2020 WL 4331523
Only the Westlaw citation is currently available.
United States Court of Appeals, Third Circuit.

IN RE: SUBOXONE (BUPRENORPHINE HYDROCHLORINE AND NALOXONE) ANTITRUST LITIGATION
Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc., Appellant

No. 19-3640
|
Argued July 1, 2020
|
(Filed: July 28, 2020)

On Appeal from the United States District Court for the Eastern District of Pennsylvania (D.C. No. 2-13-md-02445), District Judge: Honorable Mitchell S. Goldberg

Attorneys and Law Firms

Bruce E. Gerstein, Joseph Opper, Garwin Gerstein & Fisher, Wall Street Plaza, 88 Pine Street, 10th Floor, New York, NY 10036, Counsel for Plaintiff-Appellee Burlington Drug Co. Inc.

Thomas M. Sobol, Hagens Berman Sobol Shapiro, 55 Cambridge Parkway, Suite 301, Cambridge, MA 02142, Counsel for Plaintiff-Appellees Meijer Inc. and Meijer Distribution Inc.

Caitlin G. Coslett, David F. Sorensen, Berger Montague, 1818 Market Street, Suite 3600, Philadelphia, PA 19103, Peter Kohn [ARGUED], Faruqi & Faruqi, 1617 John F. Kennedy Boulevard, Suite 1550, Philadelphia, PA 19103, Counsel for Plaintiff-Appellee Rochester Drug Cooperative Inc.

Jonathan B. Berman [ARGUED], Jones Day, 51 Louisiana Avenue, N.W., Washington, DC 20001, James R. Saywell, Jones Day, 901 Lakeside Avenue, North Point, Cleveland, OH 44114, Counsel for Defendant-Appellant Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals Inc.

Anthony Russomanno, Wisconsin Department of Justice, P.O. Box 7857, Madison, WI 53707, Counsel for Amicus State of Wisconsin in support of Appellees

Randy Stutz, 10418 Ewell Avenue, Kensington, MD 20895, Counsel for Amicus American Antitrust Institute in support of Appellees

Before: GREENAWAY, JR., SHWARTZ, and RENDELL, Circuit Judges.

OPINION

SHWARTZ, Circuit Judge.

***1** Indivior, Inc., formerly Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt"), manufactured Suboxone, a prescription drug used to treat opioid addiction. Direct purchasers of Suboxone ("Purchasers") allege that Reckitt engaged in anticompetitive conduct that impeded the entry of generic versions of the drug into the market in violation of § 2 of the Sherman Act, 15 U.S.C. § 2. In a thorough, thoughtful, and well-reasoned opinion, the District Court certified a class of those who purchased Suboxone from Reckitt, and Reckitt appeals the certification order. We will affirm.

I

A

We first explain how prescription drugs enter the market. A company wishing to offer a new drug for sale must seek approval from the Food and Drug Administration ("FDA") by filing a New Drug Application ("NDA"). Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 427 (3d Cir. 2016) (citing 21 U.S.C. § 355). Once the drug is approved for sale, it is considered a "brand" or "brand-name" drug. Id. To increase competition and reduce prices, Congress enacted a streamlined method for generic manufacturers to introduce drugs by allowing them to "piggy-back" on the brand drug's "approval efforts." FTC v. Actavis, Inc., 570 U.S. 136, 142, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). Specifically, a generic drug maker may submit an Abbreviated New Drug Application ("ANDA") that may "rely on a name-brand drug company's original NDA approval for a particular drug in order to gain quicker, less costly FDA approval of a generic version." Mylan, 838 F.3d at 427.

If a generic drug manufacturer demonstrates that "the proposed generic product is both a 'bioequivalent' and a 'pharmaceutical' equivalent of the name-brand drug," then

it may "have [its] product deemed 'AB-rated' to the name-brand drug by the FDA." Id. at 427-28. [1] State laws either allow or require pharmacists to substitute these AB-rated, lower-cost generic drugs for a name-brand version. Id. at 428. Due to such substitution laws and the generic drugs' low cost, generics often significantly erode a brand drug's market share. See In re: Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig. (Motion to Dismiss), 64 F. Supp. 3d 665, 673 (E.D. Pa. 2014).

B

Reckitt developed Suboxone tablets. The FDA granted Reckitt a seven-year period of exclusivity in which other manufacturers could not introduce generic versions of Suboxone tablets. As the exclusivity period neared its end for its brand drug, Reckitt developed an under-the-tongue film version of Suboxone, which would enjoy its own exclusivity period. Generic versions of Suboxone tablets would not be AB-rated to Suboxone film, so state substitution laws would not require pharmacists to substitute generic Suboxone tablets if a patient were prescribed Suboxone film.

***2** According to the Purchasers, Reckitt's transition to Suboxone film was coupled with efforts to eliminate demand for Suboxone tablets and to coerce prescribers to prefer film. To that end, Reckitt allegedly: (1) engaged in a widespread campaign falsely disparaging Suboxone tablets as more dangerous to children and more prone to abuse; (2) publicly announced that it would withdraw Suboxone tablets from the market due to these safety concerns; (3) ended its Suboxone tablet rebate contracts with managed care organizations in favor of Suboxone film rebate contracts; (4) increased tablet prices above film prices; (5) withdrew brand Suboxone tablets from the market; and (6) impeded and delayed the market entry of generic Suboxone tablets by manipulating the FDA's Risk Evaluation and Mitigation Strategy ("REMS") process [2] and filing a baseless citizen petition. [3] Through these actions, Reckitt shifted the market to Suboxone film by the time generic Suboxone tablets hit the market and continued to dominate the Suboxone market as the exclusive maker of Suboxone film.

The Purchasers sued Reckitt, [4] alleging that its efforts to suppress generic competition amounted to unlawful maintenance of monopoly power, in violation of § 2 of the Sherman Act. The Purchasers moved to certify a class of "[a]ll persons or entities ... who purchased branded Suboxone tablets directly from Reckitt" during a specified period. App. 5-6. The proposed class representatives were Burlington Drug Company, Inc. and two other purchasers. Burlington's corporate designee testified that although Burlington was not "control[ling]" class counsel, Burlington is aware it is a "fiduciary" for the class, understands the injury claimed, and has been kept apprised of activities in the case. App. 186. In addition, Burlington has produced thousands of pages of electronic transaction level data reflecting purchases, charge backs, and sales of Suboxone tablets, as well as documents from the electronic files of ten employees.

In support of class certification, the Purchasers submitted an expert report by Dr. Russell Lamb, an economist. Dr. Lamb concluded that, due to Reckitt's allegedly anticompetitive conduct, the proposed class paid more for brand Suboxone products. [5] Dr. Lamb attributed these overcharges to Reckitt's actions that: (1) suppressed generic tablet competition, so the Purchasers had to buy brand tablets or film instead of less expensive generic tablets; (2) delayed market entry of generic tablets, increasing the time more expensive brand tablets could dominate the market; and (3) increased the price of brand tablets. To reach these conclusions, Dr. Lamb relied on internal Reckitt documents reflecting its national Suboxone strategy and economic analysis of tablet pricing. Dr. Lamb also calculated the damages attributable to this injury. Using economic modeling and data from Reckitt, he estimated, in the aggregate, the difference between the actual prices charged for brand Suboxone tablets and film and the price class members would have paid for generic and non-Reckitt-brand versions.

***3** The District Court certified the class. In re: Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig. (Class Certification), 421 F. Supp. 3d 12, 26 (E.D. Pa. 2019). As relevant to this appeal, the Court held that (1) common evidence of injury and damages showed that the Purchasers paid more for brand Suboxone products than they would have for generic tablets due to Reckitt's actions to promote film, disparage tablets, and suppress generics' market entry, id. at 62-63; (2) although the Purchasers' aggregate damages model did not allocate damages among class members, "[i]ssues regarding allocation of individual damages [were] insufficient to defeat class certification," id. at 64; and (3) Burlington was an adequate class representative because it had the requisite knowledge of the litigation, including "the basis for the claimed injury," and its interests aligned with the class, id. at 51. Reckitt appeals.

II [6]

Federal Rule of Civil Procedure 23 sets forth the requirements for class certification. Gonzalez v. Corning, 885 F.3d 186, 192 (3d Cir. 2018). As relevant here, Rule 23(b)(3) requires that common questions predominate and Rule 23(a)(4) requires that the named plaintiffs adequately represent the class, two requirements Reckitt disputes are satisfied.

A

Rule 23(b)(3) requires that "questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). "To assess predominance, a court ... must examine each element of a legal claim through the prism of Rule 23(b)(3)" by determining whether each element is "capable of proof at trial through evidence that is common to the class rather than individual to its members." Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 600 (3d Cir. 2012) (internal quotation marks and citations omitted). The Purchasers' claims require them to prove (1) "a violation of the antitrust laws" (here, unlawful monopolization by Reckitt); [7] (2) "individual injury resulting from that violation"; and (3) "measurable damages." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008), as amended (Jan. 16, 2009).

1

Reckitt first argues that the Purchasers have not provided common evidence of injury or damages [8] that matches a viable theory of liability, as required by Comcast Corp. v. Behrend, 569 U.S. 27, 37-38, 133 S.Ct. 1426, 185 L.Ed.2d 515 (2013) (holding that class certification was inappropriate when a damages model reflected injury from four antitrust injuries, but only one viable theory of antitrust liability and injury remained in the case). Reckitt does not dispute that the Purchasers have provided common evidence showing that the class paid more for Suboxone products. Reckitt, however, argues that it could lawfully raise the prices on Suboxone tablets and change its rebate program, [9] so the Purchasers do not have an antitrust injury.

***4** The Purchasers' theory of their case, however, "is not [simply] that Reckitt's pricing of brand tablets individually caused harm." Class Certification, 421 F. Supp. 3d at 62. Rather, they allege that the totality of Reckitt's actions, such as raising prices, withdrawing tablets from the market, providing rebates only for film, disparaging the safety of tablets, and delaying the generics' entry by filing a citizen petition and not cooperating in the REMS process, suppressed generic competition and thus violated the antitrust laws. They contend that such conduct resulted in the following antitrust injury: having to pay more for brand Suboxone products when less-expensive generic tablets should have been available but were not because of Reckitt's actions. [10] Reckitt incorrectly asks us to examine each of these acts individually. Rather, we look at "all the acts taken together [to determine whether they] show the willful acquisition or maintenance of a monopoly." Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 813 (3d Cir. 1984); see also Phila. Taxi Ass'n, Inc. v. Uber Techs., Inc., 886 F.3d 332, 339 (3d Cir.) (explaining that we "look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation" (citation omitted)), cert. denied, —— U.S. ——, 139 S. Ct. 211, 202 L.Ed.2d 126 (2018). The common evidence here would be used to prove that these actions occurred and together suppressed generic competition, and thereby caused the Purchasers to buy the higher-priced brand Suboxone products because Reckitt's actions made it difficult for the less expensive generics to compete. [11] Thus, common evidence exists to prove the Purchasers' antitrust theory and the resulting injury.

2

Next, Reckitt argues that the Purchasers did not satisfy the predominance requirement because their damages model only calculates aggregate damages, and the eventual need for individualized damages inquiries defeats predominance. Reckitt is incorrect. Antitrust plaintiffs may satisfy the predominance requirement by using a model that estimates the damages attributable to the antitrust injury, even if more individualized determinations are needed later to allocate damages among class members. In re Modafinil Antitrust Litig., 837 F.3d 238, 262 (3d Cir. 2016), as amended (Sept. 29, 2016). [12] For example, in Modafinil, a brand-name manufacturer entered into agreements with four manufacturers to hold off marketing generic versions of the drug, id. at 245, and direct-purchaser plaintiffs "created a damages model that calculated the savings to the class

if generic entry had occurred earlier," id. at 262. The defendants argued that this model was insufficient because it did not "attribute a certain amount of harm" from each agreement or "identify which class members were harmed by which [agreement]." Id. We rejected the need to show each class member suffered identical damages because "Plaintiffs' theory of liability is not that each individual agreement caused an individual harm," but instead "that each individual agreement contributed to the market-wide harm" and this "match[ed] Plaintiffs' damages theory." Id.

***5** Like in Modafinil, the Purchasers' model does not measure how Reckitt's scheme harmed each class member and recognizes that there could be differences among the class members concerning the precise damages they suffered. Individualized determinations, however, are of no consequence in determining whether there are common questions concerning liability. See id.; see also Tyson Foods, Inc. v. Bouaphakeo, ––– U.S. ––––, 136 S. Ct. 1036, 1045, 194 L.Ed.2d 124 (2016) ("[T]he action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately, such as damages...." (citation omitted)). Rather, we need be assured only that common issues predominate. See Tyson Foods, 136 S. Ct. at 1045. Such is the case here because the Purchasers' theory of injury and damages is provable and measurable by an aggregate model relying on class-wide data. [13] Although allocating the damages among class members may be necessary after judgment, "such individual questions do not ordinarily preclude the use of the class action device." Id. Thus, the District Court correctly found that common issues predominate.

B

Finally, Reckitt argues that Burlington is not an adequate class representative. Rule 23(a)(4) requires a district court to find that "representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent." In re Nat'l Football League Players Concussion Injury Litig. (NFL), 821 F.3d 410, 431 (3d Cir. 2016) (quoting Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 625, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997)). For a class representative to be adequate, it must have "[a] minimal degree of knowledge" about the case, id. at 430 (quoting New Directions Treatment Servs. v. City of Reading, 490 F.3d 293, 313 (3d Cir. 2007)), and have no conflict of interest with class counsel, e.g., Larson v. AT & T Mobility LLC, 687 F.3d 109, 132 (3d Cir. 2012), and members of the class, Dewey v. Volkswagen Aktiengesellschaft, 681 F.3d 170, 183-84 (3d Cir. 2012). [14] Only "fundamental" conflicts "will defeat the adequacy requirement." Dewey, 681 F.3d at 184.

Reckitt argues that the Purchasers failed to satisfy the adequacy requirement because Burlington has a risk of a conflict with class counsel and lacks control over the litigation, precluding it from protecting the class. Both arguments fail. First, each conflict that Reckitt identifies is speculative or without basis. Reckitt suggests that class counsel and the class representative could have conflicting views on (1) what allegations should be made, (2) who should be named as a defendant, (3) whether to accept a settlement, (4) whether to go to trial, and (5) whether litigation decisions will have effects on other cases. Such hypothetical conflicts cannot defeat adequacy. Id. ("A conflict that is unduly speculative, however, is generally not fundamental."); see also id. (noting that the adequacy requirement can be satisfied when "[a]t this stage in the litigation, the existence of such conflicts is hypothetical" (quoting Kohen v. Pac. Inv. Mgmt. Co. LLC, 571 F.3d 672, 680 (7th Cir. 2009))). [15]

