1st Circ. Generic-Delay Ruling Isn't Popular With Lower Courts

By **Karen Garvey and Ethan Kaminsky** (June 11, 2020)

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The U.S. Court of Appeals for the First Circuit's class certification decision in the Asacol antitrust litigation matter[1] has generated considerable attention in the district courts.

Most courts to consider the decision have either sharply criticized it or rejected it, with courts within the jurisdiction of the U.S. Court of Appeals for the Third Circuit as the lone exception.

Asacol Decision

Asacol is a prescription pharmaceutical that treats mild to moderate ulcerative colitis, a chronic inflammatory bowel disorder. The original product, produced by Proctor & Gamble Co., first appeared on the market in 1992, and it was protected by a patent that was set to expire in 2013.

In 2008, Proctor & Gamble introduced a new version called Asacol HD, designed to treat moderate, but not mild, ulcerative colitis; this new version was granted further patent protection. In 2009, Proctor & Gamble sold its Asacol franchise to Warner Chilcott Ltd.[2]

As the patent on the original Asacol formulation was about to expire, Warner Chilcott unexpectedly pulled Asacol from the market and introduced a new similar drug called Delzicol, containing the same two active ingredients and serving the same function.

By pulling Asacol and introducing Delzicol — a tactic of branded pharmaceutical companies that is often referred to as a hard switch — Warner Chilcott effectively prevented a generic version of Asacol from entering the market and extended its monopoly.[3]

Several union-sponsored health funds sued Warner Chilcott alleging violations of the competition laws of more than twenty states.[4] The plaintiffs moved to certify a class of similarly situated indirect purchasers. Key to the plaintiffs' arguments was that only a de minimis number of consumer class members were allegedly uninjured by the defendant's unlawful product switch.

Among the reasons why certain consumers would be purportedly uninjured is due to the fact that they would have continued buying branded Asacol or Delzicol even after a less expensive generic version of Asacol was introduced — i.e., that, as the plaintiffs claimed, less than 10% of class members were so-called brand loyalists.

The U.S. District Court for the District of Massachusetts accepted the plaintiffs' representation that such class members could be identified through the submission of claims forms and then removed by a claims administrator and plan for doing so.[5]

On appeal, the First Circuit reversed, holding that based on the record before it, the district court abused its discretion in certifying a class because individual issues predominated over common ones.[6] Specifically, the court held that the plaintiffs' plan to have a claims administrator identify the brand-loyal or other purportedly uninjured consumer class

members did not provide an efficient and administratively feasible way to exclude these class members as required under Federal Rule of Civil Procedure 23(b)(3).[7]

The court also held that such a procedure would violate the defendant's constitutional right to test at trial whether each class member had suffered an injury in fact.[8] As a result, the First Circuit reversed the class certification order and remanded for further consideration.[9]

Recent Decisions From Within the First Circuit

Although bound by precedent, and therefore not free to reject Asacol outright, district courts within the First Circuit have sharply criticized the decision.[10]

On Oct. 17, 2019, in In re: Loestrin, a so-called pay-for-delay case, the U.S. District Court for the District of Rhode Island granted in part and denied in part the plaintiffs' motion for class certification. Although the court certified a class consisting only of third-party payors, i.e., insurers, it denied the plaintiffs' motion to certify a class that included both consumer and third-party payors because some of the consumers in the proposed class were likely brand loyalists and therefore uninjured.[11]

Before ultimately following the binding precedent of Asacol and denying certification of the consumer-third party payor class because there was "no administratively feasible way to adjudicate these individual issues [regarding potentially uninjured class members] while paying due reverence to Defendants' Seventh Amendment and due process rights,"[12] the court emphasized that were it "writing on a clean, pre-Asacol slate, it may very well adopt a presumption of injury."[13]

It explained how it was "troubled that over ninety percent of consumers in the proposed EPP class may have been injured by Defendants' alleged unlawful conduct, but now have no practical recourse under antitrust law" and suggested that the First Circuit "reconsider" its holding.[14] In the alternative, it wondered whether "perhaps Congress will take up the issue."[15]

