Recent Actions by Supreme Court and U.S. Antitrust Authorities Illustrate Continued Focus on Antitrust Issues in the Health Care Sector

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Introduction

A few developments in the past month by the Supreme Court and the U.S. antitrust agencies serve as reminders that regulators continue to focus on antitrust enforcement in the health care sector. These recent actions, of course, are occurring during the health care reform process, which has spurred increased horizontal and vertical integration in the health care space.

First, there have been recent developments in connection with the Supreme Court’s review of two enforcement actions by the Federal Trade Commission (“FTC” or “the Commission”). On December 7, 2012, the Supreme Court confirmed it will consider the legal standards for “pay-for-delay” or “reverse payment” pharmaceutical patent settlement agreements by granting certiorari to review the Eleventh Circuit Court of Appeals’ decision in FTC v. Watson Pharm. The Eleventh Circuit had rejected the FTC’s challenge to the patent settlement agreements between Solvay Pharmaceuticals and Watson Pharmaceuticals and Par Pharmaceutical Companies that, according to the FTC, would delay entry of generic versions of Solvay’s branded testosterone-replacement drug, AndroGel. On November 26, 2012, the Supreme Court also heard oral arguments on the appropriate scope of the so-called “state action” doctrine in connection with an FTC challenge to a Georgia hospital merger between Phoebe Putney Health System, Inc. and Palmyra Park Hospital, Inc. The FTC appealed to the Supreme Court after both the District Court and the Eleventh Circuit ruled that the state action doctrine immunized the transaction from antitrust challenge.

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2 The “state action” doctrine creates an antitrust immunity when a state clearly articulates its intent to allow certain conduct that may depart from competition principles and an intent to supervise/regulate such conduct actively. Philip Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 230 (2012).

In addition to recent appeals to the Supreme Court, antitrust authorities have also challenged hospital and health insurance mergers in the past few weeks. On November 16, 2012, the FTC challenged Reading Health System’s proposed purchase of Surgical Institute of Reading L.P. Soon thereafter, Reading Health System decided to abandon the proposed transaction. Moreover, on November 28, 2012, the Department of Justice (“DOJ” or “the Department”) required a divestiture as a condition for clearing WellPoint’s acquisition of rival health insurance group, Amerigroup, requiring that the combined company divest Amerigroup’s Virginia subsidiary.

These cases are only the most recent examples of U.S. antitrust authorities’ longstanding focus on the health care sector.

After Years of FTC Scrutiny, the Supreme Court Will Finally Hear a Case Involving an FTC Challenge to Pay-for-Delay Deals

On December 7, 2012, the Supreme Court granted the FTC’s petition for certiorari to review the Eleventh Circuit Court of Appeals’ decision in Watson, in which the court rejected the FTC’s challenge to a “reverse payment” agreement between Solvay Pharmaceuticals, Par Pharmaceutical, and Watson Pharmaceuticals. For several years, the FTC has targeted “reverse payment” or “pay-for-delay” agreements, which refer to patent settlement agreements between a brand-name and a generic manufacturer that, according to those that challenge them, delay entry by the generic manufacturer in exchange for some type of compensation. These have long been a cause célèbre for the FTC and, particularly, for the current FTC Chairman Jon Leibowitz. Indeed, the Chairman recently reiterated the Commission’s focus “on egregious practices like ‘pay-for-delay’ pharmaceutical settlements.” There has been extensive litigation surrounding these types of agreements, including cases brought by the FTC as well as class actions and other cases brought

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by private parties. Nevertheless, both the Commission and private parties have found limited success in litigating these types of cases.  

In Watson, Solvay Pharmaceuticals, developer of brand-name drug AndroGel, had filed patent infringement lawsuits against generic pharmaceutical manufacturers. The generic manufacturers claimed that their generic drugs either did not infringe Solvay’s patent or that the patent was invalid. Solvay and the generic manufacturers settled these suits, with Solvay agreeing to make annual payments to each of the generic manufacturers, and the generic manufacturers agreeing to delay marketing their generic versions of AndroGel. The FTC sued the parties to the settlement agreements, claiming that the agreements were unreasonable restraints of trade. The Eleventh Circuit held that reverse payment settlement agreements do not give rise to antitrust liability if their anticompetitive effects fall within the potential exclusionary scope of the patent’s duration and subject matter, and found that Solvay’s agreement with the generic manufacturers did not violate the antitrust laws. This “scope of the patent” test is also used by the Second and Federal Circuit Courts of Appeals.

Three Circuits—the Third Circuit, the Sixth Circuit, and the D.C. Circuit—have been more receptive to claims that reverse payment settlements can violate the antitrust laws. Notably, the Third Circuit in In re K-Dur Antitrust Litig., highlights the divide in the federal appellate courts over reverse payment settlement agreements. In K-Dur, Upsher, a generic drug manufacturer, entered a settlement agreement with Schering-Plough under which Upsher agreed to refrain from marketing its generic version of K-Dur, Schering’s potassium chloride supplement, for slightly over four years. The Third Circuit held that reverse payment settlement agreements were prima facie evidence of an unreasonable restraint of trade that gives rise to antitrust liability, and that the Schering-Upsher agreement was a violation of the antitrust laws.

