at 594. See also

Schoenkopf v. Brown & Williamson Tobacco Corp., 637 F.2d 205, 210 (3d Cir. 1980) (Section 16 relief more encompassing because language is less restrictive than section 4 and because injunctive remedy is flexible, adaptable tool for enforcing antitrust laws).

While direct purchaser status is not mandated, the class must still make a showing of entitlement to injunctive relief requiring the demonstration of: (1) threatened loss or injury cognizable in equity; (2) proximately resulting from the alleged antitrust injury. See McCarthy v. Recordex Service, Inc., 80 F.3d 842, 856 (3d Cir. 1996). The narrow question before us then is whether the allegations of the class members' complaints, that DuPont's conduct precluded competition which caused Coumadin users to pay inflated prices for the drug, meet this standard.

We turn first to guidance from the United States Supreme Court. The threatened injury to the class here resembles that of the plaintiff in Blue Shield of Virginia v. McCready, 457 U.S. 465 (1982). In McCready , the plaintiff complained of a conspiracy among psychiatrists and Blue Shield to shield psychiatrists from competition. McCready's visits to her psychologist were not covered by Blue Shield, although visits to psychiatrists were reimbursed.

In deciding McCready, the Supreme Court addressed the relationship between the indirect purchaser doctrine and antitrust injury. The Court stated that whether a particular injury is too remote from the alleged violation to confer section 4 Clayton Act standing, depends upon the relationship of the injury alleged and the types of injury that Congress was targeting when it legislated particular anticompetitive conduct as unlawful. Id. at 476-78. The Court first determined that, in the absence of a risk of duplicative recovery, a plaintiff is not barred from bringing a claim under section 4 if he is a foreseeable victim of the antitrust violation. Id. at 475. Then the Court decreed that McCready's injury was "inextricably intertwined with the injury the conspirator sought to inflict," and had standing to pursue her section 4 claim. Id., 457 U.S. at 484.

As in McCready, the class alleges injury by an unlawful restraint on competition in the market, and McCready is

thus instructive. First, McCready reinforces our holding in McCarthy that the Coumadin class cannot be barred from bringing suit simply based on its indirect purchaser status. McCready held that due to the absence of duplicative recovery, McCready and her class could maintain their suit for treble damages. Similarly, here, there is no risk of duplicative recovery because the class only seeks section 16 injunctive relief.

Next, concerning remoteness, the high price paid by consumers for Coumadin clearly resulted in " `the type of loss that the claimed violations . . . would be likely to cause,' " id. at 479, (quoting Brunswick, 429 U.S. at 489). The class members here, like McCready, were "foreseeable and necessary victims" of DuPont's efforts to exclude the generic drug from the market. Indeed, if McCready, who voluntarily sought uncovered treatment from psychologists did not suffer from remoteness, then the purchasers of Coumadin, who have no choice in which warfarin sodium they purchased, were more predictable and more compelling victims of antitrust violations.

Finally, McCready determined that an antitrust injury occurred because the higher cost for services paid by McCready was so "inextricably intertwined" with the true target of the conspiracy, the psychologists, that McCready also suffered antitrust injury. Utilizing this same rationale, we find that Coumadin consumers clearly suffer antitrust injury. Coumadin purchasers were the target of DuPont's antitrust violation. Regardless of the existence of the various links of middlemen, if there were no ultimate consumer of Coumadin, prices charged for the drug by DuPont to distributors, pharmacies, etc., would be irrelevant. The excess amount paid by Coumadin users not only is "inextricably intertwined" with the injury DuPont aimed to inflict, the overcharge was the aim of DuPont's preclusive conduct. It is difficult to imagine a more formidable demonstration of antitrust injury.

The District Court's refusal to recognize standing to pursue this relief is also, as alluded to above, contrary to our jurisprudence.

The authority of McCarthy v. Recordex, 80 F.3d at 845,

strongly supports a favorable standing determination. In McCarthy, the plaintiffs had complained that they paid inflated prices for photocopies of their medical records due to a conspiracy between hospitals and copy centers to inflate the cost of records. The plaintiffs were clients of the lawyers who were the direct purchasers of the fixed price copies. Despite the plaintiffs' status as indirect purchasers, we refused to view the multifaceted chain of distribution as too attenuated to support a finding of causation. 3

Finally, decisions from our court which negated antitrust standing are distinguishable. In City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), the city brought suit against two electric companies seeking damages and an injunction precluding the merger of the companies. The City claimed that the merger would void the possibility of lower-priced electric service charged to city residents. We held that the City's injunctive relief claim failed to meet section 16 standing requirements due to a lack of causal connection between the defendant's injuries and the alleged harm and because of the absence of antitrust injury. We arrived at this conclusion, however, because an intervening regulatory scheme precluded the companies from competing, i.e., the merger was not the cause of the injury. No significant antitrust injury inquiry was required to reach this conclusion and none was undertaken. We can reasonably posit, however, that if not for this regulatory quirk, the City would have been entitled to section 16 relief because the proposed merger would have eradicated competition, a result prohibited under the Clayton Act, and detrimental to the City's electrical customers.

In Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912 (3d Cir. 1999), union health and welfare funds brought class actions against tobacco companies under antitrust laws to recover for the funds' cost of treating fund participants who had smoking related diseases. We concluded that the funds' injuries were too

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3. In McCarthy, we acknowledged the appropriateness of injunctive relief, but remanded because the District Court had not expressly addressed the question of indirect purchaser standing.

remote from the tobacco company's antitrust activity to satisfy the Associated General causal connection requirement, because the tobacco companies could have achieved their alleged aim to preclude marketing of safer tobacco products without the existence of the funds or the relationship between the funds and the smokers. The existence of smokers would be sufficient reason for such an alleged conspiracy.

In this case, the purchasers of Coumadin are akin to the smokers in Steamfitters. DuPont's efforts to keep the generic drug off the market emanate from the fact that the introduction of the generic product would force down the price paid for the anti-coagulant. The higher prices paid were the raison d'etre of DuPont's antitrust conduct.

We, therefore, conclude, under the controlling jurisprudence, that this class has satisfied the requirements of standing for injunctive relief under section 16 of the Clayton Act. The facts as alleged in the complaints plainly establish the required causal connection between DuPont's exclusionary anticompetitive conduct and the direct harm to Coumadin purchasers. Unless enjoined, DuPont's unlawful conduct will continue unchecked and the class will continue to bear the financial brunt of the antitrust violations.

IV.

We will reverse the order of the District Court dismissing the class complaints based on lack of antitrust standing and remand for continued proceedings.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit