4-22-2020

In re: Lamictal Direct Purchas

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 19-1655

In re: Lamictal Direct Purchaser Antitrust Litigation

GlaxoSmithKline, LLC
d/b/a SmithKline Beecham Corporation;
Teva Pharmaceuticals USA, Inc.;
Teva Pharmaceuticals Industries Ltd.,

Appellants

Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil Action No. 2-12-cv-00995)
District Judge: Honorable William H. Walls

Argued March 9, 2020

Before: AMBRO, KRAUSE, and PHIPPS, Circuit Judges

(Opinion filed: April 22, 2020)

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OPINION OF THE COURT

AMBRO, Circuit Judge,

This case is the latest in the years-long antitrust battle over whether GlaxoSmithKline ("GSK") and Teva Pharmaceuticals ("Teva") violated the antitrust laws through their settlement agreement to end an unrelated patent dispute over GSK's brand drug Lamictal and Teva's generic form lamotrigine. We need not reach the antitrust issues here, however, for we are concerned at present only with the District Court's class certification analysis, specifically whether common issues pertaining to the class predominate over individual issues.

Though judges must conduct a "rigorous analysis" of the facts, evidence, and arguments submitted at the class certification stage, the District Court certified this class without undertaking the analysis needed by failing to resolve key factual disputes, assess competing evidence, and weigh conflicting expert testimony, all of which bear heavily on satisfaction of the predominance requirement. Moreover, the Court confused injury with damages, despite our precedent distinguishing the two and applying a different predominance standard to each. In this context, we cannot determine whether common issues predominate, and thus we vacate and remand for a redo.

I. FACTUAL AND PROCEDURAL BACKGROUND

GSK is a pharmaceutical manufacturer that holds the patent to an anti-epilepsy drug called Lamictal. It began selling

Lamictal in 1994, and its patent was set to expire in early 2009. A patent generally excludes all other competitors from producing a drug with the same active ingredient until patent expiration. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015).

Teva is a drug maker that manufactures a generic version of Lamictal called lamotrigine. Importantly, it sought to begin marketing lamotrigine before GSK's patent on Lamictal expired.

Congress provided a pathway for Teva to do so through the Hatch-Waxman Act of 1984.[1] The Act permits a generic drug manufacturer seeking Food and Drug Administration ("FDA") approval to submit an Abbreviated New Drug Application ("ANDA") that relies on the *brand* drug's safety and efficacy studies submitted as part of that drug's New Drug Application. 21 U.S.C. § 355(j). Of several bases for filing an ANDA, one is known as a "paragraph IV" certification, in which the would-be generic manufacturer certifies that any patent protecting the brand drug is either invalid or would not be infringed by the new generic. *Id.* § 355(j)(2)(A)(vii). The Act encourages generic manufacturers to enter the market by granting the first generic to file an ANDA with paragraph IV certification (the "first filer") a 180-day exclusivity period during which only that generic, along with the brand drug, may be marketed. *See id.* § 355(j)(5)(B)(iii)–(iv). This exclusivity period is immensely profitable for the generic because it effectively grants the first filer a temporary monopoly over the generic market. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013). Because generics can rely on the safety and efficacy studies of the brand drug, they need not engage in their own

[1] The Act is officially referred to as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585.

lengthy and expensive clinical trials, and so they are priced below that of the brand. *See id.* at 142.

When a generic certifies on its ANDA that the brand's patent is invalid or will not be infringed by the generic, that certification "automatically counts as patent infringement," *Actavis*, 570 U.S. at 143, and often "provok[es] litigation" from the brand. *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 244 (3d Cir. 2016), *as amended* (Sept. 29, 2016) (citation omitted). If so, FDA approval of the generic is withheld for 30 months or until resolution of the litigation, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii); *see also King Drug Co.*, 791 F.3d at 396 n.9.

In April 2002, Teva filed the relevant paragraph IV ANDAs, and GSK followed suit by suing for patent infringement. *See King Drug Co.*, 791 F.3d at 397 (reciting the history of this litigation). But after Teva received a favorable ruling in a bench trial with respect to one of the infringement claims in 2005, the parties settled. As part of the settlement, Teva would begin selling lamotrigine on July 22, 2008, six months before it could have had GSK won the lawsuit, but later than it could have had it succeeded in litigation. In exchange, GSK promised not to launch its own generic version of Lamictal, known as an "authorized generic" ("AG").