In August 2019, in the In re: Intuniv pay-for-delay litigation, a court in the District of Massachusetts expressed similar concerns with the First Circuit's Asacol decision.[16] Unlike Loestrin, the Intuniv class consisted of only consumers.[17] The court lamented that "Asacol is likely a death knell for pharmaceutical, antitrust class actions brought by indirect purchasers" because the decision makes it "nearly impossible for indirect purchasers to show that common issues will predominate."[18]

The court stressed that in the absence of class treatment "it is likely that most putative class members' claims will go unremedied" and that while the Asacol decision "eliminates the possibility that some consumers might obtain a recovery for damages they did not suffer, it also ensures that a much larger number of Intuniv consumers will receive no remedy for harm actually suffered."[19]

In the end, though, bound to apply the Asacol precedent, the court denied certification because 8% of the proposed class would have remained brand loyalists even if a generic had made it to market and were thus uninjured.[20]

Recent Critical Out-of-Circuit Decisions

In recent months, district courts from outside the First Circuit have rejected the First Circuit's Asacol decision outright.[21]

In March, the U.S. District Court for the District of Kansas in the EpiPen antitrust class action rejected Asacol.[22] There, the plaintiffs moved to certify multiple classes of indirect purchasers (i.e., consumers and third-party payors) who alleged that they overpaid for EpiPens as a result of the defendants' anticompetitive conduct in conspiring to monopolize the market for EpiPens through a variety of means, including entering an unlawful pay-for-delay agreement with potential generic competitors.[23]

In the absence of controlling U.S. Court of Appeals for the Tenth Circuit precedent, the defendants relied on the Asacol decision to argue that the class should not be certified as it included more than a de minimus number of uninjured members, and there was no constitutionally sound and administratively feasible way to test whether those individuals were injured at trial.[24]

The court rejected the defendants' arguments and certified two classes under state antitrust law and RICO.[25] Citing pre-Asacol decisions from district courts within the Tenth Circuit in which courts had certified classes with uninjured members, the court found that the Tenth Circuit would not adopt the holding in Asacol.

Specifically, the court cited an opinion that had adopted the U.S. Court of Appeals for the Seventh Circuit's approach to the issue and recognized that "'a class will almost inevitably include persons who have not been injured by the defendant's conduct, and that fact (or even inevitability) does not preclude certification.'"[26]

The court thus rejected the Asacol holding as too rigid and adopted the Seventh Circuit's test, which holds only that if:

a class is defined so broadly as to include a great number of members who for some reason could not have been harmed by the defendant's allegedly unlawful conduct, the class is defined too broadly to permit certification.[27]

In doing so, the court further rejected Asacol's due processes holdings and adopted those from the Seventh Circuit instead, explaining that "'the identity of particular class members does not implicate the defendant's due process interest at all"' in a case like this one because "'[t]he addition or subtraction of individual class members affects neither the defendant's liability nor the total amount of damages it owes to the class.'"[28]

In May, the U.S. District Court for the Eastern District of New York likewise declined to follow Asacol.[29] In In re: Restasis, the plaintiffs moved to certify an indirect purchaser class that they alleged overpaid for prescription dry-eye medication as a result of the defendants' anti-competitive conduct.

The plaintiffs alleged that, in an effort to maintain its monopoly on Restasis after its patents expired in May 2014, the defendants worked to delay generic entry by:

(1) filing sham citizen petitions with the FDA; (2) defrauding the U.S. Patent and Trademark Office into issuing second wave patents for Restasis; (3) using those patents to file baseless patent infringement lawsuits against generic drug makers; and (4) frustrating attempts to invalidate its patents by selling them to the Saint Regis Mohawk Tribe, which licensed them back, in order to rent the Tribe's sovereign immunity.[30]

The defendants, relying on Asacol, argued against certification of a consumer class on the grounds that the class included a more than de minimis number of uninjured members and

that there was no administratively feasible way for the defendants to test those claims at trial without individual issues predominating over common ones.[31]

As in EpiPen, the Restasis court rejected the defendants' arguments and expressed "disagree[ment] with the First Circuit's conclusion in Asacol that defendant has a constitutional right to remove these individuals at the liability stage of trial."[32]