The Supreme Court’s decision to grant certiorari in Watson hopefully will provide some guidance about the legal standards in this high-profile area of antitrust law.

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9 In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2008); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); see also Butler & Jarosch, supra note 9, at 120; Langenfeld & Li, supra note 9, at 788.

10 In re Cardizem Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); cf. Andrx Pharms., Inc. v. Biovail Corp. Int’l., 256 F.3d 799 (D.C. Cir. 2001) (ruling that Biovail had sufficiently alleged an antitrust injury by demonstrating that Andrx’s agreement with Hoechst Marion Roussel, Inc. to not sell Andrx’s generic version of Cardizem CD was exclusionary).

11 686 F.3d 197 (3d Cir. 2012)
Hospital Merger Enforcement Actions Over the Last Two Decades: A Long History with a Recent Resurgence

The *Phoebe* case before the Supreme Court and the challenge involving Reading Hospital System are the most recent examples of antitrust authorities’ long-standing scrutiny of hospital mergers. The efforts of U.S. antitrust authorities to challenge hospital mergers were largely unavailing in the mid-to-late 1990s. From 1994 to 2000, the FTC, the DOJ, and state authorities lost several hospital merger challenges. After that string of losses, there was a lull in enforcement and, it seems, a period of introspection on behalf of regulators as to the reasons behind the string of losses. For example, the first FTC Chairman under President George W. Bush suggested that the agency needed to reevaluate its strategy in litigating hospital mergers.

Apparently fueled, at least in part, by an FTC study released in 2004 that concluded that many hospital mergers resulted in price increases for health insurers, U.S. antitrust authorities seem to have renewed their vigor in challenging hospital mergers over the last several years. Since 2004, the FTC has had more success in challenging several hospital mergers in Illinois, Virginia, Texas, Ohio, Georgia, and Pennsylvania, while also displaying a willingness to entertain “failing firm” defenses in connection with hospital mergers.

- In 2004, the FTC initiated a retroactive challenge of Evanston Northwestern Healthcare Corporation’s already-consummated acquisition of Highland Park Hospital. Ultimately, the Commission required conduct remedies rather than the divestitures sought by the FTC staff and ordered by the Administrative Law Judge (“ALJ”). Nevertheless, the FTC was able to secure relief in a hospital merger challenge for the first time in several years.

- In 2008, the FTC challenged Virginia-based Inova Health System’s proposed acquisition of Prince William Hospital. In proceedings involving the FTC’s motion for a preliminary injunction, the district court denied the merging parties’ motion for a scheduling order and

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an expedited status conference that would have afforded the merging parties the opportunity to present live testimony, obtain discovery, and expedite the submission of the FTC’s preliminary injunction motion with evidence.\textsuperscript{17} The parties subsequently abandoned the transaction.\textsuperscript{18}

- In July 2009, the FTC filed an administrative complaint against Carilion Health Systems retrospectively challenging Carilion’s acquisition of an outpatient imaging center and an outpatient surgical center. Thereafter, Carilion and the FTC negotiated a consent decree whereby Carilion agreed to divest assets that raised competitive concerns for the FTC.\textsuperscript{19}

- The Commission investigated Scott & White Healthcare’s acquisition of King’s Daughters Hospital, which was completed on April 1, 2009. King’s Daughters Hospital was in a precarious financial condition, and the parties invoked the “failing firm defense” as a justification for the acquisition.\textsuperscript{20} Over the course of its investigation, the Commission staff learned that another health care system, Seton Family of Hospitals, considered acquiring King’s Daughters Hospital, but balked at the deal once Scott & White and King’s Daughters Hospital entered an agreement. Believing that a combination with Seton posed fewer competitive concerns than with Scott & White and in an effort to “test” the failing firm defense, the FTC asked Scott & White to offer to sell King’s Daughters Hospital to Seton in order to afford Seton an opportunity to evaluate the transaction. After Seton completed its diligence and decided to pass on the deal, the FTC cleared Scott & White’s acquisition of King’s Daughters on December 23, 2009.\textsuperscript{21}

- In March 2011, the FTC secured a preliminary injunction in federal court to stop ProMedica Health System, Inc. from continuing to integrate St. Luke’s Hospital post-closing.\textsuperscript{22} The

\textsuperscript{17}Order, FTC v. Inova Health Sys. Foundation, File No. 08-0460 (June 2, 2008); see also Memorandum in Support of Motion for Scheduling Order and an Expedited Status Conference, FTC v. Inova Health Sys. Foundation, File No. 1:08-cv-460 (E.D. Va. May 16, 2008).


\textsuperscript{20} A “failing firm” defense refers to instances where the target of an acquisition meets the following conditions: “(1) the allegedly failing firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; and (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger.” Dep’t of Justice & Fed. Trade Comm’n, Horizontal Merger Guidelines (Aug. 19, 2010), available at http://www.justice.gov/atr/public/guidelines/hmg-2010.html#11.