AGs are generics launched by the brand manufacturer itself (or an authorized third-party distributor) via the brand's drug application rather than by a separate manufacturer via an ANDA. *See* FTC, *Authorized Generic Drugs: Short–Term Effects and Long-Term Impact* 1, 12 (2011), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf. Had the parties not settled and had Teva succeeded in the patent litigation, it would have been entitled to the 180-day exclusivity period as the generic first filer. But GSK nonetheless could have launched an AG to compete with

Teva's generic drug, as an AG is submitted as part of the brand's own drug application. *King Drug Co.*, 791 F.3d at 395–96. If the brand manufacturer, however, agrees not to launch an AG, the potential antitrust concern is the agreement will reduce competition, thereby keeping prices higher for longer and harming consumer welfare. *See id.* at 404–05.

That brings us to the issue in this case. After GSK and Teva settled the patent litigation, plaintiffs—companies that directly purchased brand Lamictal from GSK or lamotrigine from Teva ("Direct Purchasers")—filed suit, claiming the settlement violated the antitrust laws as an impermissible "reverse payment agreement" whereby GSK "paid" Teva to stay out of the market by promising not to launch an AG.[2] They argue that but for the alleged reverse payment, Teva would have launched lamotrigine sooner and GSK would have launched an AG the very day Teva entered the market. As a result, they contend they paid more for the drugs than they would have otherwise. Their theory of liability, at least with respect to those entities that purchased lamotrigine from Teva during the six-month period, is premised on the principle that, on average, the price of a generic is lower when there are two generics rather than just one.

GSK and Teva contend that even though GSK was precluded by the settlement from launching an AG, it still competed with Teva on price during the exclusivity period

[2] We previously reversed the grant of GSK and Teva's motion to dismiss in *King Drug Co.*, holding the "no-AG agreement falls under *Actavis*'s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." 791 F.3d at 394.

through its so-called Contracting Strategy. GSK claims that it had long been concerned about the effectiveness of launching an AG because doctors seemed more reluctant to switch patients from one epilepsy drug to another, meaning that those who started patients on brand Lamictal would be less inclined to switch them to a lower-priced generic once one launched. Thus GSK planned to take advantage of this nuance in the anti-epilepsy drug market and compete aggressively with Teva on price by contracting with targeted pharmacies to offer them significant discounts and rebates if they agreed to sell brand Lamictal instead of Teva's generic version. Further, and critical to their defense, GSK and Teva assert that the latter learned about this strategy *before* it began selling lamotrigine, and thus it preemptively lowered its lamotrigine prices in order to compete. As a result, GSK and Teva argue that some Direct Purchasers never paid more for lamotrigine than they would have absent the settlement.

The Direct Purchasers moved to certify a class of all companies that purchased Lamictal directly from GSK or generic lamotrigine from Teva. That noted, GSK and Teva challenge only certification as to the members who purchased generic lamotrigine from Teva (hence any reference to the Direct Purchasers that follows is limited to those Direct Purchasers). The District Court certified the class; at issue is whether this holds up.

GSK and Teva brought this timely interlocutory appeal.

II. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1337. We granted GSK and Teva's petition for leave to appeal under Federal Rule of Civil Procedure 23(f), and so have appellate jurisdiction under 28 U.S.C. § 1292(e).

We review a class certification order for abuse of discretion, which occurs if a district court's decision rests on a "clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 312 (3d Cir. 2009), *as amended* (Jan. 16, 2009) (citation omitted). "[W]hether an incorrect legal standard has been used is an issue of law to be reviewed *de novo*." *Id.* (alteration in original) (citation omitted). A District Court "errs as a matter of law when it fails to resolve a genuine legal or factual dispute relevant to determining the requirements" of Rule 23. *Id.* at 320.

III. DISCUSSION

A. The Analysis Required to Certify a Class

1. The Basics

Federal Rules of Civil Procedure 23(a) and (b) set the requirements for class certification. Rule 23(a) requires that

> (1) the class must be so numerous that joinder of all members is impracticable (numerosity); (2) there must be questions of law or fact common to the class (commonality); (3) the claims or defenses of the representative parties must be typical of the claims or defenses of the class (typicality); and (4) the named plaintiffs must fairly and adequately protect the interests of the class (adequacy of representation, or simply adequacy).

Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 590–91 (3d Cir. 2012) (citation and internal quotation marks omitted). Rule 23(b)(3), as relevant here, "requires that (i) common questions of law or fact predominate (predominance), and (ii) the class

action is the superior method for adjudication (superiority)." *Id.* (citation omitted).

