

A close-up photograph of a white lab coat. A blue stethoscope is draped over the left side of the coat. A blue tie is visible through the open collar. On the right side, a white pocket is visible with a silver pen clipped to it.

Antitrust Chronicle

MAY · SPRING 2019 · VOLUME 2(1)

THE HEALTHCARE SECTOR: TRANSATLANTIC VIEWS

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LETTER FROM THE EDITOR

Dear Readers,

The Healthcare Sector continues to be fertile ground for antitrust issues, whether in the case of hospital or pharmaceutical mergers (vertical, cross-market, etc.), pay for delay issues, patent settlements, or parallel exports, etc.

CPI is pleased to present our latest Antitrust Chronicle focusing on some of these hotly discussed topics in the Healthcare Sector in the United States and Europe.

The DOJ's Antitrust Division remains focused on anticompetitive practices in the Healthcare Sector. At the ABA Healthcare Conference on May 17, 2018, Barry Nigro, Deputy Assistant Attorney General, stated: "Because competition benefits consumers in so many ways, antitrust enforcement will continue to play an outsized role in healthcare." Mr. Nigro continued: "Protecting and fostering competition in this space is a responsibility that we at the Antitrust Division take very seriously, and, because of that, antitrust enforcement in healthcare will continue to be a high priority for the Division."

The same holds true in Europe. The European Commission regularly monitors business practices in the pharmaceutical, health services, and medical devices markets. The Commission's main enforcement actions in antitrust and mergers in the pharmaceutical sector are set out in its "Report on competition enforcement in the pharmaceutical sector (2009-2017)." The Report was drawn up in cooperation with the national competition authorities and explains how competition authorities in the EU are working together.

We hope this edition of the CPI Antitrust Chronicle will help further the discussions and add to the rich debate on these timely issues.

Lastly, please take the opportunity to visit the [CPI website](#) and [listen to our selection of Chronicle articles in audio form](#) from such esteemed authors as Maureen Ohlhausen, Herbert Hovenkamp, Richard Gilbert, Nicholas Banasevic, Randal Picker, Giorgio Monti, Alison Jones, and William Kovacic among others. This is a convenient way for our readers to keep up with our recent and past articles on the go, in the gym, or at the beach.

As always, thank you to our great panel of authors.

Sincerely,

CPI Team

SUMMARIES



Navigating Vertical Mergers in Healthcare Through a Shifting Enforcement Landscape

By Lisl J. Dunlop & Cristina M. Fernandez

At the same time that vertical mergers have become more commonplace in health-care, the way in which such deals are evaluated in the U.S. has begun to shift. In 2018 and 2019, the U.S. federal agencies litigated a vertical merger challenge to judgment for the first time in nearly forty years, re-examined what remedies are appropriate where competitive issues are present in a proposed vertical merger, considered revision of the Non-Horizontal Merger Guidelines, and have contemplated an overhaul for how merger cases in general are tried in federal courts. But far from stymieing transactions with the potential to capture value for the merged entities and their customers, close examination of recent clearances and litigation indicates that vertical deals can survive enhanced antitrust scrutiny.



Cross-Market Hospital Mergers: An Antitrust Theory Challenged by Facts and Law

By Jeffrey W. Brennan

A developing economic literature focuses on price effects from mergers between non-competing hospitals. “Cross-market” mergers occur between hospitals in separate geographic markets. In nearly every analytical respect, they are unlike horizontal and vertical mergers, and neither federal antitrust agency has ever challenged such a merger. These transactions are drawing attention over concerns they may give merging hospitals greater power over price than they individually had before the merger. Central to the theory is the presence of regional employers that provide health insurance coverage to their employees and have employees living or working in each hospital market. The concern is that these employers want individual health insurance products that cover all or most of their employees, and the hospitals can leverage this factor for a higher price as a negotiating entity for multiple hospitals than they could pre-merger for one entity. This article describes the theory’s basic underpinnings and provides commentary on its shortcomings both analytically and under current antitrust jurisprudence.



Navigating the Backwater: Vertical Mergers in Health Care

By Thomas L. Greaney

Antitrust enforcers are taking a second look at vertical mergers as a large body of theoretical and empirical work has undermined the economic foundations of the laissez-faire approach that has characterized government policies over the last thirty years. Health care markets, which exhibit many of the key pre-conditions for harm from vertical mergers, are experiencing rapid consolidation. This essay suggests that continued forbearance will result in consumer harm and close attention should be paid to vertical combinations involving the providers, payors, and middlemen.



A Stronger Second Competitor? Analyzing the Competitive Effects of the *Beth Israel-Lahey* Transaction

By Cory Capps, Kayuna Fukushima, Tetyana Shvydko & Zenon Zabinski

The economic literature provides little guidance into the circumstances under which eliminating existing competitors while simultaneously creating a closer second competitor to a market leader will increase competition. This issue was recently analyzed by the Massachusetts Health Policy Commission (“HPC”) in its evaluation of a proposed merger of several local health systems to form the Beth Israel Lahey Health (“BILH”) system, which is comparable in size to Partners HealthCare (“Partners”), the largest and most expensive system in the Boston region. The HPC investigated whether shifts in patient volume away from Partners to BILH would be sufficient to reduce healthcare spending and concluded that they likely would not. The HPC issued its findings in a cost and market impact review report and referred the merger to the Massachusetts Attorney General. After the parties agreed to various conduct remedies, including a cap on price increases, the Commonwealth allowed the merger to close. The Federal Trade Commission subsequently opted to close its investigation, though it labeled the decision a “close call.”

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When Providers Merge, is Kaiser a Competitor?

By Douglas Ross, James Harlan Corning, David Maas & Douglas Litvack

Although a federal district court twenty years ago included Kaiser hospitals as market participants when considering a merger of two non-Kaiser hospitals, the courts have not considered the matter again. But the issue remains a live one: in two recent enforcement actions, California and Washington have argued that Kaiser providers do not compete with non-Kaiser providers because commercial payers cannot substitute Kaiser providers into their networks in place of non-Kaiser providers who seek to raise price. But if non-Kaiser providers raise price after a merger in a market where Kaiser competes vigorously with commercial payers for covered lives, those providers risk losing patients who may switch to Kaiser's lower cost coverage provided through Kaiser hospitals and physicians. Consequently, the argument for inclusion of Kaiser as a market participant is strong, and can be bolstered by facts specific to the transaction under review: Kaiser's success in a particular market in competing with other commercial payers, the extent to which employers offer their employees Kaiser and a non-Kaiser option, the extent to which employees can (and do) switch between the two, and documents generated in the ordinary course of business that show non-Kaiser providers viewing Kaiser as a significant competitor in their market.

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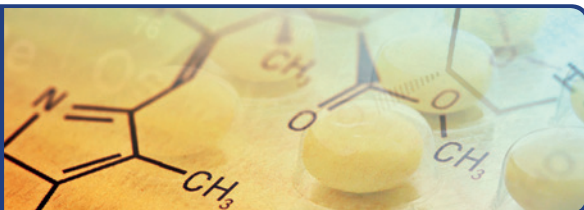


Uncertainty in Pharmaceuticals Markets

By Henri Piffaut

In a number of industries, competitive constraints come mostly from outside the market. That is notably the case in most pharmaceutical markets where patents protect the position of an operator. In these markets there is uncertainty for the incumbent of where or when the threat to the market position may come. That begs the question of how this uncertainty should be addressed in a competition law assessment. This article seeks to answer that question by focusing on pay-for-delay cases in pharma markets. Many of the developments could be equally applicable to the other markets. A common thread in pay-for-delay cases is how to objectively prove a restriction of competition based on evidence that reflects the uncertainty at the time of the agreement: should *ex post facto* evidence or the perception of the parties at the time of the conduct be used? Relying on the pay-for-delay cases *Lundbeck* and *Servier*, this article looks at how the concept of potential competition has been applied, then at the value of the transfer that changes the incentive to compete for the generic company, and finally at a test for a restriction by effect analysis.

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To Settle or Not To Settle? An Analysis of the *Servier* Patent Settlement Case and its Practical Implications

By Marie Manley & Anne Robert

Since its inquiry into the pharmaceutical sector, the European Commission ("Commission") has been monitoring patent settlement agreements. It adopted two infringement decisions so far, each of which was appealed and led to a judgment by the General Court ("GC"). The most recent development is the GC's judgment in the *Servier* case (Case T-691/14). The GC refuted (i) the Commission's assessment of the product market definition and hence the dominance abuse under Article 102 of the Treaty on the Functioning of the European Union ("TFEU"); and (ii) the Commission's finding that the settlement agreement between *Servier* and the generic company, *Krka*, infringed Article 101 TFEU. The GC agreed with the Commission that the agreements between *Servier* and the other generic companies each restricted competition "by object." This article reviews the key takeaways from, and the possible implications of, the *Servier* case for the pharmaceutical industry. It focuses in particular on some of the key issues raised by the GC's analysis from an IP and regulatory perspective.

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The Commission's Paper on the Obligation of Continuous Supply of Medicines and its Impact on Parallel Exporting Activities in The EU: A Paradigm Shift?

By Gonçalo Miguel Banha Coelho

This paper seeks to shed some light on the impact of the European Commission's Paper obligation of continuous supply of medicines in typically parallel exporting countries. It is argued that the Commission's initiative on this domain represents a backtracking from its previous liberal approach to arbitrage in parallel export cases, in particular, through the use of competition rules to foster Internal Market goals. Recent initiatives by the Portuguese pharma regulator show that the Commission's 2018 initiative acted as a lever to reverse medicines shortages domestically by curbing parallel exports. Thus, whilst in the past the Commission's doctrine was used by wholesale distributors as a defence against any encroachment in their right to carry-out parallel exports, it is now being invoked before national regulators as a lever to ensure the continuous supply of the domestic market.

WHAT'S NEXT?

For June 2019, we will feature Chronicles focused on issues related to (1) **A look back at Amex**; and (2) **Fines & Damages**.

ANNOUNCEMENTS

CPI wants to hear from our subscribers. In 2019, we will be reaching out to members of our community for your feedback and ideas. Let us know what you want (or don't want) to see, at: antitrustchronicle@competitionpolicyinternational.com.

CPI ANTITRUST CHRONICLES JULY 2019

For July 2019, we will feature Chronicles focused on issues related to (1) **The AT&T/Time Warner Saga**; and (2) **EU Arbitration & Antitrust**.

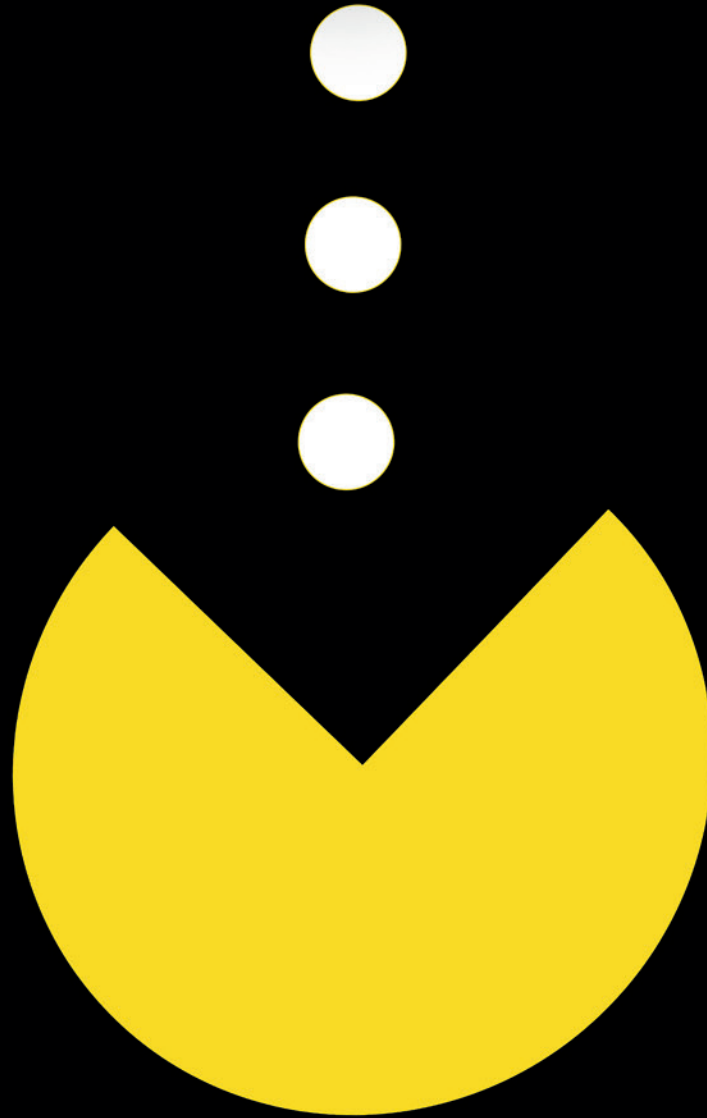
Contributions to the Antitrust Chronicle are about 2,500 – 4,000 words long. They should be lightly cited and not be written as long law-review articles with many in-depth footnotes. As with all CPI publications, articles for the CPI Antitrust Chronicle should be written clearly and with the reader always in mind.

Interested authors should send their contributions to Sam Sadden (ssadden@competitionpolicyinternational.com) with the subject line “Antitrust Chronicle,” a short bio and picture(s) of the author(s).

The CPI Editorial Team will evaluate all submissions and will publish the best papers. Authors can submit papers on any topic related to competition and regulation, however, priority will be given to articles addressing the abovementioned topics. Co-authors are always welcome.



NAVIGATING VERTICAL MERGERS IN HEALTHCARE THROUGH A SHIFTING ENFORCEMENT LANDSCAPE



BY LISL J. DUNLOP¹ & CRISTINA M. FERNANDEZ²



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I. INTRODUCTION

Vertical integration has become increasingly attractive in the healthcare industry as a means to reduce escalating healthcare costs through integrating different elements of healthcare delivery models and to capture value in the face of uncertainty about how the healthcare industry will generate revenue from services and assets in the future. Over the last few years, significant vertical integration has included players at all levels of the healthcare distribution chain: Providers, payors, pharmacy benefits management (“PBM”) companies, and others. For example, two of the largest recent transactions have been the 2018 combinations of two of the top five national health insurers, Cigna Corp. (“Cigna”) and Aetna Inc. (“Aetna”), with two of the top five PBMs, Express Scripts Holding Co. (“Express Scripts”) and CVS Health Corp. (“CVS”), respectively.

At the same time that vertical mergers have become more commonplace in healthcare, the way in which such deals are evaluated in the U.S. has begun to shift. Both the Antitrust Division of the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”) have voiced interest in a sharper focus on vertical merger enforcement. Recent years have brought the first vertical merger challenge litigated to judgment in nearly forty years; Congressional interest in prominent deals; and statements from U.S. agencies (1) re-examining what remedies are appropriate where competitive issues are present; (2) considering revision of the Non-Horizontal Merger Guidelines; and (3) contemplating an overhaul for how merger cases are tried in federal courts.

At first blush, the combined effect of recent events in U.S. vertical merger enforcement may appear to be seismic change, but closer examination of clearances and litigation by the U.S. federal agencies demonstrate that — even in the already concentrated healthcare industry — vertical mergers are still typically considered procompetitive, and they will continue to pass antitrust muster, particularly when the parties observe best practices for cost-effective navigation of transactions to closing, some of which are outlined in this article.

II. U.S. AGENCIES’ HISTORICAL APPROACH TO VERTICAL MERGER ENFORCEMENT

Section 7 of the Clayton Act prohibits mergers and acquisitions where the effect of the transaction “may be substantially to lessen competition, or to tend to create a monopoly.”³ The DOJ and FTC are the two federal agencies principally charged with merger review.⁴ These agencies review both horizontal and vertical mergers.⁵

Since vertical mergers do not involve firms that operate in the same market, they do not increase concentration in any relevant market, and accordingly, they have been viewed as generally less likely to give rise to competitive concerns. Instead, vertical combinations typically generate efficiencies, including cost reductions, and the potential for such efficiencies has traditionally been persuasive at the agencies.⁶

The FTC and DOJ have historically relied upon several theories of harm for how a vertical merger could potentially violate Section 7:

- *Foreclosure*: A vertical merger could result in “input foreclosure,” where an upstream merger partner either refuses to supply critical inputs to downstream rivals or supplies them only on disadvantageous terms that favor its own integrated downstream business unit.⁷ Alternatively, the merger may result in “customer foreclosure,” whereby the downstream firm refuses to purchase products from competitors of the upstream supplier, cutting off an important route to market for the upstream company’s competitors.
- *Barriers to entry*: A vertical merger could create post-merger market conditions that could hinder or prevent entry from other firms because of the need to enter at both levels of the market. Alternatively, the merger may reduce the potential for the merging firms to enter one another’s market, thereby eliminating a source of possible competition.

³ 15 U.S.C. § 18.

⁴ Because the DOJ and FTC have concurrent merger enforcement jurisdiction, it is not always clear whether a transaction will be assigned to the DOJ or the FTC. This is especially true in the context of vertical mergers of healthcare entities because both agencies have expertise in healthcare transactions.

⁵ Vertical mergers are those in which the merging parties are not current competitors but rather operate at different levels of the distribution chain. By contrast, horizontal mergers are between firms that operate in the same market and therefore eliminate a competitor or potential competitor.

⁶ See K. Wong-Irvin, *Antitrust Analysis of Vertical Mergers: Recent Developments and Economic Teachings*, ABA Antitrust Source, February 2019, for a summary of the economic literature on procompetitive aspects of vertical transaction and economic retrospectives on the actual impact of past transactions.

⁷ The latter version in which the upstream firm supplies only on disadvantageous terms that favor its own integrated downstream business unit is also known as “raising rivals’ costs” (“RRC”).

- *Anticompetitive information exchanges:* Theoretically, a merger could generate access to competitively sensitive business information of an upstream or downstream rival that was not previously available. The integrated firm might use that information to make it harder for the rival firm to compete, which could reduce competition in the market in which the merged firm competes with the rival. Alternatively, the firms could use that information to facilitate coordination between them on pricing and market strategies.

III. RECENT TRENDS IN VERTICAL MERGER REMEDIES

Although vertical merger enforcement in line with the above principles has long been an aspect of U.S. merger control, it has assumed a higher profile in recent years. Indeed, U.S. antitrust agencies have taken on more investigations of significant vertical transactions over the past two years, among them, AT&T Inc. (“AT&T”) and Time Warner Inc. (“Time Warner”), CVS and Aetna, Cigna and Express Scripts, and Staples Inc. (“Staples”) and Essendant Inc. (“Essendant”). In addition, U.S. government officials have recently made several public statements that signify a change in how and to what extent they will scrutinize these deals.

A. Hostility Toward Behavioral Remedies

When a transaction raises competition concerns, there are two basic types of remedies available to achieve clearance: structural and behavioral. Structural remedies restructure the merger transaction by requiring asset divestitures or similar relief. Behavioral remedies are conditions for clearance that impact the company’s future and ongoing business functions. For example, if the competitive concern with a transaction is that competitors would be denied access to an essential input or would be foreclosed from a significant aspect of the market, a potential solution could be for the merging firms to permit competitors to access that input, or permit access to key elements of distribution.

