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a brief analysis of policy and litigation fall 2005

In This Issue

The Economics Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements

Robert A. Kneuper discusses antitrust challenges to settlements of patent disputes. The FTC and other plaintiffs allege that certain patent settlement agreements delayed entry and cost consumers millions of dollars. The FTC has taken a particularly strong stand against so-called reverse payments, settlement agreements involving payments from the plaintiff patent holder to the defendant generic producer. This article reviews the key economic arguments for and against the FTC's position.

Event Studies, Toxic Stock and Non-Compete Provisions

Jonathan L. Walker discusses event study methodology, which measures the impact of a newly discovered fact on the value of a company's outstanding stock. He describes how this methodology is being used increasingly in contexts other than securities litigation. In particular, he discusses the recent use of this methodology in two cases. In one, an event study was used to disprove injury attributed to alleged legal malpractice. In the other, an event study showed the cost to a firm of having a CEO go to a competitor.

Competition by Physician-Owned Specialty Hospitals

David A. Argue discusses how increasing competition between general hospitals and specialty facilities has raised a number of antitrust issues. Controversy arises largely from the combination of physicians' unique role in patients' health care decisions and physicians' investments in specialty facilities. Physicians who invest in specialty facilities may be able to refer the most profitable patients to their own facilities, while referring the less profitable patients to the general hospitals. General hospitals have responded to physician ownership of specialty facilities by restricting admitting privileges of physicians who invest in competing facilities and by contracting with payers to prevent specialty facilities from joining payers' networks. Both of these practices have been, and likely will continue to be, subjects of antitrust litigation.

The Economics Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements

By Robert A. Kneuper

ntitrust challenges to settlements of patent disputes have become the latest focus in the ongoing debate concerning the proper relationship of antitrust law to intellectual property law. The FTC and other plaintiffs have brought a series of actions against branded and generic manufacturers that settled patent disputes in the context of Hatch/Waxman regulations - regulations designed to facilitate generic entry. In cases such as Schering/Upsher-Smith, Hoechst/Andrx, and Abbott/Geneva, the FTC and private plaintiffs have alleged that patent settlement agreements caused delays in entry and cost consumers millions of dollars. The FTC has taken a particularly strong stand against so-called reverse payments-settlement agreements involving payments from the plaintiff patent holder to the defendant generic producer. Settlements with reverse payments also often include an agreement to delay generic entry until a specific date or until certain conditions are met.

Antitrust policy concerning these types of patent settlements is in a state of flux. Plaintiffs challenging these settlements have experienced several recent setbacks in Court. The 11th Circuit recently vacated the FTC's order in the matter of Schering-Plough Corporation, et al. (The FTC has appealed the decision to the Supreme Court.) Also, a judge in the Eastern District of New York ruled against purchaser plaintiffs who challenged a patent settlement between Bayer AG and Barr Laboratories, Inc.

The FTC bases its position against reverse payments on several key economic arguments. First, the FTC contends that the parties can reach an anticompetitive settlement agreement because the patent holder would have market power but for the entry of the generic manufacturer. This market power argument is typically based on economic studies and other evidence that show that generic entry significantly reduces prices and, thus, benefits consumers. Therefore, a patent settlement agreement that delays generic entry delays this benefit and is anticompetitive. This can be of particular concern when the settlement agreement involves a generic firm that is the only filer or is well ahead of other filers in the regulatory approval process.

Second, the FTC argues that a patent holder and a potential generic entrant have strong economic incentives to negotiate a settlement that delays generic entry. The parties' incentives favor delaying entry because the patent holder's profit loss after generic entry is generally much greater than the generic firm's profit gain. Thus, both parties can gain from a delay in generic entry as long as the patent holder compensates the generic firm for profits lost due to the delay. Such compensation could take many forms, including a reverse payment.

Third, the FTC argues that a patent right can be properly viewed as a probabilistic property right. This means that there is some probability that the patent will be upheld in court, but that outcome is not certain. The financial value of the patent depends on the probability it will be upheld as well as the expected profits if the patent is upheld. In rare cases, an accurate measure of this probability can be found and used to estimate an average likely entry date by which generic entry would have occurred under litigation. That date can then be compared to the date of entry under the settlement agreement to see if the agreement

Event Studies, Toxic Stock and Non-Compete Provisions

⊣By Jonathan L. Walker ⊢

vent study methodology, which is often used in securities litigation, is used increasingly in other contexts. For example, event study methodology recently was used in the context of a legal malpractice suit and separately in an employment dispute.