GSK and Teva challenge only the District Court's predominance finding. Stated more expansively, a plaintiff "must 'demonstrate that the element of [the legal claim] is capable of proof at trial through evidence that is common to the class rather than individual to its members.'" *Marcus*, 687 F.3d at 600 (alteration in original) (quoting *Hydrogen Peroxide*, 552 F.3d at 311). "Because the nature of the evidence that will suffice to resolve a question determines whether the question is common or individual, a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." *Id.* (citation omitted). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." *Hydrogen Peroxide*, 552 F.3d at 311 (citation omitted).

To determine whether the putative class has satisfied predominance (indeed, all applicable Rule 23 requirements), the District Court must conduct a "rigorous analysis" of the evidence and arguments presented. *Id.* at 309 (quoting *Gen. Tel. Co. of the Sw. v. Falcon*, 457 U.S. 147, 161 (1982)). That involves three key aspects. First, the court must "find[]" that the requirements of Rule 23 are met and any "[f]actual determinations supporting Rule 23 findings must be made by a preponderance of the evidence." *Id.* at 307. Second, "the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits." *Id*; *see also Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011) ("That [overlap] cannot be helped."); *Marcus*, 687 F.3d at 591 ("Rule 23 gives no license to shy away from making factual findings that are necessary to determine whether the Rule's requirements have been met."). Third, the court must consider "all relevant evidence and arguments," including "expert

testimony, whether offered by a party seeking class certification or by a party opposing it." *Hydrogen Peroxide*, 552 F.3d at 307. If, after all that, the Court is convinced by a preponderance of the evidence that the plaintiffs' claims are capable of common proof at trial, then the predominance requirement is satisfied.

2. The Predominance Inquiry Here

The Direct Purchasers contend that they need not prove antitrust injury at this stage, but rather it suffices if they show only that injury is capable of common proof at trial. True enough. *See Hydrogen Peroxide*, 552 F.3d at 311–12. But they go further and say that our case is controlled by a comment in *Tyson Foods v. Bouaphakeo*, 136 S. Ct. 1036 (2016), that suggests an even lower standard for predominance whereby that criterion is satisfied unless no reasonable juror could believe the common proof at trial.

In *Tyson Foods*, the Supreme Court was reviewing a motion to decertify a class brought under the Fair Labor Standards Act of 1938 (FLSA), 29 U.S.C. §§ 201 *et seq.*, after a jury had already rendered a verdict in favor of the plaintiff class. In considering whether representative evidence was sufficient to satisfy the predominance requirement, the Court wrote that "[t]he District Court could have denied class certification on this ground only if it concluded that *no reasonable juror* could have believed that the employees spent roughly equal time donning and doffing" their protective gear. *Tyson Foods*, 136 S. Ct. at 1049 (emphasis added). According to the Direct Purchasers, this means that so long as their evidence of class-wide antitrust injury could sustain a jury finding, they meet the predominance requirement.

But contrary to the Direct Purchasers' assertion, *Tyson Foods* does not control our case, and its no-reasonable-juror

statement certainly does not overturn our longstanding rule announced in *Hydrogen Peroxide*, and reiterated in many a case, that a putative class must demonstrate that its claims are capable of common proof at trial by a preponderance of the evidence. *See, e.g.*, *Modafinil*, 837 F.3d at 248–49; *Marcus*, 687 F.3d at 591; *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 219–20 (3d Cir. 2012) (subsequent history omitted). First, *Tyson Foods* was discussing representative evidence in the FLSA context, a unique labor situation in which, often due to inadequate record keeping, "a representative sample [of employees] may be the only feasible way to establish liability." *Tyson Foods*, 136 S. Ct. at 1040; *see also Anderson v. Mt. Clemens Pottery Co.*, 328 U.S. 680, 685–88 (1946). In those cases, the accuracy and representativeness of the sample is critical, for each class member must be able to rely on that evidence in his own trial to prove liability under the FLSA. *Tyson Foods*, 136 S. Ct. at 1048. Indeed, the only two Courts of Appeals to pick up on this language did so in that context. *See Senne v. Kan. City Royals Baseball Corp.*, 934 F.3d 918, 940–41 (9th Cir. 2019) (holding in an FLSA case that the "no reasonable juror" standard applies to admissible expert testimony at the class certification stage); *Monroe v. FTS USA, LLC*, 860 F.3d 389, 400 (6th Cir. 2017) (suggesting in an FLSA case, albeit in dicta, that *Tyson Foods*'s "no reasonable juror" comment "concerned how district courts should assess the representativeness of an expert's statistical average for class certification purposes"). Second, the Court in *Tyson Foods* was asked to decertify a class *after* the jury had rendered a verdict in favor of the plaintiff class, but, finding the jury could reasonably have relied on the representative evidence, it declined to do so. 136 S. Ct. at 1047–48. Here, by contrast, the District Court reviewed the class certification motion on a blank slate.

