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A BRIEF ANALYSIS OF POLICY AND LITIGATION

CRISPR Patent Pool May Not be Successful in Providing a Free Commercialization and Development Environment for its Technology

P. Joseph Ahn

Dr. P. Joseph Ahn has expertise in microeconomics, corporate strategy, and quantitative analysis, with particular focus on technology and media industries. His work has included estimating damages, analyzing proposed regulation, and advising on multi-national tax.

The Clustered Regularly Interspaced Short Repeats ("CRISPR")-Cas9 is a powerful DNA-editing technology. It has many applications, including crop productivity, malaria-resistance, and potential cures for HIV or cancer. However, further research and commercialization of this technology is hindered by a patent dispute between the University of California at Berkeley ("UC Berkeley") and the Eli and Edythe L. Broad Institute of MIT and Harvard ("Broad Institute"), in which UC Berkeley has alleged the Broad Institute's patents either are invalid or otherwise infringe upon their own patent portfolio.

In an effort to promote development of CRISPR, the Broad Institute, Rockefeller University, Harvard University, and MIT recently granted permission for 22 of their CRISPR-Cas9 patents to be a part of a shared, global licensing platform – i.e. a "patent pool."

However, this patent pool may not be sufficient to allow full commercialization and development of the CRISPR-Cas9 technology. Despite recent attempts at reform, including the passage of the America Invents Act in 2012, patents continue to face issues of conflicting, overlapping, and fragmented rights spread across multiple patent holders. Patent pools are designed to circumvent this problem by providing a centralized holder of patents from which all participants can non-exclusively license. However, if a single patent holder holds a critical patent, it can hold up the entire pool by refusing to contribute its particular patent. Even if other critical patents are held in the pool, depending on how the rights are concentrated or how easily certain technology can be invented around, a holder of a critical patent can have significant bargaining power.

The CRISPR patent pool faces a potential hold-up. Although the U.S. Patent and Trademark Office ruled in February 2017 that the Broad Institute's CRISPR patents are valid (a decision that UC Berkeley has appealed to the United States Court of Appeals for the Federal Circuit in Washington D.C.), the Broad Institute's patents are focused on applications of CRISPR to human cells. UC Berkeley still holds the rights to multiple critical – and broader – patents that could curtail the commercial and research activities of the pool members despite their cooperation.

If UC Berkeley wins its patent battle with the Broad Institute, the CRISPR patent pool may not be successful and unrestricted development of this powerful technology may not occur.

Estimating Healthcare Rates In Disputes Over Payment To Out-Of-Network Providers

David A. Argue

David A. Argue is an expert in issues of healthcare economics. He recently co-presented on the topic of out-of-network payments at the American Health Lawyers Association annual meeting with Ann M. Bittinger, Esq.

Determining appropriate payment rates for non-contracted healthcare providers has become an increasingly important issue in healthcare dispute resolution. In theory, if a provider has no contract with a health plan, the plan's enrollees would not use that provider. In reality, plan enrollees do use non-contracted providers, which then seek payment from the plan. There are other contexts for rate disputes as well, such as when a payer is alleged not to have paid according to a contract's terms.

Patients frequently use out-of-network providers for emergency services, but they may also use out-of-network providers because of physicians' referrals or simply out of ignorance of their insurance coverage. A provider may be out of network because of a business strategy involving narrow networks or due to a breakdown in contract negotiations. In out-of-network situations, providers usually demand full charges since they have not agreed to a discount. But health plans often maintain that they will pay no more than a "reasonable" amount, perhaps the Medicare rate or a vague estimate of the cost of the service. If a court or arbiter requires that the provider be compensated, what price should be paid?

> "An economic framework can incorporate market specific information into the analysis..."

An economic perspective can provide a principled basis for determining appropriate out-of-network rates. An economic framework can incorporate market-specific information into the analysis and provide guidance for empirically sound estimates of rates. A core part of the economic framework in today's healthcare markets is the exchange of value between providers and health plans around the formation of networks. Health plans create value by steering patients to in-network providers through financial incentives. Providers create value by contributing to the attractiveness of the network. In the value transaction, providers are included in the plan's network in exchange for discounted rates. Thus the economic framework indicates that absent the value exchange, a provider would not offer discounted rates because it would not receive the value of being in-network.

In these situations, a benchmark empirical analysis, using comparable situations that reflect the business and economic realities, can help address the question. A benchmark strategy relies on finding a starting point that is comparable to the circumstances at issue. Two key aspects of comparability are the nature of the payer and the nature of the provider. Close benchmarks might be rates paid to the same provider by comparable payers on an out-of-network basis or rates paid by the same payer to comparable providers on an out-of-network basis. More often than not, however, close comparability is hard to find and adjustments are necessary.

