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Analysis: Lamictal highlights increased class action scrutiny in pharma cases.

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The US Court of Appeals for the Third Circuit on 22 April vacated class certification in a lawsuit alleging that GlaxoSmithKline and Teva suppressed generic competition to Lamictal, an anticonvulsant used to treat epilepsy and bipolar disorder. White & Case partner ***Michael Hamburger****, senior associate* ***Adam Acosta*** *and associate* ***Gina Chiappetta*** *analyse how the appellate court's decision fits into a broader trend of courts clamping down on class certification in pharmaceutical cases.*

The Third Circuit's decision to vacate class certification in Lamictal is the latest in a series of recent judgments rejecting proposed classes in pharmaceutical antitrust cases. In Lamictal, the district court failed to scrutinise the competing proof offered by the parties to ensure that each element of Rule 23 – which sets out the criteria for obtaining class certification – was met by a preponderance of the evidence. In reversing, the Third Circuit emphasised six separate times that trial courts must engage in a "rigorous analysis" of the evidence and arguments at the class certification stage. It further confirmed that putative classes must do more than point to classwide averages when defendants offer evidence suggesting that such averages mask material differences among proposed class members.

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Lamictal and other recent decisions refusing to certify classes of pharmaceutical purchasers, including the US Court of Appeals for the First Circuit's October 2018 decision in Asacol and the Third Circuit's earlier decision in Modafinil, follow from the same general rule that the Supreme Court has repeatedly announced: Rule 23 means what it says and each requirement must be established before a class can be certified. Here, we briefly discuss these cases and the related implications for parties litigating whether a pharmaceutical purchaser class should be certified.

Lamictal

The direct purchaser plaintiffs in Lamictal alleged that a patent litigation settlement involving anti-epilepsy drug Lamictal constituted an anticompetitive reverse payment agreement under the Supreme Court's FTC v Actavis decision. In support of class certification, they argued that common evidence, such as general pricing information from economic literature as well as forecasts and transactional data, showed that average generic drug prices decrease as more generic competitors enter a market. Because plaintiffs alleged that the settlement prevented more generic competitors from entering earlier, they argued that their common evidence proved that generic Lamictal prices would have been lower if not for the settlement agreement. They further argued that common impact was established because their expert had prepared a model, which also relied on hypothetical average prices, showing that each class member would have paid less for generic Lamictal if not for the challenged settlement. Even though defendants opposed using averages in this manner to prove injury to each class member, the district court held that plaintiffs' evidence satisfied Rule 23's predominance requirement and certified a direct purchaser class.

On interlocutory appeal, the Third Circuit disagreed and vacated the certification order, faulting the district court for not engaging in a "rigorous analysis" of the evidence or resolving several factual disputes concerning plaintiffs' reliance on averages. For instance, the brand manufacturer claimed that it contracted with pharmacies and promised significant discounts and rebates to those who sold its branded Lamictal product instead of the generic version. Meanwhile, the generic manufacturer contended that it learned about the brand company's contracting strategy prior to launching its competing generic product and therefore preemptively lowered the price of its generic product to compete. But in plaintiffs' hypothetical world, the brand company would have simply launched its own generic product to compete, rather than, or in addition to, adopting its contracting strategy.

According to the defendants' expert, by relying on averages and not accounting for the generic companies' pre-emptive price lowering and individualised negotiations in the actual world, plaintiffs failed to disclose that up to one-third of the proposed class likely paid less for their purchases than they would have paid in a world without the challenged settlement agreement. The Third Circuit found this point compelling and held that the district court should have seriously considered defendants' challenges to plaintiffs' use of averages to prove predominance, but instead it merely "assumed, absent a rigorous analysis", that such averages could establish classwide injury.

The Third Circuit's decision clarified how certification questions should be addressed in at least three ways. First, it rejected plaintiffs' argument that Tyson Foods v Bouaphakeo requires courts to accept any proposed common proof of impact "unless no reasonable juror could believe the common proof at trial". Rather, Tyson Foods applies only in Fair Labor Standards Act cases where representative evidence is often the only way to prove impact, and not in any other cases, where it remains plaintiffs' burden to show that their class claims are "capable of common proof at trial by a preponderance of the evidence".

Second, it criticised the district court for not distinguishing between proof of injury and proof of damages when evaluating predominance. Under the "more lenient predominance standard for damages than for injury", averages may sometimes be acceptable proof, and classes can at times be certified even though damages issues may need to be tried separately. But that does not make such averaging appropriate to prove impact, because "every plaintiff must be able to show antitrust injury [to itself] through evidence common to the class." The two issues should not be conflated.

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Finally, the district court failed to resolve key factual disputes, assess competing evidence, and weigh conflicting expert testimony. Much of the experts' injury analyses conflicted with each other, for example, yet the district court did not "scrutinise the evidence to determine what was credible".

Asacol

Although not cited in Lamictal, the Third Circuit's decision was motivated by some of the same concerns that led to the First Circuit's decision in Asacol. There, the First Circuit reversed certification of an indirect purchaser plaintiff class where about 10% of class members were uninjured – they would have purchased defendants' branded drug product even if the allegedly delayed generic drug product was available sooner. The First Circuit specifically rejected the district court's proposal to remove these uninjured purchasers only in post-trial claims administration proceedings. Instead, it agreed with defendants that it would violate their Seventh Amendment and due process rights to certify a class without affording them a manageable way to raise "genuine challenges at trial to the assertion of liability by individual members".

