The State Of Pharma Class Certification After Asacol

by Aaron Yeater, Pavel Darling and Stephen Fink; Analysis Group, Inc.

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Aaron Yeater


Pavel Darling


Stephen Fink

The landscape of class certification in pharmaceutical antitrust litigation has been changing rapidly over the past few years. The most recent evolution began with the U.S. Court of Appeals for the First Circuit's 2015 decision in In re Nexium Antitrust Litigation, which upheld class certification in a "reverse payment" case even though the class contained uninjured members. Another significant milestone was reached recently, when the same court decided In re Asacol Antitrust Litigation, which overturned certification of a class for which a particular method of removing uninjured class members had been approved by a district court. An indication that the Asacol ruling may prove to be a watershed in this area arrived when a federal judge in another circuit cited the weeks-old decision in declining to certify a class of buyers of a cancer drug, because the plaintiffs had failed to show a common method of demonstrating injury-in-fact.

This article surveys this recent evolution and offers a glimpse at what factors — in particular, economic considerations — might influence the further development of this area of the law.

Certify, Then Prune: Nexium Sets the Bar

Nexium reestablished the parameters of class certification in pharmaceutical antitrust cases with regard to the important question of how the presence of class members who were not injured-in-fact affects the certification decision. The case was brought by a group of end buyers of a heartburn medication who alleged that its manufacturer, AstraZeneca, had paid generic manufacturers to delay the launches of their versions of the drug. The district court found that the class included some number of members who had demonstrated loyalty to the branded version of the medication. These "brand-loyal" class members were not injured by the delayed entry of the generic, because the price of the branded product would have increased following the introduction of generic products. Nevertheless, certification was allowed by the district court, even though a portion of the class did not have standing under Article III.

That certification was upheld by the First Circuit, which reasoned that the number of uninjured class members was de minimis, and that it was satisfied that "prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members." The court went on to offer just such a method, consisting of affidavits of unrebutted testimony of injury. The presence of this method was sufficient to ensure that common questions would predominate over individual questions, satisfying Federal Rule of Civil Procedure 23(b).

Two years later, a district court in In re Solodyn Antitrust Litigation cited Nexium as part of its rationale for certifying a class in a case in which the manufacturer of an acne medication was alleged to have made reverse payments in exchange for delayed generic entry. In a brief discussion, the Solodyn court rejected the manufacturer's argument that more than a de minimis number of injured plaintiffs were present in the class. Explaining that de minimis should be defined in "functional terms," the court ruled that the number of allegedly uninjured plaintiffs was insufficient to defeat the predominance requirement of certification because plaintiffs would still be able to show antitrust injury for "at least the vast majority of putative class members."

How Many Is Too Many? Asacol Weighs the Cost

Against this backdrop, Asacol seemed to signal an effort to limit what can be sanctioned under Nexium. In this case, the drugmaker Warner Chilcott was accused of having engaged in "product hopping" strategies, delaying generic entry of an ulcerative colitis drug to facilitate the introduction of a newer, patent-protected formulation of the original product. The district court certified a class of end buyers, even though it conceded that approximately 10 percent of the class would not have switched to a generic version of the drug, and hence had not suffered any anticompetitive harm. Purporting to follow Nexium, the district court held that the uninjured members could be removed in the damages phase of the trial by a claims administrator, who would review affidavits from class members. The First Circuit disagreed, holding that this remedy would deprive Warner of its due process and Seventh Amendment rights to dispute the fact of injury at trial. "[W]here injury-in-fact is a required element of a claim," the opinion stated, "a class

cannot be certified based on an expectation that the defendant will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact."

Before evaluating the effect of the Asacol decision, it is worth noting that some of the issues discussed in the opinion were raised in Nexium itself, most tellingly in the dissenting opinion by Judge Kayatta. He criticized the majority opinion for ignoring "the larger issue … that a court of appeals should not assume that Rule 23 has been satisfied on the basis of a culling method that it itself has proposed." A wiser course, Judge Kayatta opined in his Nexium dissent, was to remand the case for the district court to fashion the appropriate method for weeding out uninjured class members, leaving it to the appeals court to evaluate the suitability of such a method. "Throwing up an idea to see if it might stick is just not what courts of appeals do best," he wrote tartly.

He also objected to what he took to be the majority's bald statement that the fact that approximately 5.7 percent of the members of the proposed Nexium class were uninjured was insufficient to defeat the "functional" certification of the class. "The relevant inquiry for a court considering certifying a class that includes uninjured members," Judge Kayatta wrote, "is whether the court will be able to feasibly cull out those members before entry of judgment."

Perhaps most important, Judge Kayatta pointed out that while a small percentage of the class may be brand-loyal, the affidavit process would require an individual review of each and every affidavit submitted by class members, which in the Nexium case could have numbered in the tens of thousands, if not more. Said differently, one cannot find the needle in the haystack (or thousands of needles, in this case) without searching all the hay. Therefore, even if the number of uninjured class members were de minimis, the cost of identifying them and confirming their de minimis status may be prohibitive and frustrate class certification.