***6** Second, Reckitt's claim that Burlington has ceded control of this litigation to class counsel, and that this creates a risk of conflicts, does not render Burlington an inadequate representative. Reckitt cites no precedent from this Court for its argument that a class representative must "control" the litigation. Indeed, we have observed that "it is counsel for the class representative and not the named parties ... who direct and manage [class] actions. Every experienced federal judge knows that any statements to the contrary [are] sheer sophistry." In re Cmty. Bank of N. Va., 622 F.3d 275, 292 (3d Cir. 2010) (alterations and omission in original) (quoting Greenfield v. Villager Indus., Inc., 483 F.2d 824, 832 n.9 (3d Cir. 1973)). Moreover, Burlington is not a disengaged representative. The record shows that Burlington is aware of its role as a fiduciary, understands the basis for the claimed injury, has an incentive to recover its proportionate share of damages, monitors the litigation, produced documents, and has the requisite interest in and knowledge about the case to satisfy the adequacy requirement. NFL, 821 F.3d at 430; In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 784 (3d Cir. 1995).

Accordingly, Reckitt's attack on Burlington's adequacy as class representative lacks merit.

III

For the foregoing reasons, we will affirm the District Court's order certifying a direct purchaser class.

All Citations

--- F.3d ----, 2020 WL 4331523

Footnotes

1 An "AB-rating" denotes that the generic is "bioequivalent" and "pharmaceutically equivalent to the brand drug, meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 645 (2d Cir. 2015).

2 The FDA can require REMS from manufacturers to ensure that the benefits of a drug outweigh its risks. 21 U.S.C. § 355-1(a)(1). A REMS can include elements such as medication guides, package inserts, and communication plans for healthcare providers. § 355-1(e). If the FDA requires a REMS for a generic product, the FDA can require that the ANDA sponsor coordinate with the brand-name to create a Single Shared REMS program. § 355-1(i). However, brand-name manufacturers cannot use REMS "to block or delay approval of" ANDAs. § 355-1(f)(8).

3 Persons or entities can raise concerns to the FDA regarding drug approvals through a citizen petition, and "[t]he filing of a citizen petition can substantially delay approval of a generic drug." FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 152 (3d Cir. 2019). Congress has passed restrictions on using citizen petitions to delay drug approvals. Id. at 152 n.7.

4 This appeal concerns only the Purchasers.

5 As the Purchasers clarified at oral argument, the class consists of direct purchasers of name-brand Suboxone tablets, but the alleged injuries are for paying more for name-brand tablets and, for certain members who also purchased film, paying more for film as a result of Reckitt's alleged anticompetitive conduct. Therefore, the damages the Purchasers seek are overcharges for name-brand tablets, and paying more for name-brand tablets and film than they would have for generic tablets.

6 The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15(a). We have jurisdiction under 28 U.S.C. § 1292(e) and Federal Rule of Civil Procedure 23(f).
"We review a class certification order for abuse of discretion, which occurs if the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." Grandalski v. Quest Diagnostics Inc., 767 F.3d 175, 179 (3d Cir. 2014) (internal quotation marks and citation omitted).

7 Section 2 of the Sherman Act makes it unlawful to "monopolize, or attempt to monopolize ... any part of the trade or commerce among the several States." 15 U.S.C. § 2.

8 "Proof of injury (whether or not an injury occurred at all) must be distinguished from calculation of damages (which determines the actual value of the injury)." In re Lamictal Direct Purchaser Antitrust Litig., 957 F.3d 184, 194-95 (3d Cir. 2020) (quoting Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 188 (3d Cir. 2001), as amended (Oct. 16, 2001)).

9 Reckitt acknowledges, however, that nonpricing conduct, such as the allegations that Reckitt falsely disparaged the tablets' safety, if proven, would be unlawful and subject to common evidence.

10 Reckitt's price-cost argument is inapt. This case is not one involving a pricing scheme alone. Rather, this case includes a scheme to suppress generic competition through a series of actions that will be proven by common evidence. Higher tablet pricing and the cancellation of tablet rebates were just two acts used to keep generic tablets out of the market, and which led the Purchasers to pay for higher priced Suboxone tablets when, in a competitive market, they would have been able to purchase less expensive generic tablets. When reviewing similar allegations, we have held that common evidence that class members paid higher prices than they otherwise would have easily satisfies the predominance standard. In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 528 (3d Cir. 2004).

