

Litigation and Enforcement Highlights - August 2018

This month we highlight new developments in several high profile antitrust enforcement cases and pharmaceutical legal actions, including 1) new challenges to the proposed Beth Israel-Lahey merger, 2) expanded probe into generic drugs price-fixing scheme, 3) conclusion to Allergan's patent saga, and 4) the future of Maryland's price gouging law.

Massachusetts Health System Merger Hits Roadblock, with Rocky Road Ahead

We have our eye on the proposed merger of Beth Israel Deaconess Medical Center and Lahey Health, which has been under regulatory review since December 2017. As we [covered](#) on The Source, it has been smooth sailing for the planned merger as it received the green light from Massachusetts state officials including the Department of Public Health and the Public Health Council, up until now.

The Massachusetts Health Policy Commission (HPC), the final regulatory agency to review the deal, released a [preliminary report](#) finding that the proposed merger would increase healthcare costs by tens of millions a year. The panel projects, conservatively, that prices for inpatient care would increase by 5% to 6.7%, and prices for outpatient care would increase by 8.4 to 12.2%.^[1] The HPC also warns that the consolidation would substantially increase market concentration in the state, giving the merged entity a market share that is nearly equal to that of Partners HealthCare, the largest hospital network in Massachusetts. The reduced competition would provide the combined system with greater bargaining power and the ability to demand higher prices for healthcare services. However, Beth Israel and Lahey Health argue that their merger would allow them to compete with health giant Partners and challenge its market power and ability to charge high prices. However, while theoretically possible, the HPC is skeptical that such phenomenon would actually take place.

Prior to the release of the report, Attorney General Maura Healy sent a [letter](#) to the HPC voicing her concerns about the deal's potential anticompetitive impact. Healy warns that "nationally, health care prices tend to increase after mergers," and that the merger could reduce access to care, especially for people in low-income communities. This may be a sign that this merger could face additional hurdles in the form of legal action from the AG. The Source will continue to follow this proposed merger and bring the latest updates on its development.

Humana Joins State and Federal Antitrust Probe of Generic Drug Price-Fixing Scheme

Early this month, health insurance giant Humana filed a lawsuit against nearly 30 generic drug manufacturers, alleging they conspired to fix the prices of 16 widely used generic drugs, forcing the insurer to pay inflated prices.[\[2\]](#) This lawsuit, filed in the U.S. District Court for the Eastern District of Pennsylvania, follows on state and federal investigations into similar claims that have been ongoing since 2016. Humana claims to base its [complaint](#) on findings from those investigations, as well as "personal knowledge," alleging that the drug manufacturers "conspired to manipulate the relevant markets, allocate these markets among themselves, and obstruct generic competition." The complaint further claims the manufacturers "agreed to fix, increase, stabilize, and/or maintain the price of the drugs," causing Humana to spend more than \$1.7 billion. The complaint accuses many big name generic manufacturers, including Mylan, Novartis, and Teva of these abuses, and is seeking treble damages under the Clayton Antitrust Act.

In a multidistrict litigation (MDL) that continues to expand under ongoing investigations, the Department of Justice and attorneys general representing 45 states and the District of Columbia are suing 18 pharmaceutical companies alleging similar claims of generic drug price-fixing.[\[3\]](#) Humana draws from that case extensively in its complaint and perceptively summarizes the current prescription drug pricing debate as follows: "The United States is a venue ripe for illegal anticompetitive exploitation of prescription drug prices due to laws that regulate how prescription drugs are prescribed and how the prescriptions can be filled."

Joined forces from state, federal, and private enforcement may act to rein in anticompetitive practices in the pharmaceutical industry, and along with legislative efforts, finally help bring down drug prices.

Allergan Gets Nail on the Coffin in Patent Transfer Ploy

We continue to follow the Allergan patent transfer saga, which The Source covered extensively in [previous Highlights](#). You will recall that in an attempt to shield its best-selling drug from generic competition, Allergan transferred its patent rights to Restasis to a Native American tribe, seeking to invoke the tribe's sovereign immunity to avoid inter partes review (IPR) at the U.S. Patent and Trade Office. In the most recent development, the Federal Circuit Court of Appeals [upheld](#) the U.S. Patent Trial and Appeals Board's ruling rejecting the sovereign immunity claim.[\[4\]](#) Back in April, Allergan's challenge of the IPR process also saw [defeat at the Supreme Court](#). This final outcome of Allergan's extended legal fight sheds new light on how other pharmaceutical patent owners should tread going forward. The courts, having conclusively shut down the sovereign immunity loophole and endorsed the IPR process for future patent challenges, are surely sending a message to other brand manufacturers that Allergan's tactics cannot be used to block generic competition and maintain monopolies to raise drug prices.

4th Circuit Won't Reconsider Rejection of Maryland Price Gouging Law

In a blow to state efforts to control high drug prices, the 4th U.S. Circuit Court of Appeals refused to reconsider its ruling that Maryland's 2017 price gouging law is unconstitutional. In [April](#), a three-judge panel of the 4th Circuit held that Maryland's landmark law, which punishes generic drug manufacturers for price gouging, violates the dormant commerce clause of the Constitution, and is therefore invalid, with Judge Wynn issuing a strong dissent.[\[5\]](#) Attorney General Brian Frosh's request for rehearing en banc, or before all the judges of the court, was ultimately denied by a vote of 9-3 in front of the entire bench. Nevertheless, as The Source previously

highlighted, given that other appeals courts have upheld similar laws, the new decision may now set the stage for a Supreme Court review. The Source will be watching this case closely and be sure to bring you the latest developments.

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.

[1] Massachusetts Health Policy Commission, *Review of The Proposed Merger of Lahey Health System; CareGroup and its Component Parts, Beth Israel Deaconess Medical Center, New England Baptist Hospital and Mount Auburn Hospital; Seacoast Regional Health Systems; and Each of their Corporate Subsidiaries into Beth Israel Lahey Health*, July 18, 2018

[2] Humana Inc. v. Actavis Elizabeth, LLC et al., 2:18-cv-03299

[3] In re: Generic Pharm. Pricing Antitrust Litig., MDL No. 2724

[4] St. Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc., Fed. Cir., No. 18-01638

[5] Ass'n for Accessible Medicines v. Frosh, 4th Cir., No. 17-2166