Similar issues arose in submissions to the court in Asacol. As in Nexium, different subgroups of class members had different reasons for being uninjured-in-fact: some had stopped taking Asacol during the relevant period; others had expressed a preference for a branded version of the ulcerative colitis drugs in question; still others expressed preferences for entirely different medications to treat the condition. Because the defendant, Warner, made clear that it intended to challenge the fact of injury for some members of the class, the claims administrator could not, as in Nexium, rely on unrebutted testimony. The need to identify those uninjured class members — potentially in the thousands — rendered the process administratively unworkable and ran afoul of Rule 23(b). This, Warner submitted, was not the kind of scheme blessed by Nexium.

Implications

At first glance, the First Circuit's reasoning in these cases seems to focus on a procedural question: whether it is a violation of due process to certify a class based on evidence to be provided later, and presumed to be unrebutted. And indeed, that is the rationale articulated by the court. One can imagine a class that could be successfully certified with similar circumstances under Asacol. For example, class members understood to suffer

injury if they filled a certain prescription from a particular manufacturer would only need to submit a record of such a purchase — evidence that could, in theory, be disputed, although the defendants would need to raise concerns about that evidence at the class certification stage. Yet that requires irrefutable evidence, such as administrative claims data, that often can itself require a detailed analysis and, in some cases, interpretation. And in these cases in particular, the question expands beyond what prescriptions class members did take to questions of what prescriptions they would have taken.

More pertinent to the decision are the substantive economic issues raised by Warner as the basis for rebutting the potential evidence submitted by class members. In Asacol, the court cited to the defendant's evidence of class members who stopped taking Asacol during the relevant period (and, therefore, for whom a switch to the generic was unlikely), as well as other patients who may have expressed a preference for the branded formulation of the new Warner product Delzicol over generic Asacol. Additional patients faced no copay for their prescription and would therefore not be sensitive to the availability of a cheaper generic alternative, and would not switch unless directed to do so by physicians or state regulations.

The insight to be gained here is the link between the record in discovery and the grounds for objecting to the class under Asacol. Each of these questions about the nature of uninjured class members was presented during the class certification stage by defendants' expert, with significant analysis of price and prescription data in support. Experts for both plaintiffs and defendant agreed that there was a group of uninjured class members, and the district court used the analyses of both experts to conclude that it was approximately 10 percent of the class, based primarily on the prevalence of brand-loyal consumer class members. The question on which the Asacol court focused is whether the factors that identify that 10 percent could be summarized in a declaration, and whether the defendant had presented plausible reasons to doubt the reliability of those declarations.

Going forward, defendants may place additional emphasis on articulating the reasons why some class members are uninjured — in particular, those that may result in similar issues regarding the feasibility of identifying such class members — in order to lay the groundwork for potential objections they will make to any declarations. In cases involving allegations of delayed generic entry (whether "product hopping" or more traditional reverse payment and so-called sham litigation cases), a particularly relevant question to establish during fact and expert discovery will be the likelihood that consumers will switch to the generic upon entry. Since this is also a critical question to any claim of damages, the analyses will likely be complementary.

These changes in approach will likely impact both plaintiffs and defendants in similar cases involving pharmaceuticals. For example, plaintiffs now have an added incentive to clarify the class definition and exclusions to avoid potential Asacol issues, and may tailor the exclusions using objective criteria that could be proven without the need for declarations during an administrative phase. Defendants, on the other hand, may present additional evidence of how class members would respond not only to the earlier but-for entry of the generic, but also to other changes in the competitive environment that would influence their purchasing decisions. These may include, for example, earlier

releases of alternative treatments (including improved formulations of similar products), and changes in marketing and promotional activity that may result in patients choosing entirely different products in a but-for scenario.

More broadly, one can expect that Asacol will make waves in class certification for a broader set of cases. As noted above, the decision has already been cited in the Third Circuit in In re Thalomid and Revlimid Antitrust Litigation, where the opinion noted that "[s]imilarly, here, Plaintiff [sic] have not provided an appropriate common method of proving injury-in-fact given the presence of brand loyalists." Notably, the court in Thalomid rejected several of the defendant's other claims as either de minimis or speculative, reinforcing the importance both of the brand-loyalty issue and of expert testimony and fact discovery. Given the Asacol court's unwillingness to defer evidence of injury until trial, several other courts in matters outside of pharmaceutical antitrust have been petitioned to take note of Asacol. In these cases, the relevant question may be whether defendants have provided sufficient basis for the court to expect that evidence of injury will be disputed at trial (as the court foresaw in Asacol), or will go unrebutted (as the court assumed in Nexium).

In summary, Asacol offers some precision in interpreting the burden of class certification: plaintiffs must either resolve questions of injury before certification or credibly assert that questions of injury can be resolved efficiently and without controversy. But it also makes clear that defendants must establish, via credible fact and expert evidence, that the fact of injury can be rebutted for a significant portion of class members.

Aaron Yeater is a managing principal and Pavel Darling and Stephen Fink are vice presidents at Analysis Group Inc.

Disclosure: An Analysis Group team that included Yeater, Darling and Fink was retained by counsel for Warner Chilcott to support Dr. Bruce Strombom in his testimony in the In re Asacol Antitrust Litigation case discussed here. Additionally, Analysis Group teams were retained by counsel for the defendants in both the In re Nexium Antitrust Litigation and the In re Solodyn Antitrust Litigation cases also discussed here.