\textsuperscript{22}J. Entry, FTC v. ProMedica Health Sys., Inc., No. 3:11-cv-00047 (N.D. Oh., Mar. 29, 2011).
preliminary injunction stopped the transaction pending a trial on the merits in front of the FTC’s ALJ. After a full administrative hearing, the ALJ ruled that the merger was anticompetitive and ordered ProMedica to divest St. Luke’s Hospital. The Commission reviewed and affirmed the ALJ’s determinations and ordered ProMedica Health System, Inc. to divest St. Luke’s Hospital to an FTC-approved buyer. The case is currently on appeal at the Sixth Circuit Court of Appeals.

- In April 2012, a district court granted the FTC’s request for a preliminary injunction to stop OSF Healthcare System’s proposed acquisition of Rockford Health System. After the FTC secured the preliminary injunction, the parties abandoned the proposed transaction.

- As discussed above, in April 2011, the FTC issued an administrative complaint seeking to block Phoebe Putney Health System’s acquisition of Palmyra Park Hospital, Inc. from HCA in Albany, Georgia. The FTC also filed a motion for a preliminary injunction in federal court. On June 27, 2011, the district court denied the FTC’s motion on the ground that the merger was immune from antitrust challenge by virtue of the “state action doctrine.” On December 14, 2011, the Eleventh Circuit affirmed the district court’s decision. The Supreme Court granted the FTC’s petition for certiorari, and heard oral argument on November 26, 2012.

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31 FTC v. Phoebe Putney Health System, Inc., 663 F.3d 1369 (11th Cir. 2011).
As mentioned above, the FTC challenged Reading Health System’s proposed acquisition of Surgical Institute of Reading L.P., which eventually concluded with Reading abandoning the deal.33

DOJ Review of Health Insurance Mergers: Several Actions Culminated in a Recent Enforcement Action

Like the FTC, the DOJ also actively reviews mergers in the health care field. The DOJ recently has focused much of its antitrust attention on mergers in the health insurance sector, having sought to prevent or limit a number of health insurance mergers since 2004.

- In December 2005, the DOJ required PacifiCare to divest its health insurance businesses in Tucson, Arizona, and Boulder, Colorado as a condition to clearing its proposed merger with UnitedHealth.34

- In February 2008, the DOJ required UnitedHealth Group, Inc. to divest United’s Medicare Advantage business in Las Vegas, Nevada as a condition to clearing its proposed merger with Sierra Health Services, Inc.35

- On March 8, 2010, Blue Cross Blue Shield of Michigan abandoned merger plans to acquire Physicians Health Plan of Mid-Michigan after the Department informed the parties that it intended to file a suit to block the transaction.36

- As mentioned earlier, Amerigroup Corp. agreed to divest its entire Virginia subsidiary in order to consummate its merger with WellPoint, Inc.37

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Health Care Continues to Be a Focus for Antitrust Authorities in Other Ways Too

Beyond the areas discussed above, the FTC and the DOJ have scrutinized business practices in several different industries in the health care space.

The FTC has secured consent decrees as a condition to clearing numerous medical device and pharmaceutical transactions over the last several years, involving both branded and generic companies in the human health and animal health space. The FTC has initiated litigation to stop non-hospital mergers in the health care field, with mixed degrees of success. The Commission also filed a brief as amicus curiae in a case before the U.S. District Court of the Eastern District of Pennsylvania arguing that when brand-name manufacturers make minor, non-therapeutic changes to a drug, those changes may stymie competition from generic pharmaceutical drug companies.

The DOJ currently remains in litigation against Blue Cross Blue Shield of Michigan (“BCBSM”) over certain BCBSM contractual provisions, including particular most-favored-nation clauses with certain Michigan hospitals. The DOJ is alleging that BCBSM’s contractual provisions foreclose entry by other health insurance providers and increase health care costs. Additionally, in February 2011, the Department reached a settlement agreement with United Regional Health Care System to stop United from entering into contracts that allegedly impede health insurance companies from


contracting with competing health care service providers.\textsuperscript{42} Over the last several years, the DOJ has also initiated criminal and civil antitrust action against hospitals and their employees based on allegations of bid-rigging, price-fixing, and other anticompetitive agreements.\textsuperscript{43}

Finally, the FTC and the DOJ issued joint antitrust guidance in October 2011 for the formation and conduct of Accountable Care Organizations (“ACOs”), formed by hospitals or physicians and created pursuant to the Affordable Care Act’s Medicare Shared Savings Program.\textsuperscript{44} This guidance supplements continued enforcement against physician groups over potentially anticompetitive agreements.\textsuperscript{45}

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Regulators’ actions over the past decade, along with the events of the last few weeks, illustrate that the health care sector remains a key priority for antitrust regulators, and there is every reason to believe it will continue to be so in the foreseeable future.


Please contact Cadwalader’s [Antitrust](mailto:andrew.forman@cwt.com) and [Health Care](mailto:andrew.forman@cwt.com) Groups or any of the following Cadwalader lawyers if you have any questions about this Alert.

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