Asacol confirmed that merely seeking class certification "provides no occasion for jettisoning the rules of evidence and procedure, the Seventh Amendment, or the dictate of the Rules Enabling Act". As the Supreme Court has held, parties have no "different rights in a class proceeding than they could have asserted in an individual action".

The Asacol ruling has been cited extensively for this point, including outside of the pharmaceutical context. Indeed, relying on Asacol, the US Court of Appeals for the District of Columbia Circuit recently held that where plaintiffs' proposed evidence found a lack of injury to thousands of class members, the district court correctly concluded that common issues did not predominate as to impact. But Asacol also is notable for refusing to allow relaxed standards for proving damages to be used as a means of showing that all or nearly all class members were injured: classes cannot simply reduce aggregate damages to paper over a failure to prove classwide impact.

AndroGel and Modafinil

In two other direct purchaser cases, the courts rigorously assessed the proffered evidence and found that plaintiffs failed to establish Rule 23's numerosity requirement: they did not show that "the class is so numerous that joinder of all members is impracticable". These decisions are in stark contrast to earlier direct purchaser pharmaceutical actions, which often merely noted that the class members were geographically dispersed and held that this fact alone suggested joinder would be impracticable.

First, in AndroGel, the US District Court for the Northern District of Georgia denied a motion to certify a class of 33 direct purchasers that were challenging alleged reverse payment settlements. Rather than simply accepting that the number of class members alone made the class numerous enough, the district court recognised that "unlike the typical class action, in which there are a number of individual plaintiffs with relatively small claims, the plaintiffs' proposed class consists of very large, sophisticated companies with very large claims." The court explained that this "means that even though these proposed plaintiffs are widely distributed, they also have the means and the motivation to join this action if they so choose." The plaintiffs did not appeal.

This denial of class certification follows from a similar denial on numerosity grounds by the Third Circuit in Modafinil. There, the Third Circuit vacated a class certification order because the district court incorrectly "considered the late stage of the litigation as relevant" to whether certification should be granted and "failed to properly consider the ability and motivation of the plaintiffs to proceed as joined, as opposed to individual, parties". Despite the geographic dispersion of the proposed 22-member class, the Third Circuit observed that the proposed class members appeared likely to proceed as joined parties. This was in part because of the sizable claims of the proposed class members, including three absent class members that each had claims estimated at over $1 billion even before trebling. Accordingly, they could "hardly be considered as candidates who need the aggregative advantages of the class device". On remand, the district court denied certification for similar reasons.

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Lessons learned

For litigators, the common thread in these decisions is that courts are more likely to seriously scrutinise antitrust plaintiffs' proffered evidence before granting or denying certification than they were in the past. In addition, appellate courts have become more active reversing erroneous certification decisions through interlocutory appeal, rather than following the traditional path of addressing these issues only if they are raised after a trial on the merits. Based on these decisions, litigants should follow certain best practices when preparing for and briefing class certification.

First, do not offer only perfunctory attempts to prove or disprove any Rule 23 element. In years past, for example, many litigants gave short shrift to certain Rule 23(a) requirements, such as adequacy or numerosity. But as Modafinil and AndroGel show, the once-overlooked Rule 23(a) elements can be fatal for plaintiffs who assume district courts will not rigorously analyse the evidence, so antitrust defendants should not reflexively skip past them and focus only on Rule 23(b) issues. By the same token, it is not enough for plaintiffs to argue that adequacy or numerosity exists in a given case merely because earlier class certification orders often found that these elements were satisfied. Rather, parties and courts must address the unique facts and market conditions at issue on a case-by-case basis, with litigators on both sides prepared to argue whether the evidence establishes all Rule 23 elements.

Second, be creative. The novel Seventh Amendment and due process arguments raised by the defendants in Asacol, for example, had not gained much traction in earlier cases. But because they logically flowed from existing Supreme Court precedent like Tyson Foods, the First Circuit readily adopted them. Defendants may be able to achieve the same outcome by continuing to raise logically sound arguments that build off of established precedent, such as the contention that all commercial entities within a single corporate family – a parent company and all of its subsidiaries, for example – should be treated as one class member when conducting the numerosity analysis, rather than counting each of them separately as some courts have done. And plaintiffs, of course, must continue to find ways of actually establishing impact to each class member, as well as feasible methods for identifying and removing uninjured class members at or before trial.

Third, class action plaintiffs that rely on broad averages do so at their own peril, as do class action defendants that do not pressure-test all potential vulnerabilities with such averages. A key theme in Lamictal and Asacol is that including uninjured entities or individuals in a proposed class raises due process and predominance concerns that are likely fatal to certification. Where averages may hide the existence of uninjured class members, such averages are problematic both because they risk imposing liability on defendants when it is known that they did not injure a large number of class members – as in Asacol; and because they may not actually prove injury to the remaining class members. As the DC Circuit has held, where a plaintiffs' proposed common proof of impact "detects injury where none could exist", such false positives "shred the plaintiffs' case for certification" because whatever else the evidence may be doing, it is not proving injury to the proposed class members.

White & Case represented defendants in the In re Asacol Antitrust Litigation and In re AndroGel Antitrust Litigation. Any views expressed in this article are solely those of the authors.

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