Instead, the court found that the claims administrator process that the First Circuit rejected in Asacol was sufficient to safeguard the defendants' constitutional rights.[33] In doing so, the court determined that the claims administration procedure was sufficient to address the concerns that U.S. Supreme Court Chief Justice Roberts set out in his Tyson Foods Inc. v. Bouaphakeo concurrence, in which he wrote that "Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not."[34]

The court explained that:

uninjured class members here will "not contribute to the size of any damage award," and, by identifying and removing such class members during the claims administration process, plaintiffs' proposal satisfies Chief Justice Roberts's concerns.[35]

The court further found that its conclusion was in line with U.S. Court of Appeals for the Second Circuit case law.[36]

Conclusion

The criticisms that have been levied against the First Circuit's Asacol decision — both from within and outside of the First Circuit — are notable because they rely on not just legal precedent but also on common sense and genuine concern for consumers.

At this point, it remains to be seen whether the First Circuit will revisit the issues that it tackled in Asacol and take to heart the criticisms that have been lobbed against the decision, but it would not be surprising to see additional courts take up the mantle of opposition.

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[1] In re Asacol Antitrust Litig., 907 F.3d 42, 57-58 (1st Cir. 2018).

[2] See Asacol, 907 F.3d at 45.

[3] Id. at 45-46.

[4] Id.

[5] Id. at 47.

[6] Id. at 57-58.

[7] Id. at 51-52.

[8] Id. at 53-55.

[9] Id.

[10] In re Loestrin 24 Fe Antitrust Litig., 410 F. Supp. 3d 352, 404 (D.R.I. 2019).

[11] Id. (ultimately certifying a TPP only class).

[12] Id.

[13] Id.

[14] Id.

[15] Id.

[16] In re Intuniv Antitrust Litig., No. 1:16-CV-12396, 2019 WL 3947262, at *7-8 (D. Mass. Aug. 21, 2019), reconsideration denied sub nom., In re Intuniv Antitrust Litig. (Indirect Purchasers), No. 1:16-CV-12396, 2019 WL 5789837 (D. Mass. Nov. 6, 2019).

[17] Id.

[18] Id. at *7 n.8.

[19] Id.

[20] Id. at *8.

[21] See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., No. 17-MD-2785, 2020 WL 1180550, at *21 (D. Kan. Mar. 10, 2020); In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig., No. 18-MD-2819, 2020 WL 2555556, at *18 (E.D.N.Y. May 5, 2020). It should be noted that courts in the Third Circuit seem more inclined to follow the Asacol decision than others. See In re Thalomid & Revlimid Antitrust Litig., No. CV 14-6997, 2018 WL 6573118, at *13 (D.N.J. Oct. 30, 2018) (applying the holding from Asacol and denying certification); In re Niaspan Antitrust Litig., No. 13-MD-2460, 2020 WL 2933824, at *27 (E.D. Pa. June 3, 2020) (same).

[22] EpiPen, 2020 WL 1180550, at *21.

[23] Id. at *4

[24] Id. at *28-36.

[25] Id. at *61-62.

[26] Id. at 30 (quoting In re Urethane Antitrust Litig., No. 14-1616, 2013 WL 2097346, at *1 (D. Kan. May 15, 2013); Messner v. Northshore Univ. HealthSystem, 669 F.3d 802, 823 (7th Cir. 2012)).

[27] Messner, 669 F.3d at 824.

[28] EpiPen, 2020 WL 1180550, at *37 (quoting Mullins v. Direct Dig., LLC, 795 F.3d 654, 670 (7th Cir. 2015)).

[29] Restasis, 2020 WL 2555556, at *18.

[30] Id. at *2.

[31] Id. at *7.

[32] Id. at *19-20 (citing In re EpiPen, 2020 WL 1180550 at *28-32, *36-37; Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1049 (2016)).

[33] Id. at *19.

[34] Id. at *20 (citing Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1053 (2016)).

[35] Id.

[36] Id. (citing Hickory Sec. Ltd. v. Republic of Argentina, 493 F. App'x 156, 160 (2d Cir. 2012)).