Event study methodology measures the impact of a newly discovered fact on the value of a company's outstanding stock. The stock's daily price movements and implicit daily returns are observed over a benchmark period known as an estimation window. Changes in the value of a market index are also observed over the same estimation window. By observing daily returns to the particular stock and also to an appropriate market index over the estimation window, one can predict daily returns to the stock given the observed daily returns to the market index. The difference between expected returns and actual daily returns are abnormal returns that cannot be explained by general movements in the market and must be attributable to some other factor. Under certain circumstances, it may be appropriate to attribute statistically significant abnormal returns to a specific fact that became known to the market during an event window, that period of time over which the market learned the fact.

In the malpractice suit, the defendant law firm had counseled a buyer in a corporate acquisition. The primary consideration in the sale was restricted stock in the buyer. Subsequently, the buyer's stock price plummeted, rendering the restricted stock paid as consideration virtually worthless. One of the acquired firm's shareholders sued the buyer's counsel. The buyer had issued convertible preferred stock during the due diligence period of the acquisition. The plaintiff shareholder alleged that the convertibility features rendered the preferred stock "toxic," presumably meaning that the new preferred was fatal to the company's legacy shareholders' interests. The plaintiff contended that the preferred shareholders could manipulate the convertibility feature to drive the common stock price below the fair market value and take over the company for a pittance. Although no one ever converted the preferred stock for common, the shareholder

claimed that the buyer's stock fell when the market became aware of the potential for manipulation. According to the shareholder, the buyer's counsel either hid the purportedly relevant details about convertibility or defaulted on an obligation to bring them to the shareholder's attention. The buyer's counsel had several defenses. For example the details of the preferred offering were publicly available and were made available to the sellers, and much of the proceeds from the preferred offering ultimately flowed to the plaintiff shareholder. In addition, an event study showed the absence of evidence that the preferred offering affected the value of the consid-

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eration at all. The buyer's common stock did not suffer statistically significant negative abnormal returns over any reasonable event window related to the announcement of the convertibility feature. Neither actual conversion of preferred stock for common nor the threat of conversion caused the subsequent fall in value of the stock that the shareholder received as payment pursuant to the acquisition.

In the employment case, event study results were relevant to the reasonableness of a non-compete provision. The chief operating officer of a large corporation received an offer to become the chief executive officer (CEO) of a rival. Litigation followed over the enforceability of non-compete provisions in the executive's employment agreement. Event study methodology was useful in quantifying the harm that can accrue to a company's

equity value when it loses a senior officer and the greater harm that can accrue by losing the officer to a close rival. The analysis concerned equity values for a dataset of companies that lost executives to become CEOs elsewhere. The dataset began with all 165 CEO appointments reported at ceogo.com over the period January 2002 through March 2004. In 112 cases, the new CEO was promoted from within rather than hired from elsewhere. In 34 instances, there were technical reasons that the observations could not be used in the event studies, e.g., the former employer was not publicly traded or some other potentially material information was disclosed contemporaneously with the CEO appointment. The 19 usable observations were divided into six instances where the executive left to become CEO within the same 4 digit SIC code and 13 instances in which the executive went to a different 4-digit SIC code.

For the instances in which firms lost executives to become CEOs at close rivals, the median abnormal return was negative 2.4%, indicating that a tremendous amount of equity value can be destroyed when a firm loses a senior officer to become CEO at a rival. For perspective, the average market capitalization of the S&P 500 companies is \$18.4 billion; 2.4% of that is \$443 million. For the instances in which firms lost CEOs to firms other than close rivals, the median abnormal return was negative 0.9%. The difference between 2.4% and 0.9%, 1.5% of market capitalization, is an approximation of the harm companies may seek to avoid through non-compete provisions restricting their most senior managers from immediately joining close rivals. This amounts to \$276 million when applied to the average capitalization of S&P 500 companies. Nonparametric statistical tests showed that the medians and differences in medians were statistically significant.

Jonathan L. Walker and Stuart D. Gurrea designed and conducted the analyses discussed in this article.



Competition by Physician-Owned Specialty Hospitals

By David A. Arque

ompetition between general hospitals and specialty facilities, such as specialty hospitals or ambulatory surgery centers, has become an increasingly important healthcare antitrust issue. The growth of specialty facilities, especially those with physician owners, has resulted in a flurry of private antitrust litigation. Two principal issues that have arisen are (1) whether general hospitals should be required to offer admitting privileges to physicians who have invested in a competing specialty facility and (2) what constitutes appropriate use of exclusive contracting by general hospitals. Analyses of these issues involve understanding the complementary and competitive nature of physician-hospital relationships.