Our non-FLSA class certification decisions that post-date *Tyson Foods* have reiterated that district courts are

required, per *Hydrogen Peroxide*, to resolve factual determinations by a preponderance of the evidence at the class certification stage.[3] *See, e.g., Ferreras v. Am. Airlines, Inc.*, 946 F.3d 178, 183 (3d Cir. 2019) ; *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483–84 (3d Cir. 2018); *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 304 (3d Cir. 2016). We hold that our standard—plaintiffs must prove their claim is capable of common proof by a predominance of the evidence—continues to apply to class certification determinations outside of the FLSA context.

With that in mind, we turn to the Direct Purchasers' claim. The injury element is at issue here. Recall that their theory of liability is that they suffered an antitrust injury because but for the reverse-settlement agreement, each would have paid less for lamotrigine than it actually did. This requires the Direct Purchasers to prove by a preponderance of the evidence that they could establish, through *common* proof at trial, facts supporting an antitrust injury, namely: 1) GSK would have launched an AG but for the reverse-settlement; and 2) as a result, all class members would have paid less for lamotrigine in this but-for world. If each individual class member could rely on this same proof to prove the elements of its claim, then the injury is capable of common proof at trial.

3. Whether the Direct Purchasers' Claims Are Capable of Common Proof

GSK and Teva opposed certification, arguing before the District Court that the Direct Purchasers were unable to show that injury is capable of common proof at trial because their proof impermissibly relies on averages, which, in a market

[3] We recognize that whether the *Tyson Foods* no-reasonable-juror standard should control was not squarely presented in those cases.

characterized by individual negotiations and a discounted-brand competition strategy, masks the fact that many—up to one-third of the entire class—likely paid no more, or even *less*, for lamotrigine than they would have if GSK had launched an AG. Because each class member could not rely on the same common evidence to show injury, individual issues predominate; hence they contend the District Court erred by accepting the Direct Purchasers' expert testimony that relied on these averages without conducting a rigorous analysis of the competing expert reports and resolving the competing factual disputes on which the reports rely.

We agree that a more rigorous analysis is needed. The District Court refused to "address the multi-leveled microeconomic analysis of what each Defendant would or would not have possibly done in the but-for world, and instead focuse[d] on whether the presence of the Contracting Strategy raises individualized issues that defeat predominance." *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, No. 12-CV-00995, 2018 WL 6567709, at *6 (D.N.J. Dec. 12, 2018). Without that inquiry, it is impossible to determine whether the Contracting Strategy raised individualized issues.

The Direct Purchasers' expert, Dr. Russell Lamb, opined that evidence common to the proposed class as a whole "demonstrates that the prices paid by all or nearly all proposed Class members for lamotrigine tablets were impacted (artificially inflated) by the allegedly illegal agreement between GSK and Teva," and thus the class was "injured by the Defendants' alleged[ly] anticompetitive conduct." J.A. 487–88. This "common evidence" includes: (1) economic literature showing that, on average, prices of generics are lower as more enter the market; (2) Teva's own general pricing forecast tending to discount a generic by 50% without competition, but by 65% when facing an additional competitor; and (3) transaction-level sales data showing that the average

actual price paid was consistent with these predictions. Lamb also created a model purporting to show the price each purchaser would have paid absent the settlement, and he opined that the prices would have been lower both had GSK just launched an AG[4] *and* had it launched an AG along with the Contracting Strategy. But, as GSK and Teva accurately point out, that model still relies on an *average* hypothetical price, which again fails to account for individual negotiations or the effect of GSK's Contracting Strategy on each Direct Purchaser.

GSK and Teva's expert, Dr. James Hughes, countered that it is "not possible, absent individualized inquiry, to determine whether any particular member of the proposed [c]lass suffered injury in the form of higher prices as a result of the alleged anticompetitive conduct." J.A. 265–66. He rebutted many of Dr. Lamb's findings, primarily criticizing the use of averages—contending that Lamb committed "meaningful error" when he assumed an aggregate "actual" price that he applied to all class-members, which failed to acknowledge that purchasers paid "dramatically different prices," dropped charge-backs and discounts, and ignored low "outlier" prices. Further, Dr. Hughes criticized Dr. Lamb's reliance on general forecasting documents using average prices, rather than lamotrigine-specific prices. Hughes created his own model, using lamotrigine-specific prices from Teva company documents, to show that, when accounting for Teva's preemptive response to the Contracting Strategy, the price of

[4] While the parties dispute whether GSK would have used both strategies—launching an AG and engaging in the Contracting Strategy—simultaneously, Lamb conducted a "sensitivity analysis" as part of his model purporting to show that, either way, the price of lamotrigine would have been lower absent the settlement agreement.

lamotrigine was likely *lower* for some purchasers than it would have been had GSK launched an AG. Based on this, Hughes found that 25 of the 33 generic-only purchasers likely paid the same or lower prices in the actual world under the Contracting Strategy than they would have paid had GSK launched an AG. In effect, the amount each purchaser would have paid absent the settlement required an individual analysis because Teva did not respond to the Contracting Strategy uniformly.