Consider a stylized example in which a provider group fails to come to a network agreement with both a large health plan and a small health plan, and as an out-of-network provider, the group demands full charges from payers. Suppose that in response, the small health plan arranges single-case agreements for the small number of its enrollees who use the group, but that the large health plan ignores the group's demand for full charges, insisting it will pay the Medicare rate. Add one other fact: an out-of-network specialty hospital in the area has agreed to accept a modest discount off charges from the large health plan.

Two potential benchmarks for resolving the plan-provider dispute exist in this scenario. Neither benchmark is perfectly comparable, but both may be workable with adjustments. The first is the single-case agreements between the provider group and the small health plan. Adjustments would be needed for the fact that these are single-case agreements rather than comprehensive terms, and that they are with a small-volume health plan rather than a large source of patients. The second benchmark is the out-of-network rate between the large plan and the specialty hospital.

This rate is comparable for being out-of-network with the large plan, but it is with a specialty hospital rather than a provider group. Still, relying on the economic principles discussed above, it is possible to understand the nature of the adjustments that would be necessary. If the only available

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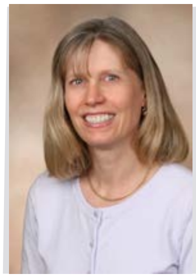
Delaware District Court Highlights Pricing Behavior and Lack of Effort to Find Alternative Bidders in Decision to Block Radioactive Waste Cos.' Merger

Stephanie M. Mirrow



Stephanie M. Mirrow has worked on numerous mergers and acquisitions across a broad range of industries. She previously was an economist in the Antitrust Division of the U.S. Department of Justice.

A Delaware district court recently blocked the proposed merger of EnergySolutions, Inc. ("Energy Solutions") and Waste Control Specialists LLC ("WCS"). U.S. District Judge Sue L. Robinson, siding with the United States Department of Justice ("DOJ"), found that the merger is substantially likely to lessen competition in the market for disposal of higher-activity low-level radioactive waste ("LLRW") and lower-activity LLRW. Judge Robinson also dismissed the merging parties' failing firm defense, indicating the merging parties failed to demonstrate that Energy Solutions is the only available purchaser.

DOJ alleged that the merger would substantially lessen competition for disposal of LLRW and asserted four product markets for such disposal: 1) higher-activity operational LLRW; 2) lower-activity operational LLRW; 3) higher-activity decommissioning LLRW; and 4) lower-activity decommissioning LLRW. The Court collapsed these into two markets, finding that the disposal options are essentially the same for operational waste and decommissioning waste.

The merging parties asserted that Energy Solutions and WCS have different methods for disposing of higher-activity LLRW. Higher-activity LLRW can be sent to WCS's compact waste facility for direct disposal, but Energy Solutions' facility cannot directly dispose of higher-activity LLRW. Higher-activity LLRW must go through a process called concentration averaging before it can be disposed of at Energy Solutions' facility. The merging parties also argued that DOJ's alleged market for lower-activity LLRW was overbroad, because WCS's exempt cell facility can only accept lower-activity LLRW that is below certain radioactive concentrations.

> "The Court's conclusion reflects its concern that there existed another potential bidder that was not given the time or information needed to prepare an alternative bid..."

While recognizing that Energy Solutions and WCS have different methods for accepting and disposing of higher-activity LLRW, the Court concluded that the merging parties were the only competitive alternatives for the disposal of higher-activity LLRW. In its analysis, the Court states that the "most significant indicator that WCS and Energy Solutions offer competitive alternatives for disposal of higher-activity LLRW is that Energy Solutions charges its customers a single price for both processing [concentration averaging] and disposal" and that Energy Solutions has changed its prices to win higher-activity LLRW disposal business from WCS. The Court cites to several examples and corroborating internal reports that indicate Energy Solutions lowered its price in response to competition from WCS and that customers switched back and forth between Energy Solutions and WCS due to price discounts.

The Court also found that Energy Solutions and WCS compete for lower-activity LLRW. It concluded that customers have been able to negotiate better prices due to competition between Energy Solutions and WCS's exempt cell and have switched back and forth between the two merging parties to get lower prices. Again, the Court cited to several customer examples and internal reports as evidence of this price competition.

The Court's conclusions affirm the importance of pricing behavior in considering whether two firms compete in the same market. The Court considered specific examples of pricing, price changes and customer responses to price changes as the strongest indicators of whether the merging parties competed in the same product markets.

The Court's decision also highlights the difficulties in successfully asserting a failing firm defense. The U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (§11) state that a merger is not likely to enhance market power if imminent failure of one of the merging firms would cause the assets of that firm to exit the relevant market. A showing of failure typically requires the following three conditions: (1) the firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully (Chapter 11); and (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers that pose a less severe danger to competition than does the proposed merger.