The FTC and DOJ historically maintained that behavioral remedies can be effective for handling competition concerns in the context of vertical mergers, and the agencies routinely cleared transactions conditioned on these remedies.⁸ More recently, however, both the DOJ and FTC have remarked that behavioral remedies should be used sparingly to avoid remedies that look like regulatory schemes in need of monitoring.

Specifically, since his confirmation in late 2017, Makan Delrahim, current chief of the DOJ’s Antitrust Division, has consistently emphasized that the DOJ is a law enforcement agency, not a regulatory agency. According to AAG Delrahim, behavioral remedies require the agencies to regulate the market “through complex decrees that ignore the profit-maximizing incentives of private actors.”⁹ AAG Delrahim has said such remedies are “overly intrusive and unduly burdensome for both businesses and government.”¹⁰ By contrast, AAG Delrahim has underscored that structural remedies like divesting the source of anticompetitive harm substantially eliminate the risk of harm.¹¹ In 2018, the FTC echoed AAG Delrahim’s statements when Bruce Hoffman, director of the FTC’s Bureau of Competition, described the FTC’s role as an antitrust enforcer, not the “price police.”¹²

⁸ See, e.g. *U.S. v. Google Inc. and ITA Software, Inc.*, Case 1:11-cv-00688 (2011)(available at <https://www.justice.gov/atr/case-document/file/497636/download>); *U.S. v. Comcast Corp., General Electric Co. and NBC Universal, Inc.*, Case 1:11-cv-00106 (2011)(available at <https://www.justice.gov/atr/case-document/file/492196/download>).

⁹ Assistant Attorney General Makan Delrahim Delivers Keynote Address at American Bar Association’s Antitrust Fall Forum, Washington, D.C. (Nov. 16, 2017), available at <https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-keynote-address-american-bar> (last visited Apr. 9, 2019).

¹⁰ *Id.*

¹¹ Assistant Attorney General Makan Delrahim Delivers Remarks at the Antitrust Division’s Second Roundtable on Competition and Deregulation, Washington, D.C. (Apr. 26, 2018), available at <https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-antitrust-divisions-second> (last visited Apr. 9, 2019).

¹² Remarks of Then-Acting Director, Bureau of Competition, D. Bruce Hoffman, *Vertical Merger Enforcement at the FTC*, Credit Suisse 2018 Washington Perspectives Conference, Washington, D.C. (Jan. 10, 2018), available at https://www.ftc.gov/system/files/documents/public_statements/1304213/hoffman_vertical_merger_speech_final.pdf (last visited Apr. 9, 2019).

B. Congressional Interest in Significant Transactions

Although Congress plays no direct role in antitrust enforcement, it is becoming increasingly common for it to scrutinize significant merger transactions. For example, in September 2015, the House Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust (“Subcommittee”) held a hearing on health insurer mergers and their effect on competition.¹³ Specifically, the Subcommittee examined the then-proposed *Aetna-Humana* and *Anthem-Cigna* horizontal mergers, both of which were later abandoned after being blocked by the DOJ and federal courts.

Similarly, the Subcommittee also held a hearing to evaluate the later-approved *Aetna-CVS* vertical merger in February 2018.¹⁴ Questions from the Subcommittee focused primarily on two concerns: (1) whether, in a concentrated marketplace like healthcare, dominant businesses have the ability and incentive to use their dominance to exclude competitors; and (2) whether the proposed merger was necessary to accomplish the goals expressed by Aetna and CVS.¹⁵

Additional Congressional hearings remain a possibility for future vertical transactions. And though the antitrust agencies make independent decisions, any Congressional hearings may impact how the agencies’ approach to scrutinized transactions either by manifesting congressional pressure or by piloting arguments earlier in the clearance process.

C. Revision of the Non-Horizontal Merger Guidelines

The DOJ and FTC maintain two guidance documents relating to merger enforcement — the Horizontal and Non-Horizontal Merger Guidelines.¹⁶ The Non-Horizontal Merger Guidelines have not been updated since 1984, and the U.S. antitrust enforcement agencies have recently acknowledged that they no longer use them.¹⁷ Consequently, prominent antitrust experts called for the guidelines to either be updated or withdrawn.¹⁸

The FTC responded to this rallying cry by voicing support for soft guidance through closing statements and commentary rather than through formal guidelines.¹⁹ FTC Chairman, Joseph Simons, stated that a revision of the Non-Horizontal Merger Guidelines would present difficulties because analysis of vertical deals is more complex than analysis of horizontal deals.²⁰ Moreover, Chairman Simons emphasized that any revised guidelines would need bipartisan support “so that they last and they’re not reversed.”²¹ By contrast, AAG Delrahim recently confirmed that the DOJ has been working since 2018 on as-yet-unpublished revisions to the guidelines without input from the FTC.²² AAG Delrahim noted, however, that “a joint product would only be better because it would pull from the experience of the two agencies.”²³

13 Healthy Competition? An Examination of the Proposed Health Insurance Mergers and the Consequent Impact on Competition, A Hearing Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law of the Committee on the Judiciary House of Representatives (Sept. 29, 2015), available at <http://src.bna.com/vyg> (last visited Apr. 9, 2019).

14 Competition in the Pharmaceutical Supply Chain: the Proposed Merger of CVS Health and Aetna, A Hearing Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law of the Committee on the Judiciary House of Representatives (Feb. 27, 2018), available at <https://judiciary.house.gov/hearing/competition-pharmaceutical-supply-chain-proposed-merger-cvs-health-aetna/>; <https://judiciary.house.gov/hearing/competition-pharmaceutical-supply-chain-proposed-merger-cvs-health-aetna/> (last visited Apr. 9, 2019).

15 *Id.*

16 Note however that neither set of guidelines is a statement of law.

17 Bryan Koenig, DOJ Vertical Merger Guidelines Called “Badly Out of Date,” LAW360.COM, Nov. 1, 2018 available at <https://www.law360.com/articles/1098243> (last visited Apr. 9, 2019).

18 *Id.*

19 Remarks of FTC Commissioner Christine S. Wilson, *Vertical Merger Policy: What Do We Know and Where Do We Go?*, Keynote Address at the GCR Live, South Miami Beach, FL (Feb. 1, 2019), available at https://www.ftc.gov/system/files/documents/public_statements/1455670/wilson_-_vertical_merger_speech_at_gcr_2-1-19.pdf (last visited Apr. 9, 2019).

20 Matthew Perlman, FTC, DOJ May Team Up on Vertical Merger Guidelines, LAW360.COM, Mar. 29, 2019 available at <https://www.law360.com/articles/1144678/ftc-doj-may-team-up-on-vertical-merger-guidelines> (last visited Apr. 9, 2019).

21 *Id.*

22 *Id.*

23 *Id.*

D. Move to Two-Phase Merger Trials

In the wake of the DOJ's failed challenge to the proposed merger of AT&T and Time Warner, AAG Delrahim revealed that the DOJ is contemplating seeking two-phase trials in some merger actions.²⁴ Under a two-phase trial rubric, federal courts would first evaluate whether a merger violates the law and then consider remedies offered by the merging companies.²⁵ AAG Delrahim indicated that such a move would focus the courts on the question of whether the government has proved that a proposed deal is illegal before considering whether a remedy proposed by the merging entities resolves competitive concerns.²⁶ Further, and in accordance with these ideas, AAG Delrahim cautioned companies that they should expect the DOJ to focus on potential post-litigation remedies during vertical merger investigations.²⁷

It is likely that a two-phase trial would reinforce AAG Delrahim's preference of avoiding behavioral remedies by leaving the question of the adequacy of a remedy proposed by the parties until after a trial on the merits of the government's case, although it remains to be seen whether the DOJ will be successful in convincing a court to manage a merger challenge in this fashion. Notably, and as discussed below, the remedy proposed by the merging parties in *AT&T-Time Warner* was important to the trial court's and appellate court's decisions, coming after the DOJ failed in its effort to exclude testimony concerning the companies' proposed remedy.

E. Recent Agency Enforcement

Perhaps even more than their recent public statements, the FTC's and DOJ's reviews of several recent proposed vertical deals, including some in the healthcare industry, illuminate how the agencies might approach these transactions moving forward.

1. AT&T-Time Warner

On February 26, 2019, the DOJ ended its challenge to the proposed merger of AT&T and Time Warner when the D.C. Circuit Court of Appeals upheld the district court's decision that the transaction did not violate antitrust laws.²⁸ *AT&T-Time Warner* was the first vertical merger challenge litigated to judgment in nearly forty years — showcasing the agencies' renewed interest in vertical merger enforcement and shift away from behavioral remedies. The DOJ sued to block the transaction on the basis of vertical foreclosure concerns. According to the DOJ's complaint, the merger would substantially lessen competition in the video programming and distribution market nationwide by enabling AT&T to control Time Warner's "must have" programming content to "hinder its rivals by forcing them to pay hundreds of millions of dollars more per year for Time Warner's networks."²⁹ The DOJ further alleged that the merged entity "would use its increased power to slow the industry's transition to new and exciting video distribution models that provide greater choice for consumers."³⁰

The district court ruled in favor of the merging parties, pointing out the DOJ's concession that the merger would also result in hundreds of millions of dollars in annual cost savings to AT&T customers and that "no competitor will be eliminated by the merger's proposed vertical integration."³¹

The appellate court likewise declined to enjoin the deal, but it did not rule out the potential for successful challenges to vertical mergers in the future. Rather, the court abstained from speaking definitively on the proper legal standard for evaluating vertical mergers and instead invoked the deferential "clearly erroneous" standard of review to hold that the district court had not clearly erred in its fact-intensive finding that the DOJ failed to meet its threshold burden of showing that the proposed merger would likely increase the bargaining leverage of Time Warner's networks.³² Like the district court, the D.C. Circuit focused in large part on Time Warner's self-imposed behavioral remedy — specifically its

24 Kelcee Griffis, "AT&T-Time Warner Trial Sets Poor Example, Delrahim Says," LAW360.COM, Mar. 20, 2019 available at <https://www.law360.com/articles/1141075/at-t-time-warner-trial-sets-poor-example-delrahim-says> (last visited Apr. 9, 2019).

