Litigation and Enforcement Highlights – May 2018

Several major court decisions were handed down last month that may leave lasting impacts in terms of price and competition in the healthcare industry. Specifically, the 4th Circuit Court of Appeals ruled Maryland's Price Gouging Law unconstitutional, while the Supreme Court upheld inter partes review, a controversial patent review process. In antitrust enforcement, the Justice Department began its review of the Cigna-Express Scripts merger.

4th Circuit Strikes Down Maryland Price Gouging Law

In a significant victory for the pharmaceutical industry, the 4th U.S. Circuit Court of Appeals found Maryland's landmark 2017 law, which punishes generic drug manufacturers for price gouging, unconstitutional.[1] In a 2-1 opinion, Judge Thacker wrote that the law "violates the dormant commerce clause [of the U.S. Constitution] because it directly regulates the price of transactions that occur outside Maryland." However, the opinion emphasized that the decision "in no way mean[s] to suggest that Maryland and other states cannot enact legislation meant to secure lower prescription drug prices for their citizens." The ruling reversed the lower court's decision in a lawsuit originally brought by the generic pharmaceutical industry led by the Association for Accessible Medicines (AAM), a generic trade group. U.S. District Judge Marvin Garbis of Maryland declined to block the law from going into effect in a ruling in September 2017.

The disputed law (HB 631) was passed in April 2017 amid increased national attention on rising drug prices. It required a drug manufacturer or distributor to justify any price increase of 50 percent or more within the preceding two years for an essential drug and allowed the state attorney general to sue generic drug manufacturers and impose fines of up to $10,000 for unconscionable price hikes. Maryland Governor Larry Hogan allowed the proposed law to go into effect without his signature due to similar constitutional concerns. AAM argued that the law "would harm patients because the law would reduce generic drug competition and choice, thus resulting in an overall increase in drug costs due to increased reliance upon more-costly branded medications."

Notably, the law did not include brand-name drugs due to concerns that it would not withstand legal challenges, as lawsuits have been filed against similar price transparency laws in other states, including California[2] and Nevada,[3] which target brand-name drug makers. The decision against Maryland's law could spell trouble for similar efforts by other states that attempt to rein in drug prices. Given the fact that other appeals courts have upheld similar laws,[4] however, Maryland's attorney general may appeal the decision to the U.S. Supreme Court. As Circuit Judge James Wynn wrote in a lengthy dissenting opinion, the ruling "renders numerous state consumer protection statutes unconstitutional, and significantly expands federal courts' authority to second-guess States' efforts to protect their citizens," and "[n]either the Framers [n]or the Supreme Court intended for the Commerce Clause to serve such a purpose." In the legal fight against soaring drug prices, the action may be far from over.

Supreme Court Upholds Patent Review Process in Blow to Brand-

name Drug Makers

On April 24, the Supreme Court handed down a decision seen as a blow to brand-name drug makers. In the 7-2 ruling, the Supreme Court held that inter partes review (IPR), a controversial procedure for reviewing patent disputes, does not violate constitutional rights of patent owners. An IPR allows a third-party (non-patent holder) to challenge the patent before a U.S. Patent and Trademark Office (USPTO) appeals board without going through traditional court filings. It is seen as a speedier and less-expensive way to invalidate patents than pursuing lawsuits in court. Pharmaceutical companies argue that IPR threatens valuable research efforts and that patents should only be revoked in a federal court along with a constitutional right to jury. Justice Clarence Thomas, writing for the majority, disagreed, stating that: "The decision to grant a patent is a matter involving public rights… Inter partes review is simply a reconsideration of that grant, and Congress has permissibly reserved the PTO's authority to conduct that consideration."

The IPR process was created in 2011 and gained significant media attention recently when Allergan transferred its patent rights to Restasis to a Native American tribe to protect the best-selling drug from generic competition. Allergan hoped to avoid the review process by use of the tribe's sovereign immunity (See Source Blog post). The tactic failed, however, when a U.S. patent appeals board denied the claim of tribal immunity in February 2018. Given the new Supreme Court ruling, Allergan is in an even weaker position to shield its patents from generic challenges. This decision is seen as a win for biosimilar drug makers that regularly battle brand-name manufacturers' monopolies in the effort to introduce lower-cost generic competition.

Justice Department Reviews Cigna-Express Scripts Merger As Drug Pricing Lawsuit Proceeds Against Cigna

The Department of Justice (DOJ) has begun reviewing the proposed merger between Cigna Corp. and Express Scripts Holding Co. The $67 billion deal is a so-called vertical integration that combines companies operating in different parts of the supply chain – health insurance (Cigna) and pharmacy benefit management (Express Scripts) – which therefore do not directly compete against each other. While horizontal mergers between the same type of companies traditionally face significant regulatory hurdles, as seen in DOJ's denial of the Aetna-Humana and Anthem-Cigna deals, vertical mergers have faced less antitrust scrutiny. With an increased number of similar transactions in recent months, however, federal regulators may be taking a closer look at vertical integration. Soon after the announcement that the Justice Department will review the deal, DOJ requested additional information related to the proposed merger from both Cigna and Express Scripts. Nonetheless, the companies still expect the proposed deal to close by the end of the year.[5]

Meanwhile, Cigna faces a class-action lawsuit alleging the insurance giant overcharged its members by more than 10 times the amount the insurer paid for certain prescription drug costs.[6] The original lawsuit was brought in October 2016 and recently moved to the discovery phase when U.S. District Judge Warren Eginton denied Cigna's motion to dismiss, finding that Cigna "intentionally sought to charge excess amounts for prescription drugs and that it required the pharmacies to conceal from the insureds the amounts of the prescription drug costs."

That's all for this month's Litigation and Enforcement Highlights. Stay tuned for the latest developments in these cases and check back next month for more litigation and

enforcement actions on the Source blog. In the meantime, be sure to check out the Enforcement page of the Source for timeline and geographic trends of federal, state, and private enforcement actions.

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[1]Ass'n for Accessible Medicines v. Frosh, 4th Cir., No. 17-2166, 4/13/18.

[2]PhRMA v. Brown, No. 2:17-at-01323; http://phrma-docs.phrma.org/files/dmfile/sb17-complaint.pdf.

[3]PhRMA and BIO v. Sandoval, No. 2:17-cv-02315.

[4]Dana A. Elfin, *Spiked Maryland Rx Pricing Law Could Kill Similar Efforts*, Bloomberg Law, Apr. 16, 2018.

[5]Matthew Perlman, *DOJ Asks Cigna, Express Scripts For More Info on $67B Deal*, Law 360, Apr. 24, 2018.

[6]Negron v. Cigna and OptumRx, No. 3:16-cv-1702.