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Healthcare Rates In Disputes

benchmark rates are for different types of providers (like different types of facilities or physician specialties) or different types of health plans (like those with different degrees of patient steering), it may nevertheless be possible to estimate differentials between in-network and out-of-network rates.

Other approaches that may be considered are using cost coverage or "reasonable" profits as a basis for determining out-of-network rates. However, although these approaches are intuitively appealing, they are seldom practical for health care service providers. Many providers' cost structures cannot be dissected adequately to make determining costs and profits for a specific service possible. Organizations like hospitals or multi-specialty clinics share fixed costs across different services and payers, and attribution of costs by service is unlikely to be well founded in economics. Attempting to focus on incremental costs instead would be inconsistent with the economic realities of average-cost pricing necessary to make the sum of revenue across individual patients cover the provider's variable and fixed costs.

As long as networks exist, out-of-network payment rates will be matters of dispute. The economic principles that determine negotiated rates guide empirical analyses like benchmarking, which is applied to the parties' contract terms to estimate appropriate out-of-network rates. As appealing as it is to aim for a "fair" profit or to cover "reasonable" costs, such approaches are almost always unrealistic to implement. With careful consideration of the facts and the available information, and with appropriate adjustments, it is often possible to arrive at reasonable, economically justifiable out-of-network rates.

Pricing Behavior and Lack of Effort

The Court considered the merging firms' argument that WCS is a failing firm. The Court highlighted several facts concerning WCS's financial situation, including WCS's failure to make an operating profit since it entered the business in 2012. The Court also recognized that it is uncertain whether WCS will become profitable in the future. However, the Court also considered the arguments made by DOJ concerning WCS's position as an ongoing firm, including, for example, the credit extended to WCS by its parent Valhi, WCS's current ability to meet payroll and pay bonuses and WCS's investment in future growth opportunities. The Court concluded that it would require careful and time intensive consideration to weigh the evidence presented by each side. The Court further concluded that it need not decide the issue of whether WCS would be able to meet its financial obligations in the near future or be able to reorganize under Chapter 11, because the merging parties failed to demonstrate that Energy Solutions is the only available purchaser. Specifically, the Court found that WCS's parent, Valhi, essentially engaged in a single bidder process in 2015 and then agreed to several deal protection clauses that made it impossible to entertain other offers. These deal protection clauses included a no-talk provision without a fiduciary out, a provision prohibiting WCS from furnishing non-public information to others, and a no-shop provision which prohibits WCS from taking any action that would facilitate or encourage any alternative bidders. The Court also highlighted the existence of an alternative potential bidder that was "left in the dark" once WCS agreed to Energy Solutions' offer.

The Court's conclusion reflects its concern that there existed another potential bidder that was not given the time or information needed to prepare an alternative bid, and that contractual restrictions imposed by Energy Solutions made it impossible for WCS to respond to other companies that expressed interest in purchasing WCS after the transaction was announced. The Court's decision indicates that merging firms should carefully consider the efforts to solicit reasonable alternative offers if a failing firm defense is anticipated.

EI News and Notes

Directed Verdict in Robinson-Patman Case

EI Chairman Barry C. Harris was the economic expert for Argos USA during a Robinson-Patman litigation in federal court in St. Thomas, Virgin Islands. Plaintiff Spartan Concrete Products alleged that Argos had provided a competitor of Spartan's an illegal 10% volume discount in its purchase of cement. Spartan was seeking damages of between \$6.3 million and \$8.8 million. Dr. Harris submitted an expert report that concluded that Spartan had not demonstrated injury to competition and that its damage estimates were flawed and not reliable. Judge Gomez ruled that Spartan had not met the necessary elements of proof and granted Argos' motion for a directed verdict. Kent Mikkelson and Lona Fowdur worked with Dr. Harris. Argos was represented by McGuire Woods LLP.

STATACorp Adopts Econometric Techniques

Econometric techniques for productivity analysis developed by EI Vice President Kevin Caves and his co-authors in academia have recently been integrated into STATA, a leading statistical software package used globally by economists and empirical analysts. A recent STATA journal article explains that its new e-class command implements the method of Ackerberg, Caves and Frazer (2015, Econometrica 83: 2411-2451). Productivity analysis has a wide range of applications, including the measurement of scale economies in high-fixed-cost industries, quantifying the benefits of investing in new technologies, and various antitrust applications.

Study on Broadband Networks

EI Principal Hal J. Singer and Ed Naef and Alex King of CMA Strategy Consulting author a study, "Assessing the Impact of Removing Regulatory Barriers on Next Generation Wireless and Wireline Broadband Infrastructure Investment." This study evaluates the impact of the FCC's recent efforts to remove barriers to investment into next-generation wireless and wireline broadband networks, and thereby to accelerate the transition from legacy copper networks to next-generation services.

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