25 *Id.*

26 *Id.*

27 Jenna Ebersole, "DOJ Considering Seeking Two-Phase Merger Trials After AT&T-Time Warner, Delrahim Says," MLex Market Insight, Mar. 20, 2019.

28 *United States of America v. AT&T Inc.*, 916 F.3d 1029 (D.C. Cir. 2019).

29 Complaint, *United States of America v. AT&T Inc.*, Case No. 1:17-cv-02511 (D.D.C. filed Nov. 20, 2017).

30 *Id.*

31 *United States of America v. AT&T Inc.*, 310 F. Supp. 161, 164 (D.D.C. 2018).

32 *AT&T Inc.*, 916 F.3d at 1038-43, *supra* note 29.

irrevocable offers to engage in “baseball style” arbitration — finding that since programming blackouts were contractually no longer possible, Time Warner could not have increased bargaining leverage.³³

2. Cigna-Express Scripts

On September 17, 2018, the DOJ cleared insurer Cigna’s \$67 billion acquisition of PBM company Express Scripts with no conditions. In its closing statement, the DOJ explained that it had analyzed whether the merger would “(1) substantially lessen competition in the sale of PBM services or (2) raise the cost of PBM services to Cigna’s health insurance rivals.”³⁴ The DOJ found the horizontal overlap in the parties’ PBM business caused no competitive concern because it noted that “Cigna’s PBM business nationwide is small” and the market still includes two other large PBMs, CVS Caremark and Optum, as well as several smaller ones.³⁵ As to the possibility that the combined company might raise the cost of PBM services for Cigna’s health insurance rivals, the DOJ concluded that this was unlikely “due to competition from vertically-integrated and other PBMs” and the fact that the newly-combined Cigna-Express Scripts would allow Optum to continue to compete for PBM customers that purchase medical insurance from Cigna.³⁶

But here, the DOJ’s sign-off came only after costly investigation. The DOJ issued a second request for information. At minimum, a second request extends the initial 30-day review period under the Hart-Scott-Rodino Act, and depending on the number of topics and custodians at issue, a second request can cause impose substantial time and cost burdens while delaying the parties’ ability to close the transaction. In the context of *Cigna-Express Scripts*, the investigation took six months and reportedly included review of over two million documents and interviews with over 100 industry participants.

3. Aetna-CVS

On October 10, 2018, the DOJ and five states conditionally approved the \$69 billion merger of Aetna and CVS. Consistent with *Cigna-Express Scripts*, the DOJ approved the *CVS-Aetna* deal only after a costly second request. In contrast with *Cigna-Express Scripts*, however, the merger approval was contingent on the sale of Aetna’s nationwide Medicare Part D prescription drug plan business.³⁷ Without this divestiture, the DOJ and the five state attorneys general would have challenged the transaction based on concerns relating to a horizontal aspect of the merger. Specifically, the agencies were concerned that the combination of Aetna’s and CVS’s Medicare Part D individual prescription drug plans could lead to increased prices, inferior customer service, and decreased innovation in that market.³⁸

With respect to the vertical aspects of the merger, the DOJ stated it had “thoroughly considered whether the merger would raise the cost of (i) CVS/Caremark’s PBM services or (ii) retail pharmacy services to Aetna’s health insurance rivals,” and “after a careful analysis, the [Antitrust] Division determined that the merger [was] unlikely to cause CVS to increase costs to Aetna’s health insurance rivals due to competition from other PBMs and retail pharmacies.”³⁹ Accordingly, the DOJ concluded that no remedy beyond the divestiture of the individual PDP business was required.⁴⁰

Interestingly, the transaction was also reviewed by state insurance and other regulators, which viewed it differently. Two such regulators, in California and New York, demanded that the combined company refrain from raising premiums to pay for the acquisition. The California Department of Managed Health Care further required CVS-Aetna to keep premium increases “to a minimum” for five years (but did not define a threshold for maximum premium hikes). New York’s Department of Financial Services also required CVS-Aetna to maintain its New York provider networks’ access to the same percentage of independent pharmacies before and after the merger for a period of three years. The company was also required to submit annual reports detailing the pharmacy rebates Aetna receives and the amount returned to customers.

³³ *Id.*

³⁴ Statement of the Department of Justice Antitrust Division on the Closing of Its Investigation of the Cigna-Express Scripts Merger (Sept. 17, 2018), available at <https://www.justice.gov/atr/closing-statement> (last visited Apr. 9, 2019).

³⁵ *Id.*

³⁶ *Id.*

³⁷ Justice Department Requires CVS and Aetna to Divest Aetna’s Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger (Oct. 10, 2018), available at <https://www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d> (last visited Apr. 9, 2019).

³⁸ Complaint, *United States of America v. CVS Health Corp.*, Case No. 1:18-cv-02340 (D.D.C. filed Oct. 10, 2018).

³⁹ *United States v. CVS and Aetna Questions and Answers for the General Public* (Oct. 10, 2018), available at <https://www.justice.gov/opa/press-release/file/1099806/download> (last visited Apr. 9, 2019).

⁴⁰ *Id.* Note that the post-closing integration has been held up while the divestiture remedy proceeds through judicial review under the Tunney Act.

4. Staples-Essendant

On January 28, 2019, the FTC announced that it had accepted a consent order clearing the acquisition of Essendant, the largest wholesale distributor of office products in the U.S., by Staples, the largest retailer of office products in the world. Despite the antitrust agencies' recent resistance to behavioral remedies, this acquisition was cleared by the FTC with a behavioral remedy, namely a firewall to limit Staples' access to commercially sensitive information of Essendant's office supply customers, which compete with Staples.⁴¹

Somewhat remarkably, the FTC commissioners were split three to two along party lines in voting on whether to allow the merger. The majority, consisting of the FTC's Republican members, Joseph Simons, Noah Phillips, and Christine Wilson, found no evidence to support "any claims of likely anticompetitive harm other than the one for which remedy has been obtained."⁴² Commissioner Wilson specifically noted that while some competitive harm is possible as a result of vertical integration, "integrating operations at different levels of production often yields clear economic benefits," and urged the agency to act only when the "theory and the facts both point to a potential diminution in competition."⁴³ The dissenting Democratic commissioners, Rebecca Slaughter and Rohit Chopra, doubted that the merger was in the public interest, even with the majority's behavioral remedy. Commissioner Slaughter expressed concern about the FTC's enforcement of vertical mergers generally, noting that "the current approach to vertical integration has led to substantial underenforcement."⁴⁴

IV. KEY TAKEAWAYS FOR FUTURE CONSOLIDATION IN HEALTHCARE

Despite numerous recent changes in the vertical merger enforcement landscape, large vertical transactions continue to succeed. As a result, the trend toward vertical integration in healthcare will likely continue as entities are encouraged by recent clearances. But healthcare companies throughout the distribution chain should anticipate that U.S. antitrust agencies will continue to challenge vertical transactions.

When considering a vertical transaction, therefore, the merging entities should contemplate whether the proposal includes any horizontal overlap or would implicate any of the FTC's and DOJ's traditional theories of economic harm for vertical mergers. But the parties should also consider the possibility of unconventional theories of economic harm, particularly until the DOJ makes an update to the Non-Horizontal Merger Guidelines. In addition, the parties should anticipate that the agencies' in-depth investigations of significant vertical transactions will continue, including exploration of potential post-litigation remedies and possibly concurrent Congressional hearings and/or investigations by state insurance and antitrust regulators. Such investigations could result in significant costs and delay to parties' ability to close transactions.

To navigate a transaction successfully to closing, parties to vertical deals might consider the following:

- The parties should evaluate and document the potential transaction's procompetitive effects and enhanced efficiencies early in the process, and these benefits should form an integral part of the parties' decision to undertake the transaction. Notably, creating clear documentation to support the benefits of the intended combination early in the process will provide a good basis for presenting a cognizable efficiencies case.
- Depending on the size and complexity of the deal, it may be prudent for the parties to hire an economist to analyze the proposed transaction. Having such an assessment in hand will better position the parties to quickly respond to government economists throughout the investigation and, if necessary, defend against challenge.

41 FTC Imposes Conditions on Staples' Acquisition of Office Supply Wholesaler Essendant Inc. (Jan. 28, 2019), available at <https://www.ftc.gov/news-events/press-releases/2019/01/ftc-imposes-conditions-staples-acquisition-office-supply> (last visited Apr. 9, 2019).

42 Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Essendant, Inc. by Staples, Inc., FTC File No. 181-0180, (Jan. 28, 2019), available at https://www.ftc.gov/system/files/documents/public_statements/1448328/181_0180_staples_essendant_majority_statement_1-28-19.pdf (last visited Apr. 9, 2019).

43 Statement of Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Essendant, Inc. by Staples, Inc., FTC File No. 181-0180, (Jan. 28, 2019), available at https://www.ftc.gov/system/files/documents/public_statements/1448307/181_0180_staples_essendant_wilson_statement.pdf (last visited Apr. 9, 2019).

