The Interplay: Key Decisions at the Intersection of Antitrust and Life Sciences - July 2024

JULY 31, 2024

Federal Circuit Allows Teva Patents to Remain in Orange Book. The Federal Circuit recently granted Teva Pharmaceutical's motion for a stay of removal of its patents from the Orange Book in its ongoing dispute with Amneal Pharmaceuticals, Inc. Listing patents in the Orange Book allows branded drugmakers to bring patent infringement actions to stop sales of proposed generic versions, which can then trigger a 30-month stay on FDA approval of generic versions. The Federal Trade Commission (FTC) has warned about Orange Book listing abuses and pushed Teva and other drugmakers to delist certain patents, including Teva inhaler patents. On June 10, 2024, Teva sought a stay of a district court order requiring it to correct or delete certain Orange Book patent information while it appeals an order finding that Teva infringed Amneal Pharmaceutical's patents. Teva argued that it would suffer irreparable harm if it were required to remove the patents, since it would be unable to seek the 30-month stay under the Hatch-Waxman Act. Amneal responded that it was "mere speculation" that Teva would be unable to seek the 30-month stay and thus could not show how it would be irreparably harmed. On July 10, 2024, the Federal Circuit granted the stay in a two-page order, concluding that "[b]ased on the papers submitted, and our expedition of the completion of briefing and argument on the merits, we conclude that a stay is warranted under the circumstances of this case at this time." The stay will remain in place "until further notice of this court." The case is *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, Case No. 24-1936 (Fed. Cir. 2024).

FTC Issues Interim Report on PBMs. On July 9, 2024, the FTC issued an interim report on a study that it launched in 2022 regarding pharmacy benefit managers (PBMs) and their role as facilitators between drugmakers and insurers. The report says that enforcers found that industry consolidation has led to six PBMs purportedly "control[ling]" 95% of all prescriptions in the United States. The report goes on to say that these PBMs "wield enormous power and influence over patients' access to drugs and the prices they pay." The report also claims that PBMs are responsible for overcharges on two cancer drugs—Gleevec and Zytiga—and Chair Khan's statement accompanying the report claimed that "[t]his overcharging represents billions of dollars in drug spending and reveals the incentives PBMs can have to preference their own affiliated pharmacies regardless of what is best for patients." Commissioner Holyoak voted against issuing the interim report, saying in a statement that "[t]he report does not provide any empirical evidence as to the state of competition in the

prescription drug market but rather simply describes the high-level nature of the healthcare system in the U.S.," and that "[t]he report's failure to offer empirical evidence to support claims about the market power of PBMs is particularly troubling." The FTC has indicated it will continue to investigate the PBM industry and publish a final report.

State of Vermont Sues PBMs. On July 17, 2024, the State of Vermont sued two PBMs and their subsidiaries for violating Vermont's Consumer Protection Act. Vermont alleges that the two PBMs have, as a result of "massive consolidation," acquired "near complete control of the pricing, dispensing, and reimbursement systems for all prescription drugs for their" clients. Vermont claims that defendants have "engaged in deceptive acts" in commerce, including by misrepresenting: (1) that their construction of formularies lowers the cost of prescription drugs; (2) that the payments they receive from manufacturers lower the cost of prescription drugs; and (3) misrepresenting that the formulating decisions are evidence- or value-based decisions. Vermont also claims that the defendants engage in unfair acts and practices, including because, (1) they use their market position to drive up prices, while excluding access to lower priced drugs; and (2) patients have no choice other than to pay inflated prices because the defendants have "near complete control over the pharmaceutical pricing chain." The case is *State of Vermont v. Evernorth Health, Inc., et al.*, Case No. 24-cv-02759 (Vt. Sup. Ct.).

Class Certification Denied in EpiPen Direct Purchaser Litigation. On July 1, 2024, a court in the District of Minnesota denied class certification in the *In re EpiPen Direct Purchaser Litigation*. Plaintiffs Rochester Drug Co-Operative, Inc. and Dakota Drug, Inc.—two drug wholesalers—allege that Mylan engaged in conduct that violates both the Racketeer Influenced and Corrupt Organizations Act and Section 2 of the Sherman Act. They sought to certify a class of drug wholesalers that bought EpiPens directly from Mylan. The court denied the motion for class certification. First, the court found that plaintiffs failed to meet Rule 23(a)(1)'s numerosity requirement because, after factoring in the statute of limitations, the class would only have 46 members. The court observed that the "paradigmatic class action involves many members with small claims… [t]his case isn't like that." The court also found that plaintiffs failed to meet Rule 23(a)(4)'s adequacy requirement. Unlike the two named plaintiffs, the court found that some drug wholesalers actually benefitted from Mylan's pricing structure and plaintiffs therefore could not adequately represent all class members. Finally, the court found that plaintiffs failed to meet Rule 23(b)(3)'s predominance requirement. The court determined that plaintiffs failed to adequately demonstrate that the alleged bribery and kickback scheme that Mylan allegedly engaged in with PBMs was the cause of their harm and had not shown that causation could be proven through common proof. The case is *In re EpiPen Direct Purchaser Litigation*, Case No. 20-cv-827 (D. Minn.).

Summary Judgment Denied in Contact Lens Antitrust Litigation. On July 9, 2024, a court in the Middle District of Florida denied defendant Alcon's motion for summary judgment on plaintiff Lens.com's Sherman Act and Clayton Act claims. Lens.com, a gray market reseller of contact lenses, pursued two theories of anticompetitive conduct alleging : (i) a hub-and-spoke conspiracy between Alcon, a manufacturer of soft contact lenses, and other contact lens manufacturers, distributors, and providers and (ii) a vertical conspiracy between Alcon, its distributors, and providers. For instance, Lens.com alleged that Alcon maintained a unilateral pricing policy (UPP)

agreement between it, its distributors, and providers, that providers monitored UPP violations by other providers, and distributors enforced the UPP using do-not-sell lists. Lens.com alleged that Alcon put it on a do-not-sell list due to perceived UPP violations. The court found that there are triable issues of fact regarding the existence of both a horizontal/hub-and-spoke conspiracy and a vertical conspiracy. The court also found that Lens.com alleged facts sufficient to support two relevant product markets: (1) a market for all contact lenses, because contact lenses and other forms of vision correction are not interchangeable; and (2) due to the unique situation of the alleged contact lenses market, where patients are prescribed specific brands and models of contact lenses and are unable to switch to other brands, the market for Alcon-branded contact lenses. The case is *In re Disposable Contact Lens Antitrust Litigation*. Case No. 19-cv-706 (M.D. Fla.).

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