The controversy between general hospitals and physicians regarding specialty facilities arises largely from the combination of the unique role that physicians have in patients' health care decisions and physicians' investment in specialty facilities. Physicians' unique role in healthcare decisions exists because they often have the most information about patients' health and the best course of treatment. Physicians typically plan and supervise patients' medical treatment, including any in-hospital care. Moreover, with sufficient ex-ante information, and an understanding of reimbursement rates, physicians can determine which patients are likely to be the most profitable for a hospital. Medicare patients, in particular, often can be readily segregated into more-profitable and less-profitable categories because Medicare payment rates do not differentiate sufficiently between episodes of high-cost and lowcost hospital care.

Physicians' informational advantage about the likely course (and profitability) of patients' facility care can be converted to a competitive advantage for a facility that can align the physicians' financial interests with its own. Specialty facilities achieve that alignment of incentives through physician investment, whereas federal law limits general hospitals from similar physician investment. A physician's ownership share typically entitles him or her to a share of a specialty facility's profits, which gives the investor-physician a financial incentive to refer the most profitable patients to his or

her own facility. Consistent with this incentive, the Medicare Payment Advisory Commission ("MedPAC") reports that the portion of patients who are Medicaid-insured at specialty hospitals tends to be much lower than at general acute care hospitals. MedPAC also reports that specialty hospitals tend to be more profitable.

General hospitals face certain constraints that affect their competitive response to specialty facilities. General hospitals provide physicians with access to full-service facilities, and they often provide back-up patient transfer services for specialty facilities. In neither case are general hospitals allowed to charge specialty facilities for making these services available. Specialty facilities' ability to compete with general hospitals would be significantly limited, however, if these "free" services were not available. In effect, investor-physicians (and their specialty facilities) receive an implicit subsidy from general hospitals by receiving services without paying for them. General hospitals have adopted alternative approaches to the subsidy issue in part because no price mechanism governs the overall relationship between physicians and general hospitals. Among these approaches are (1) limits on or the revocation of admitting privileges of physicians who invest in competing facilities and (2) exclusive contracts with payers that prevent specialty facilities from joining payers' networks.

In response to privileges restrictions by general hospitals, specialty facilities have petitioned the courts to require general hospitals to grant admitting privileges to investor-physicians. General hospitals' refusals to grant privileges are effective (and thus controversial) because, all else equal, patients are likely to prefer physicians who can admit patients for virtually any medical service to physicians who can admit patients only to a specialty facility for limited services. By refusing to grant privileges to investor-physicians, general hospitals eliminate part of the subsidy that investor-physicians and specialty facilities would otherwise receive.

Exclusive contracting, the other controversial measure taken by general hospitals, is not new to healthcare. Historically, HMO's have realized substantial cost savings

El News and Notes

World's Largest Gaming Company Created

William P. Hall provided economic analysis to Harrah's Entertainment, Inc. for its \$9.4 billion acquisition of Caesars Entertainment, Inc. Assisted by Paul E. Godek and Laura A. Malowane, Hall was retained by both parties through counsel at Latham & Watkins and Skadden, Arps, Slate, Meagher & Flom. The FTC's 11-month investigation into several geographic markets concluded with a 5-0 Commission vote to close the investigation with no enforcement action. Hall testified on behalf of Harrah's in May before the New Jersey Casino Control Commission with respect to the competitive effects of the merger among Atlantic City casinos.

JCI Acquires Battery Business

Philip B. Nelson and Robert D. Stoner worked on JCI's acquisition of Delphi's global battery business. JCI was represented by Foley & Lardner and Delphi was represented by Drinker, Biddle, and Reath. JCI is the global leader in automotive batteries. While Delphi's North American automotive battery manufacturing assets were not included in the immediate transaction, the transaction will allow JCI to receive a multi-year supply agreement with GM, Delphi's largest customer, with the likely eventual absorption of those battery assets into those of JCI. The transaction was consummated after the Federal Trade Commission decided not to challenge it.

Monopolization Case In Puerto Rico

Kent W Mikkelsen was retained to provide an expert report and deposition testimony on behalf of El Día. El Dia was accused in U.S. District Court of monopolization and attempted monopolization of certain printing services in Puerto Rico. Citing Mikkelsen's findings on multi-product discounts, predatory pricing and geographic and product market, El Dia's counsel successfully moved for summary judgment. El Dia was represented by Baker & Hostetler and by Fiddler Gonzalez & Rodriguez.