44 Statement of Commissioner Rebecca Kelly Slaughter Concerning the Proposed Acquisition of Essendant, Inc. by Staples, Inc., FTC File No. 181-0180, (Jan. 28, 2019), available at https://www.ftc.gov/system/files/documents/public_statements/1448321/181_0180_staples_essendant_slaughter_statement.pdf (last visited Apr. 9, 2019).

- In the event that the parties identify potential competition issues, they should consider whether the issues can be remedied through limited divestitures. The FTC's recent consents and public statements suggest that it may be willing to agree to behavioral remedies in the right circumstances,⁴⁵ but these cases appear to be limited to implementing firewalls to restrict the flow of competitive information. Moreover, the DOJ has maintained its hostility to behavioral remedies, leaving parties with the choice of litigating or abandoning their transaction.
- Finally, don't forget state antitrust, insurance, and other regulators. Competition is an important aspect of many agency investigations, and may be coupled with a particular focus on the impact of a transaction on a state or narrower regional population.

⁴⁵ In addition to Staples-Essendant, the FTC also entered into a consent order permitting Northrop Grumman to acquire Orbital ATK contingent on the use of a firewall to protect competitively sensitive information from improper use or disclosure. See FTC Imposes Conditions on Northrop Grumman's Acquisition of Solid Rocket Motor Supplier Orbital ATK, Inc. (June 5, 2018), available at <https://www.ftc.gov/news-events/press-releases/2018/06/ftc-imposes-conditions-northrop-grummans-acquisition-solid-rocket> (last visited Apr. 9, 2019).

CROSS-MARKET HOSPITAL MERGERS: ECONOMIC THEORY CHALLENGED BY FACTS AND ANTITRUST LAW



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I. INTRODUCTION

A developing economic literature is focusing on potential price effects from mergers between hospitals that do not compete with one another.² So-called “cross-market” mergers occur between hospitals that have non-overlapping service areas and — as the name indicates — are located outside each other’s relevant geographic market. Cross-market hospital mergers involve firms that are not each other’s rivals for inclusion in health insurer networks or for patient admissions. Patients, employers, and health insurers do not view these merging parties as reasonable substitutes for patient services.

In an antitrust context, cross-market hospital mergers obviously contrast in material ways from horizontal mergers. The latter involve hospitals that are located in the same geographic market, typically to some degree are considered substitutes, have overlaps in their service areas, compete for the same set of potential patients, compete over price, and compete for inclusion in commercial insurer networks. Horizontal mergers eliminate competition between the parties, and the Federal Trade Commission and Department of Justice have a well-documented history of proving in court that such mergers sometimes may lessen competition substantially or tend to create a monopoly, in violation of Section 7 of the Clayton Act, 15 U.S. C. § 18.

The federal antitrust agencies have not sued to enjoin any cross-market hospital mergers. This no doubt reflects the fact that the parties to these transactions have virtually no pre-merger competitive interaction. Nonetheless, cross-market hospital mergers are drawing attention over concerns that, under certain circumstances, they may increase the merging parties’ bargaining power when negotiating with health insurers for contracts to participate in health plan networks.

This article discusses the theory’s basic underpinnings and offers a brief overview of published studies on the price effects of consummated cross-market hospital mergers. It discusses shortcomings in the theory that constrain it as a viable tool for antitrust enforcement. These arise from a lack of an empirically grounded and reliable analytical framework tied to competition and market power and from questions about whether antitrust law is a remedy to the alleged harms.

II. CROSS-MARKET HOSPITAL MERGER ANTITRUST THEORY

Cross-market antitrust theory generally posits³ that the potential for economic harm from such a hospital merger may arise where at least one area employer that offers health insurance to its workers has employees who reside and/or work in each merging hospital’s service area (a “multi-region employer”). This feature links the two separate hospital geographic markets such that, according to the theory, an opportunity may arise for the merged system to acquire bargaining leverage in rate negotiations with payors. Under the theory, this result is possible even though each merging hospital faces the identical set of rivals and competitive conditions in its individual relevant market after the merger that it faced before the merger.

A. Payor-Hospital Bargaining — General

How does cross-market theory explain this? It starts from a model of payor-hospital bargaining over the terms of a hospital’s participation in the payor’s health plan network — a model the FTC advances for intra-market mergers — that generally is as follows. Assume a market in which Hospital A is negotiating with a payor over a traditional fee-for-service network contract. Generally, as to rates, Hospital A weighs the trade-off of either accepting a lower-than-desired price or risking exclusion from the network; exclusion tends to put the hospital at a disadvantage relative to its competitors in competing for patients.

² See G.S. Vistnes & Y. Sarafidis, *Cross-Market Mergers: A Holistic Approach*, 79 Antitrust L.J. 253 (2013) (“V&S”). See also L. Dafny, K. Ho & R.S. Lee, *The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry* (Oct. 5, 2018), available at www.people.fas.harvard.edu/robinlee/papers/PriceEffects.pdf (“DH&L”); M.S. Lewis & K.E. Pflum, *Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions*, available at <http://www.kevinpflum.com/papers/Lewis.Pflum.Hospital.BP.pdf> (also published at 48 RAND J. Econ. 579) (2017) (“L&P”). The latter two papers tie cross-market theory to empirical analyses of consummated hospital mergers. D.A. Argue and S.D. Stein provide a critique and analysis of this theory in “*Cross-Market Health Care Provider Mergers: The Next Enforcement Frontier*,” 30 *Antitrust* 25 (Fall 2015) (commenting on the above-cited Vistnes & Sarafidis and earlier publications by Lewis & Pflum and Dafny, Ho and Lee) (“Argue & Stein”). See also D.A. Argue and L. Fowdur, “*An Examination of New Theories on Price Effects of Cross-Market Hospital Mergers*,” (2016), available at <https://pdfs.semanticscholar.org/c909/cc1194b13cda18059ec26d85a2c4f1623b00.pdf> (presented to American Hospital Association) (“Argue & Fowdur”). The shorthand references “V&S,” “DH&L” and “L&P” in this paper were first used by Argue & Stein.

³ Space does not permit a fully comprehensive description of the economic analyses set forth in the papers cited in note 1. The article attempts only to summarize cross-market theory’s basic analytical underpinnings in these papers and to offer observations about them.

The payor weighs the trade-off of either paying a higher-than-desired price or risking Hospital A's refusal to participate in the network; this exclusion may diminish the network's appeal for employers and their employees,⁴ and tend to lessen the network's sales potential. Hospital A and the payor each have their own "walkaway" or "threat" price – a price at which it would refuse to sign a contract because the price (for Hospital A) is too low or (for the payor) is too high. Under this model, the contract price typically falls between the two walkaway points.

Under this bargaining model, the price at which the parties reach agreement approximates the value that health plan enrollees and their employers place on having in-network access to Hospital A. This value tends to be higher, and so too the negotiated price, to the extent other in-network hospitals are viewed as significantly weaker alternatives to Hospital A — a situation that strengthens Hospital A's bargaining position. The reverse is also true. Adding Hospital A to a network that already includes an essentially equal alternative to Hospital A adds relatively less incremental value to the network, and therefore tends to weaken Hospital A's bargaining position. From the payor's perspective, exclusion of Hospital A from the health plan network will reduce to some degree the network's marketability to employers. The significance of that reduction, and the extent to which the payor will pay a higher rate to Hospital A to avoid its exclusion, depends on whether the network includes a reasonable substitute for Hospital A. Absent such a substitute, excluding Hospital A may require the payor to reduce premiums to compete successfully for the employer's business.

B. Applying this Bargaining Theory to Cross-Market Mergers

Next, assume that Hospital A merges with Hospital B, which is located in a different geographic market.⁴ Two sets of economists — Gregory Vistnes & Yianis Sarafidis ("V&S") and Leemore Dafny, Kate Ho and Robin S. Lee ("DH&L") — identify two scenarios in which the authors posit that this merger might enable each hospital to obtain a higher price, even though the competitive landscape within each hospital's respective market remains the same before and after the merger. Each scenario stems from factors that cause a linkage or non-separability between the markets in a payor contracting context, as described below.

The cross-market link has potential hospital price implications under this theory, if an employer whose employees reside in different hospital markets desires to purchase coverage from health plans that meets all of its employees' needs. The link may also have price implications if health plans operate a marketing strategy that charges the same premium to an employer per employee regardless of where the employee lives. V&S refer to the first scenario as the "employer choice" model and the second as the "health plan pricing" model, but the scenarios are commonly known by the terminology of "common customers" and "common insurers," respectively, that DH&L use.

Both scenarios stem from the merged system's ability (under the theory) to negotiate with payors from a position that enables it credibly to threaten the network with the loss of two hospitals simultaneously if the parties do not strike a deal. The models assume that the merged system can make this threat because it will negotiate on an "all or nothing" basis (i.e. neither hospital will participate in the network unless the insurer agrees to include both). The models also assume that payor networks will include hospitals from a broader region than a single geographic hospital market.

Prior to the merger, a threat by either individual hospital not to contract with an insurer affects only one hospital market. The central question under cross-market merger antitrust theory is whether a post-merger ability to threaten a payor simultaneously in two hospital markets, when prior to the merger each hospital could threaten the payor in only one, creates anticompetitive bargaining leverage for the merged system. As explained by V&S, this leverage will result at the expense of health plans "[i]f the loss in profits [to the plan] from losing both hospitals is greater than twice the loss from losing either individual hospital."⁵ DH&L describe that same concept in stating that a cross-market merger can increase hospital bargaining power only if "the sum of the marginal contributions of each hospital to the insurer's objective (e.g. profits) is less than the marginal contribution of *both* hospitals jointly to the insurer."⁶

As noted, the literature describes two potential scenarios that link two separate hospital markets. In one, the common customer model (where the multi-region employer desires to offer health plan options that are attractive to a majority of its employees), simultaneous loss of multiple hospitals in a provider network would likely make the network less attractive to the multi-region employer. Under the assumption that losing multiple hospitals from a network disproportionately affects network value (relative to the sum of losing each hospital individually), the theory implies that the merger provides the hospital system with increased bargaining leverage.