11 Reckitt relies mainly on Comcast, 569 U.S. 27, 133 S.Ct. 1426, to argue that the Purchasers' theory of injury for which they have common evidence does not match any viable theory of liability, so certification is wrong. Comcast is distinguishable. In Comcast, plaintiffs alleged four theories of antitrust injury, but the district court certified a class based on one theory. 569 U.S. at 31, 133 S.Ct. 1426. The damages model plaintiffs used estimated damages based on the combined effects of all four theories; but the district court held that certification was still proper. Id. at 31-32, 133 S.Ct. 1426. The Supreme Court held that class certification was wrong because "the model failed to measure damages resulting from the particular

antitrust injury on which petitioners' liability in this action is premised." Id. at 36, 133 S.Ct. 1426. That is, the model "identifie[d] damages that are not the result of the wrong" suffered by the certified class. Id. at 37, 133 S.Ct. 1426.

This case is unlike Comcast because there is only one theory of antitrust injury, and that theory corresponds to a theory of liability. To make Comcast seem applicable, Reckitt construes the Purchasers' claim as one alleging that Reckitt unlawfully raised prices (the liability theory, which Reckitt argues is not viable), and the Purchasers paid higher prices as a result (the injury theory). Raising prices, however, was just one aspect of Reckitt's alleged monopolistic conduct, which is better described as a multifaceted yet single scheme to move the market to Suboxone film to stifle competition from generic tablets. As a result, the Purchasers could not purchase less-expensive generic tablets. Thus, while Reckitt would argue that each of the six allegedly anticompetitive actions represents a different theory of liability, in fact there is one theory of liability proven by a variety of acts resulting in one antitrust injury.

12 See also Kleen Prods. LLC v. Int'l Paper Co., 831 F.3d 919, 929 (7th Cir. 2016) (upholding use of aggregate damages model and explaining that "at the class certification stage, plaintiffs are not obliged to drill down and estimate each individual class member's damages," as "the allocation of that total sum among the class members can be managed individually"); Vaquero v. Ashley Furniture Indus., Inc., 824 F.3d 1150, 1155 (9th Cir. 2016) (same); Carriuolo v. Gen. Motors Co., 823 F.3d 977, 988 (11th Cir. 2016) (same).

13 To calculate aggregate damages, Dr. Lamb relied on Reckitt's sales data and explained that he could allocate individualized damages based on this same data. Accordingly, even individualized damages assessments would require common evidence. Moreover, in this case, the class includes seventy-two direct purchasers seeking only to recover the money spent to buy name-brand Suboxone products that would not have been spent had generic competition existed, and not lost profits. Reckitt has produced their sales information. From this common evidence, the Purchasers proposed a trial plan for the pro rata allocation of Purchasers' damages. See In re Lidoderm Antitrust Litig., No. 14-md-02521-WHO, 2017 WL 679367, at *11 (N.D. Cal. Feb. 21, 2017) (approving aggregate damages model using pro rata formula); see also Lamictal, 957 F.3d at 194-95 (observing that "damages need not be 'susceptible of measurement across the entire class for purposes of Rule 23(b)(3)' " (quoting Modafinil, 837 F.3d at 260)).

14 Reckitt does not dispute that Burlington has a minimal degree of knowledge of the litigation.

15 Further, Reckitt's hypothetical conflicts would apply to most class actions. For example, Reckitt suggests as one conflict that class representatives may seek to add defendants to increase potential recovery, while class counsel might avoid adding defendants due to "the cost of complicating the case" and "extending the timetable before resolution." Appellant's Br. at 50. Such a conflict is possible in many class actions. Ironically, however, this conflict is not even at risk in this case because the Purchasers' allegations and facts focus exclusively on Reckitt, and there is no other defendant to add.