Final Analysis Wins Verdict

Stephen E. Siwek testified as a rebuttal witness in U.S. District Court in Maryland on behalf of Final Analysis, a satellite communications firm. Final Analysis was suing General Dynamics for breach of contract and wrongful termination of a partnership. Siwek, who was assisted in his analysis by Gale R. Mosteller, testified on issues related to damages. The jury returned a verdict worth \$129.9 million for Final Analysis.

Reverse Payments in Patent Settlement Agreements . . (Continued from Page 1)

delayed generic entry. If the FTC cannot reliably estimate the patent holder's probability of prevailing under litigation (which is usually the case), the FTC generally infers delay from the fact of a substantial reverse payment.

Some economists have criticized the reasoning underlying the FTC's position against reverse payments. One criticism is that the FTC overstates the consumer benefits of generic entry. Such entry reduces product prices but also may reduce promotional activities. Promotions tend to increase the demand for the branded products, and certain types of promotions can provide significant benefits to consumers. Thus, reductions in promotions can reduce consumer welfare over time. In certain situations, the consumer welfare losses from reduced promotional activity due to generic entry can partially or fully offset the consumer welfare gains from the fall in price. This argument can be particularly relevant in cases when the availability of an important drug depends heavily on promotions.

In addition, some economists argue that the FTC should not infer an anticompetitive delay of entry from the fact of a reverse payment. These economists argue that reverse payments can be made for reasons unrelated to delayed entry. For example, they contend that a very risk averse patent holder might make a reverse payment simply to avoid the uncertainties and costs associated with litigation. An alternative explanation for reverse payments involves informational asymmetries - differences in information available to the parties to the patent dispute. For example, the

branded company may have different information than the generic company concerning important issues, such as the validity of the patent. In theory, information asymmetries could lead a patent holder to make a reverse payment.

Thus far, these criticisms have not convinced the FTC to change its position against reverse payments. The FTC views the criticism regarding the reduction in promotional activities as tantamount to arguing that competition does not work. It views the proposed other explanations for reverse payments as theoretical constructions that are often inconsistent with the evidence in a particular case. Overall, the parties to a settlement with a substantial reverse payment will face an uphill battle in overcoming the FTC's presumption that such an agreement is anticompetitive. Nevertheless, the evidence relating to these various economic arguments should be carefully considered in assessing the antitrust risks associated with a particular settlement agreement. Such evidence may show that a settlement with a reverse payment is not anticompetitive.

Robert A. Kneuper recently joined EI after analyzing antitrust matters for over 10 years at the Federal Trade Commission. While at the FTC, he played a major role in developing antitrust policy positions for cases involving patent settlements and was lead economist on both the Schering and Hoechst/Andrx cases.

Physician-Owned Specialty Hospitals (Continued from Page 3)

because they received lower rates from hospitals in exchange for exclusivity. General hospitals, with more comprehensive service offerings, typically are better positioned than specialty facilities to offer exclusive contracts. Exclusive contracts are effective competitive responses by general hospitals because they substantially constrain physicians' ability to influence patients' choice of hospital. Patients are less likely to follow a recommendation to use their investor-physician's specialty facility if that facility is not in the patients' health insurance network. Thus, these contracts unlink physicians' incentives to refer patients to a particular facility and their ability to influence patient choice. Nevertheless, payers may be reluctant to exclude specialty facilities if, as these hospitals argue, they provide lower-cost and higher-quality care.

There is little case history on how the courts view these issues from an antitrust perspective. In some circumstances, as the recent Third Circuit appellate decision in *Gordon v. Lewistown Hospital*

exemplifies, general hospitals' actions are not seen as likely to harm competition because sufficient competition exists without the specialty facility. Even if a general hospital has market power, the courts may rule in its favor. In Trinko v. Verizon, the U.S. Supreme Court recognized the value of incentives for firms to invest in "economically beneficial facilities." The courts may view the unprofitable services typically provided by general hospitals, either as parts of their overall mission or due to regulatory requirements, as "economically beneficial" services that require funding from other more profitable hospital services. If so, the courts may want to uphold the incentive to provide that funding, although questions remain regarding the actual impact of specialty facilities competition on the ability to provide those unprofitable services. Regardless, the courts will be dealing with the competitive impact of an assortment of "second-best" approaches that have arisen in the absence of other market mechanisms.

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