⁴ The models discussed here also apply to cross-market mergers involving multi-hospital systems. The example above of a merger between single hospitals is only for convenience.

⁵ V&S, *supra* note 2 at 275.

⁶ DH&L, *supra* note 2 at 5-6 (emphasis in original).

The other scenario, the common insurer model, pertains to health plans that have a business strategy to charge the same premium to all employees of a multi-region employer, no matter in which hospital market the employees live or work. Economists have different theories about how this effect could come about. According to V&S, if a plan that uses this strategy loses a network hospital in one market and finds it necessary to reduce premiums to compete for the employer's business, then the plan would reduce premiums in all markets where employees of that employer reside or work. Affecting the amount of that reduction is the plan's prediction of how its health plan rivals will respond. V&S model a hypothetical scenario to show that "a multi-market hospital system can threaten a health plan with a greater profit loss than the systems' individual hospitals could threaten on their own."⁷

According to DH&L, the common insurer effect might occur through two different mechanisms. In one, a hospital subject to a regulatory cap may find that it can raise rates in another market after a merger with a non-regulated hospital. In the second, which the authors identify but largely dismiss as irrelevant, the combined system could "internalize pricing effects across markets" with different elasticity of demand for insurance.⁸

DH&L and Matthew S. Lewis & Kevin E. Pflum ("L&P") provide empirical analyses of cross-market mergers consummated in the decade or so prior to 2010. L&P, using a "difference in differences" approach, estimated hospital prices after numerous cross-market transactions across the U.S., finding that the average estimated net reimbursement rates at these hospitals increased by about 17 percent after joining an out-of-market hospital system.⁹ DH&L estimated that hospitals, post-cross-market merger within the same state, raised prices by 7-10 percent; they also report that their evidence suggest that mergers of "proximate" hospitals -- defined as being within a 30-90 minute drive time -- had the largest price increases.¹⁰ The V&S article does not contain empirical analyses of particular cross-market hospital mergers.¹¹

Readers should review the articles in full to understand the methods, conclusions and caveats that the authors ascribe to their results. Two pieces by economist David Argue — one with Scott Stein and another with Lona Fowdur — examine the V&S, DH&L and L&P analyses in more detail and with their expertise and perspectives as economists.¹² Below are observations about the V&S, DH&L and L&P analyses, some of which Argue et al. also addressed.

III. CHALLENGES IN CROSS-MARKET THEORY, PREDICTED EFFECTS AND LEGAL REMEDY

A. Some Theoretical and Empirical Issues

1. The theory assumes that a cross-market health system has good information about employers and health plans that enables it to exercise pricing power. One source of this power arises from a multi-region employer's policy to select health plans that appeal to a majority of its employees. The authors do not explain how a hospital necessarily would know that the employer had that policy and not an equally rational policy to purchase a health plan that best serves employees in the first market and another health plan that best serves employees in the second market. The latter policy would sever the link between markets that is central to the cross-market effects theory. (Even if the employer had the first policy prior to the merger, by changing to the latter after the merger, it would sever the link and avoid the hypothetical price increase.) Lack of information could also undermine the theoretical bargaining power when a health plan's pricing strategy is to charge the same premium to all employees of a multi-market employer; it is unclear how a hospital would know the payor's downstream pricing strategy.

⁷ V&S, *supra* note 2 at 283.

⁸ DH&L, *supra* note 2 at 12.

⁹ L&P, *supra* note 2 at 3.

¹⁰ DH&L, *supra* note 2 at 28.

¹¹ V&S, *supra* note 2 at 259 (noting that citations to trade press reports about higher prices after cross-market mergers are not to suggest "proof" of an antitrust problem but "an indication that there is a need for a more careful analysis" of such mergers). The authors aim to "show that under some circumstances, cross-market hospital mergers *may* reduce competition even in the absence of any significant patient substitution between the merging hospitals" but "do not . . . mean to imply that most (or even many) such mergers should raise competitive concerns or a presumption of competitive harm." *Id.* (emphasis in original).

¹² See *supra* note 2 (citing pieces). Argue & Stein is from 2015; Argue & Fowdur is from 2016. Their comments pertain to earlier versions of the L&P and DH&L articles discussed herein (dated 2017 and 2018, respectively).

2. Important for a price effect under V&S and DH&L is a disproportionate effect of a merged system's participation in an insurer's network on the insurer's profits, relative to the effect of each individual hospital within the system. It is not obvious why this situation would typically exist. Employees in the first market are displeased when a network excludes a hospital in their market, but are indifferent to network exclusions in the second market; employees in the second market show the identical bias. The employer wants to satisfy all its employees and presumably values them equally. An exclusion in one market would seem as likely to dissatisfy the employer as much as an exclusion would in the other market, both before and after the merger.

3. V&S and DH&L focus on multi-region employer influences on hospital-payor bargaining, but the fact remains that in each relevant geographic market involved in the cross-market merger, the hospital must continue to compete on price and quality within the unchanged constraints imposed by its competitors in that market. It is unclear how a cross-market merged firm would navigate between its theoretical increase in cross-market bargaining power due to the existence of multi-region employers and their employees, and at the same time remain price competitive within each of its geographic markets, in which single-market employers presumably are located as well. As DH&L note, "in reality, insurers compete to be offered by multiple employers; furthermore, the prices and networks over which they bargain are not typically employer-specific."¹³ This makes it very difficult to discriminate on price to specific employers, and a risky strategy for cross-market firms if its prices are not competitive in each relevant market.

It might be easier to discriminate if the hospital system negotiated directly with multi-region employers, but employers could respond by not contracting directly. If a multi-region employer did seek to contract directly with a hospital, then it would seem more likely that the hospital system, rather than discriminate, would offer competitive rates to secure the account and not drive the employer to another cross-market system or to a commercial insurer. Moreover, if a cross-market merger did result in pricing power, "entry" via merger by another pair of cross-market hospitals potentially could restore bargaining leverage to the payor or multi-region employer.

4. Addressing the price effects found by L&P and DH&L, Argue & Stein assert that "[d]ata issues abound in these empirical models."¹⁴ One issue is that the models' underlying data sources do not include actual transaction prices negotiated pre-merger and post-merger by any cross-market hospital system with commercial insurers. Instead, L&P and DH&L used merging parties' publicly reported aggregated pre- and post-merger total revenue data, after subtracting Medicare revenue but not Medicaid revenue (the latter, unlike Medicare revenue, is not publicly available), and made various adjustments to formulate their proxies for prices. Not reported is how closely these aggregated proxies match actual price changes for hospital services. In their empirical analysis, moreover, DH&L did not identify and instead only estimated the existence of common customers — a foundational element of their anticompetitive effects theory. They explain that this is due to a lack of, or access to, the data by which to find them.¹⁵ L&P "found *no* evidence that prices were influenced by employers operating in multiple markets," but did not draw conclusions from that.¹⁶

5. A reasonable potential explanation for a hospital price increase after a cross-market merger is the transfer of one merging party's superior bargaining team to the other merging party. Particularly if one party is significantly larger, has more resources, and maintains more and better data, this would not be a surprising outcome. DH&L do not dispute this, but state that this factor does not explain why they found price effects to be greater where the merging parties' markets were adjacent (separated by a 30-90 minute drive time) as opposed to being more than 90 minutes apart.¹⁷ This response leads to another questionable aspect of the price study: By arbitrarily defining a separate market to be as short a drive away as 30 minutes, DH&L may have captured intra-market, not cross-market, effects. Arbitrary market definition may skew the empirical results in many other ways as well.

6. Another reasonable potential explanation for a hospital price increase after a cross-market merger could be that the merged firm improved quality in the system and the new price is quality adjusted. DH&L state that they controlled for this as to target hospitals, and found that "*acquirers* are raising their own prices, suggesting that significant quality improvements . . . are unlikely to be the source of price increases."¹⁸ This comment lacks empirical foundation. There is no inherent reason why a buyer's quality cannot improve following a merger. Efficiencies from the merger could have funded the improvements, as could capital expenditures that were budgeted in prior years and unrelated to the merger. The price increase at the acquiring hospital also could have occurred pursuant to a contract preceding the cross-market merger.

¹³ DH&L, *supra* note 2 at 11.

¹⁴ Argue & Stein, *supra* note 2 at 29.

¹⁵ DH&L, *supra* note 2 at 24-25.

¹⁶ L&P, *supra* note 2 at 38-39 (emphasis added).

¹⁷ *Id.* at 14.

¹⁸ DH&L, *supra* note 2 at 3, 15 (emphasis in original).

B. Application of Antitrust Law

An antitrust challenge to a cross-market merger would face significant difficulties. Under of Section 7 of the Clayton Act, a cross-market hospital merger does not eliminate competition because the parties were not rivals and does not change market concentration. The transaction is not horizontal and therefore falls outside the framework of the FTC-DOJ Horizontal Merger Guidelines. It is not vertical because it occurs at the same level of distribution. Vertical mergers have two principal potential anticompetitive risks: Foreclosure of competitors from an upstream or downstream input that is necessary to compete, and facilitation of collusion when a horizontal rival deals with the integrated firm in a vertical transaction. Neither risk applies to a cross-market merger.