Here, the District Court abused its discretion when it assumed, absent a rigorous analysis, that averages are acceptable. As is clear from the dueling expert reports, the acceptability of averages depends largely on the answer to several factual predicates, most importantly: 1) whether the market is characterized by individual negotiations; 2) whether Teva preemptively lowered its pricing in response to the Contracting Strategy; and 3) whether and to what extent GSK, absent the settlement agreement, would or could have pursued both the Contracting Strategy and an AG. The Court did not resolve these factual disputes, which would have required it to weigh the competing evidence and make a prediction as to how they would play out at trial. Further, much of each expert's analysis turned on his sources of evidence for pricing and discounting data, many of which were in tension. It was up to the District Court to scrutinize the evidence to determine what was credible and could be used in the expert analysis.

This lack of analysis perhaps was due to the Court's assumption that antitrust injury here occurred "at the moment the price of generic lamotrigine was artificially inflated by the no-AG agreement, even if GSK's Contracting Strategy later on possibly eroded some or all of the inflated price." *Lamictal*, 2018 WL 6567709, at *6. But that assumption misunderstood GSK and Teva's argument—the prices were never inflated to begin with because Teva preemptively lowered its prices before launching; thus some Direct Purchasers never suffered

an overcharge. But the District Court cannot simply make that assumption—rather, whether Teva preemptively lowered its prices is a factual matter hotly contested by the parties. And the Court was required to resolve that dispute by a preponderance of the evidence.

Thus, contrary to the District Court's belief, addressing the micro-level analysis here, even though it touches on the merits, was necessary in order to determine whether the Direct Purchasers, in light of the competing expert reports and evidence, could show that common issues predominated by a preponderance of the evidence. While averages may be acceptable where they do not mask individualized injury, *see Gates v. Rohm & Haas Co.*, 655 F.3d 255, 266 (3d Cir. 2011), we cannot determine whether that occurred here because of the lack of analysis. Accordingly, we vacate and remand for the District Court to analyze the evidence and arguments submitted as part of class certification.

B. Injury and Damages

To compound matters, the District Court appears to have treated the parties' arguments as a dispute about damages, rather than antitrust injury, reasoning that "[t]he use of averages to develop the aggregate amount of *damages* does not suggest [the Direct Purchasers] will be unable to ensure recovery is only for *injured* parties." *Lamictal*, 2018 WL 6567709, at *6 (alteration in original) (emphases added) (citation omitted). That was amiss, as averages here were used to show *injury—i.e.*, the Direct Purchasers were overcharged for lamotrigine because of the reverse-settlement—in addition to damages.

We have consistently distinguished injury from damages. *See, e.g.*, *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 188 (3d Cir. 2001), *as amended*

(Oct. 16, 2001) *(*"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)."). This is significant, as we apply a more lenient predominance standard for damages than for injury. While every plaintiff must be able to show antitrust injury through evidence that is common to the class, *see Hydrogen Peroxide*, 552 F.3d at 311, damages need not be "susceptible of measurement across the entire class for purposes of Rule 23(b)(3)," *Modafinil*, 837 F.3d at 260 (citation omitted). *Accord Tyson Foods*, 136 S. Ct. at 1045 ("When one or more of the central issues in the action . . . can be said to predominate, the 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 and internal quotation marks omitted). This merging of differing standards led the District Court to apply our more permissive damages standard to the class certification question, reasoning "that some generic purchasers were injured more or less strongly than others is not only permitted, but is a reason for why averages are appropriate in the damages calculation." *Lamictal*, 2018 WL 6567709, at *7 (footnote omitted). This misreading also calls for a remand.

IV. CONCLUSION

Because the District Court did not conduct a rigorous analysis of the competing expert reports that rely on competing evidence and assume competing facts, we are unable in the first instance to determine whether the Direct Purchasers have met the predominance requirement by a preponderance of the evidence. Also, the Court incorrectly conflated injury with damages in its analysis. We therefore vacate the class certification order and remand for the District Court to conduct the required analysis.