Regarding vertical mergers, the U.S. Court of Appeals for the District of Columbia Circuit recently said this: “Unlike horizontal mergers, the government cannot use a short cut to establish a presumption about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share. Instead, the government must make a ‘fact-specific’ showing that proposed merger is ‘likely to be anticompetitive.’”¹⁹ No short cut to establish a presumption applies to a cross-market merger either,²⁰ and making a fact-specific showing of anticompetitive harm in the absence of a horizontal or vertical relationship makes such a showing very difficult. Legal challenges to mergers that are neither horizontal nor vertical (i.e. conglomerate mergers) are extremely rare and the antitrust agencies effectively abandoned the theories underlying them over forty years ago.²¹

Hospital organizations often provide many health services in addition to inpatient and outpatient care, such as physician, ancillary (e.g., imaging and home care) and sometimes health insurance. The relevant geographic markets for any of these other services may not exactly match the market for inpatient services. A cross-market hospital merger may therefore have a horizontal or vertical component that would fall within the ambit of Section 7. This possibility does not advance the cross-market hospital merger theory, which addresses market effects for services for which the parties have no pre-merger interaction.

Cross-market merger theory faces similar challenges under other antitrust statutes. Section 1 of the Sherman Act, 15 U.S.C. § 1, prohibits agreements that restrain trade unreasonably. The pre-merger absence of actual or potential competition or vertical dealings between the parties, such that the merger restrains no pre-existing commerce, leaves the cross-market merger theory seemingly as difficult to prove under Section 1 as Section 7.

Section 2 of the Sherman Act, 15 U.S.C. § 2, prohibits monopolization, attempts to monopolize and conspiracies to monopolize achieved through exclusionary conduct. Even if either merging party had a market share at monopoly or near-monopoly levels, a post-merger price increase, in the absence of exclusionary conduct, would not state a claim under Section 2. The “charging of monopoly prices” without such conduct “is not unlawful.” *Verizon Communications v. Trinko*, 540 U.S. 398 (2004).

It is unlikely that a court would rule that a cross-market merger agreement itself meets the exclusionary element, since it does not exclude competitors or increase market share. Analogies to forms of conduct that can be anticompetitive under Section 2, such as tying arrangements, monopoly leveraging and bundled pricing, also suffer from the absence of competitor foreclosure.

The premerger absence of actual or potential competition or vertical relationships would likely raise similar hurdles for a claim under Section 5 of the FTC Act, 15 U.S.C. § 45, which proscribes unfair methods of competition.

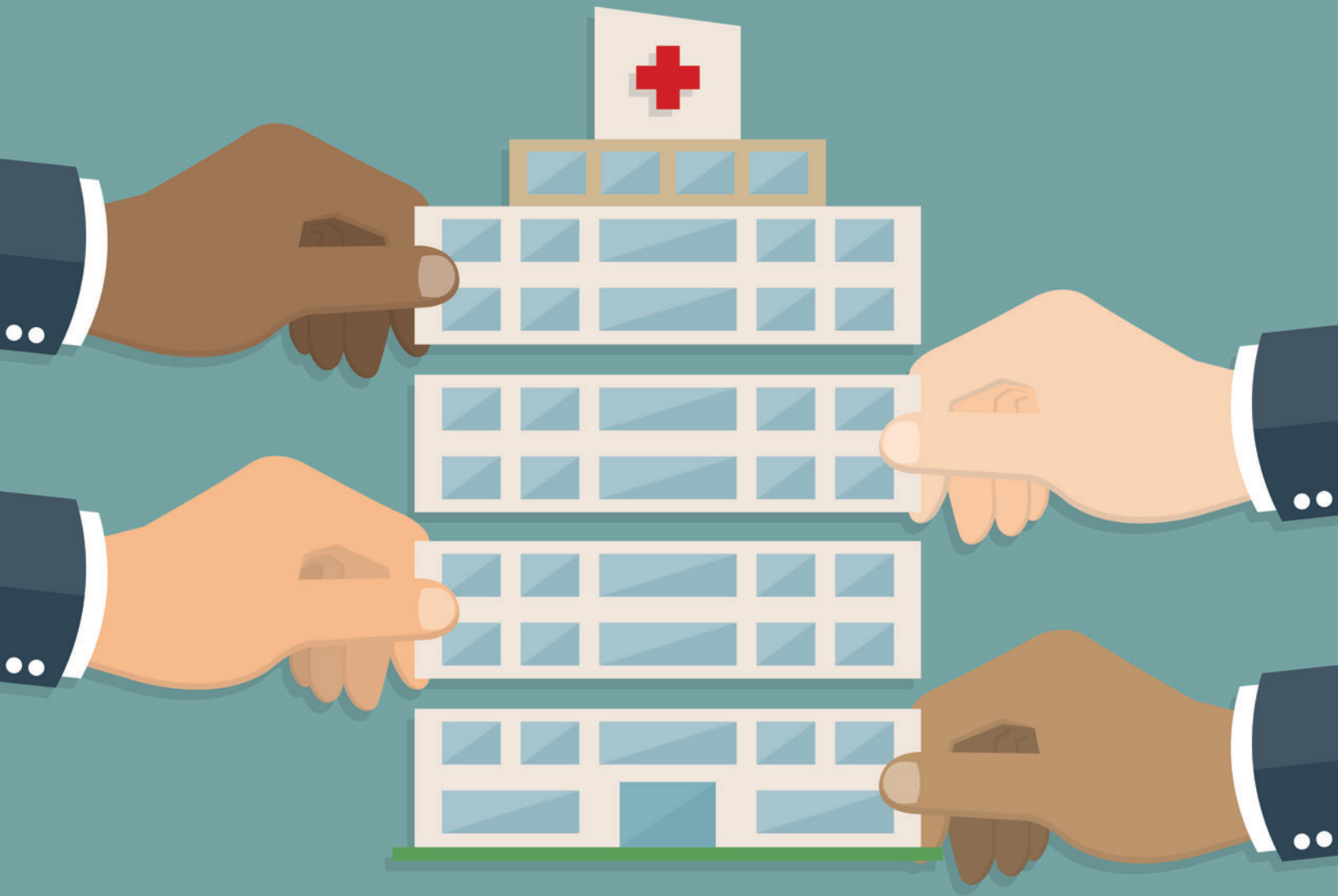
Cross-market hospital mergers have many potential benefits, such as enhancing scale to absorb more financial risk and drive down costs and increase quality, improving capabilities to manage population health, streamlining costs, improving analytics by accessing more key health data, bringing needed healthcare services to rural and disadvantaged areas. They can do this without eliminating competition between the merging parties. Merger policy should continue to allow these transactions to proceed without the cost and potential chilling effect of investigations. This policy should prevail at least until, and unless, economic learning and empirical evidence develop to a point of reliably predicting, upon application of a sound analytical framework, when a merger between hospitals in separate markets may likely harm consumers in violation of antitrust law.

¹⁹ *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019) (citations omitted).

²⁰ DH&L appear to acknowledge the cross-market theory's limitations as predictive tool for enforcers, stating that “the direction of a cross-market effect in any particular setting may not be possible to sign theoretically.” DH&L, *supra* note 2 at 10.

²¹ See ABA Section of Antitrust Law, *Antitrust Law Developments* (8th ed. 2017) at 404 and cases cited therein.

NAVIGATING THE BACKWATER: VERTICAL MERGERS IN HEALTH CARE



BY THOMAS L. GREANEY¹



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I. INTRODUCTION

Long a part of the backwaters of antitrust enforcement, vertical mergers have recently attracted the attention of academics and enforcers. The Federal Trade Commission's hearings on vertical merger policy and the issue of whether to publish new Vertical Merger Guidelines,² along with recent cases including the Department's unsuccessful challenge to AT&T's acquisition of Time Warner³ and speeches by enforcement officials⁴ illustrate a renewed focus on vertical combinations. It is widely recognized that the Department of Justice Non-Horizontal Merger Guidelines are out of date and do not reflect modern economic thinking or government enforcement policy. Indeed, a large body of theoretical and empirical work has served to undermine the economic foundations of the *laissez-faire* approach that has characterized government policies over the last thirty years.⁵

The health care sector, which has recently experienced significant vertical consolidation, exhibits textbook conditions of a market susceptible to consumer harm. Provider, payer, pharmaceutical, insurance, and intermediary management markets exhibit key pre-conditions for harm from vertical mergers: Most are highly concentrated, exhibit durable barriers to entry, and have historically performed poorly.⁶ Applying contemporary economic analyses of health care markets, much derived from retrospective studies of hospital mergers, courts have closed the door on large horizontal mergers in the hospital, insurance, and physician sectors.⁷ Over the last decade these cases clarified understanding about important characteristics of health care competition, such as the highly localized nature of provider and insurance markets, the two-stage competition characterizing provider networks, and the availability of alternatives to mergers to achieve integrative efficiencies.

Perhaps chastened by their experiences in court, and unwilling to risk litigation setbacks before an increasingly business-friendly judiciary, the FTC and Department of Justice have displayed no enthusiasm for taking on vertical issues involving health care delivery or payment. This essay argues that the agencies should learn the lessons of past lax antitrust enforcement in health care and undertake administrative and litigation policies designed to identify and curb excessive vertical consolidation. Detailing examples of unwise forbearance, this article will discuss the Justice Department's refusal to challenge the vertical aspects of the *CVS/Aetna* merger and the FTC's failure to tackle hospital acquisitions of physician practices.

II. THE CASE FOR PAYING CLOSE ATTENTION TO VERTICAL MERGERS IN HEALTH CARE

Contemporary economic analyses have sharply questioned the basis for a *laissez-faire* approach to vertical combinations. The modern account demonstrates that preconditions underlying Chicago School's analysis "rarely hold" and "can obscure how a particular merger may raise real competitive concerns."⁸ While vertical mergers do not increase concentration they may enable conduct that limits rivalry at the horizontal level. Indeed, it is important to remember that harms from vertical consolidations arise from their effects on *horizontal* competition. That is, vertical mergers create "inherent exclusionary incentives as well as the potential for coordinated effects similar to those that occur in horizontal mergers."⁹ By combining inputs with distribution, for example, a vertical merger can enhance incentives for the merged firm to exclude its downstream or upstream rivals, either by raising their costs or cutting off their access to critical resources. Professor Steven Salop's extensive body of work provides a sound economic model of foreclosure risks and maps the potential legal framework for applying the so-called "raising rivals' cost"

2 Federal Trade Commission, HEARING #5 ON COMPETITION AND CONSUMER PROTECTION IN THE 21ST CENTURY (Nov. 1, 2018) <https://www.ftc.gov/news-events/events-calendar/ftc-hearing-5-competition-consumer-protection-21st-century>.

3 *U.S. v. AT&T*, 310 F.Supp 3d (D.D.C.2019); Federal Trade Commission, In the matter of Sycamore Ptns.II, Staples, Inc. and Essendant Inc. File No. 181-0180 (Jan. 28, 2019).

4 E.g. Makan Delrahim, Assistant Att'y Gen., Dep't of Justice, Harder Better Faster Stronger: Evaluating EDM as a Defense in Vertical Mergers. Remarks at George Mason Law Review 22nd Annual Antitrust Symposium (Feb. 15, 2019).

5 See Jonathan B. Baker et al., "Five Principles for Merger Enforcement Policy," (summarizing theoretical and empirical literature); Steven A. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale Law Journal 1962 (2018).

6 See Thomas L. Greaney, *The New Health Care Merger Wave: Does the "Vertical, Good" Maxim Apply?* 46 J. L., Medicine & Ethics 918 (2018); Martin Gaynor, "Examining the Impact of Health Care Consolidation," Statement Before the Energy and Commerce Oversight Committee, U.S. House of Representatives, February 14, 2018.

7 See, e.g. *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016)(hospitals); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016)(hospitals); *Saint Alphonsus Medical Center-Nampa & FTC v. St. Luke's Health System*, 778 F.3d 775, 793 (9th Cir. 2015)(physicians); *U.S. v. Anthem, Inc.*, 855 F.3d 345 (D.C. Cir. 2017)(insurance); *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1 (D.D.C. 2017)(insurance).

8 Steven A. Salop & Culley, *Potential Competitive Effects of Vertical Mergers: A How-To Guide for Practitioners* (Dec. 8, 2014), available at <http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=2404&context=facpub>.

9 Baker et al., *supra* note 5 at 8.

principles to vertical mergers.¹⁰ Unfortunately, owing to the disinclination of enforcement agencies in challenging vertical mergers, case law is sparse and precedent has failed to keep up with the economic learning.

Vertical mergers are proliferating in health care. Indeed, one can discern a reactive pattern, as unsuccessful horizontal mergers among the nation's largest commercial insurers has been followed by linkages between some of those same insurers with pharmacy benefit managers and one with the nation's largest pharmacy chain. Following suit, the nation's largest Medicaid managed care company has proposed to acquire a significant rival, and Medicare Advantage and Medicare prescription drug plan sponsors have become highly concentrated. In sum, the nation is only a few mergers away from having a very small contingent of vertically integrated middlemen responsible for insurance, benefit structure, and provider contracting across the entirety of public and private health care in the United States.

Market structure is an important starting point for analyzing vertical mergers.¹¹ Every sector of health care delivery and payment is characterized by high concentration. The data is striking: Over 90 percent of inpatient acute care hospital markets are concentrated and the four largest commercial insurers have over 80 percent of the nation's commercial insurance business, with half of all markets comprised of two insurers controlling over 70 percent of the market. Although physician markets are less concentrated, 65 percent of all MSAs have highly concentrated physician specialty markets and approximately 40 percent of local primary care markets are concentrated. The three largest pharmacy benefit management companies control over 70 percent of the business and two pharmacy chains control between 50 and 75 percent of the market in the nation's largest markets.¹²

Courts must evaluate the potential for competitive harm from vertical mergers arising from enhanced incentives of the merged firm to exclude its upstream or downstream rivals either by raising their costs or cutting off their access to critical resources. Not unlike horizontal merger analysis, that determination requires a probabilistic assessment based on incentives and experience. As economists have noted, highly concentrated markets protected by entry and mobility barriers create strong incentives to disadvantage rivals via exclusion or raising rivals' costs. In addition, conduct and context help inform the evaluation. While such inquiries are necessarily highly fact intensive, the need for vigilance over vertical consolidation in health care is particularly acute based on long experience demonstrating that market dominance achieved by mergers can give rise to anticompetitive conduct. The history of antitrust law in the health care sector is littered with examples of hospitals, physician organizations, and insurers that have taken advantage of their dominant market positions, barriers to entry, and the absence of effective regulatory oversight to undertake actions that disadvantage rivals and impair competition.¹³

The assessment of the likely competitive effect also requires evaluating the efficiency benefits that may flow from integration. However, as they have done in horizontal merger cases, courts evaluating such claims in vertical cases should be careful to scrutinize whether alleged efficiencies are plausible and merger specific. While there are undeniably potentially significant benefits resulting from vertical integration among health care providers, there is less evidence that such benefits flow from integration of payers and providers. Moreover, the assumption commonly made that cost saving and quality improvements inevitably flow from hierarchical structures is unwarranted. Analyses by Professor Lawton Burns and others illustrate that economic integration in health care has often failed to generate clinical integration that produces either cost savings or improved efficiency.¹⁴ Not unlike horizontal mergers, vertical mergers are subject to problems associated with culture clashes, inadequate pre-merger information, and challenges inherent in management integration. As Martin Gaynor put it, "consolidation is not coordination."¹⁵

10 Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L. J. 1962 (2018). Salop, *supra* note 8, *Invigorating Vertical Merger Enforcement*. Professor Salop offered a roadmap for developing presumptive rules and generally revising the government's vertical merger guidelines in his testimony at the FTC hearing on vertical mergers. See FTC Hearing #5, *supra* note 2.

11 Several participants in the FTC hearing proposed presumptions for vertical merger guidelines that employ among other factors market share concentration data. See e.g. Salop testimony, FTC Hearing #5, *supra* note 2.

12 For sources of these data, see Greaney, *supra* note 6; Gaynor, *supra* note 6. Leemore Dafny, "Health Insurance Industry Consolidation: What Do We Know From the Past, Is It Relevant in Light of the ACA, and What Should We Ask?" Testimony before the Subcommittee on Antitrust, Competition Policy, and Consumer Rights of the Senate Committee on the Judiciary (2015).

13 See Thomas L. Greaney & Barak D. Richman, *CONSOLIDATION IN PROVIDER AND INSURER MARKETS: ENFORCEMENT ISSUES AND PRIORITIES*, Part I of the American Antitrust Institute White Paper Series on Competition in Payment and Delivery of Health Care Services (June, 2018), available at <http://www.antitrustinstitute.org/content/aa-i-issues-part-i-new-white-paper-series-competition-delivery-and-payment-healthcare>.

14 See, e.g. Lawton Burns, Testimony before the Investigatory Hearing on the Merger of Aetna into CVS Health Care Corporation, California Department of Insurance (June 19, 2018).

15 Martin Gaynor, "Examining the Impact of Health Care Consolidation," Statement Before the Energy and Commerce Oversight Committee, U.S. House of Representatives, February 14, 2018 at 11.

The bottom line is this: If antitrust is to undergo an “invigoration” of vertical merger law, the health care sector should be high on the agenda of enforcers. As noted above, the various sectors of the health care industry are uniquely susceptible to the risks of foreclosure and raising rivals’ costs. Moreover, it should be remembered that as a general matter, antitrust law has been relatively lenient in dealing with exclusionary conduct and does little to curb extant market power.¹⁶ Both conditions are prevalent in health care markets. As Professor Herbert Hovenkamp has contended, it is appropriate to apply the more demanding “incipiency” standard in cases such as vertical mergers, “where a merger is likely to lead to conduct that is both anticompetitive but also is difficult or impossible for antitrust law to reach once the merger has occurred.”¹⁷

III. OVERLOOKED VERTICAL HEALTHCARE MERGERS

The absence of case law and agency guidance regarding vertical health care mergers is problematic because it sends an “all clear” signal to practitioners: As noted earlier, vertical mergers are proliferating in a number of sectors of healthcare delivery and payment. Two important cases in which enforcers have declined to pursue challenges illustrate the government’s overly cautious approach.

Despite the extensive merger activity involving hospitals acquiring physician practices, government antitrust enforcers have never challenged such mergers. This is especially troublesome in view of economic evidence that such mergers result in higher prices and higher spending.¹⁸ In its first litigated case involving a physician merger, *Saint Alphonsus Medical Center-Nampa & FTC v. St. Luke’s Health System*,¹⁹ the FTC prevailed in a challenge to a horizontal merger involving the acquisition of a physician group by a hospital system that would have increased the hospital’s existing share of the primary care physician market to approximately 80 percent. Although the factual findings in the case tended to strongly support a finding of vertical foreclosure (which a rival hospital urged the court to consider), the FTC chose not to pursue that aspect of the case. Ultimately, the district court and Ninth Circuit followed the FTC’s lead and focused only on the merger’s horizontal effects without addressing the vertical theory. This missed opportunity, coupled with the agency’s failure to bring any vertical challenges to hospital/physician consolidation, provides a strong incentive to test the water with highly concentrative vertical acquisitions.

A second case, currently under review by the District Court for the District of Columbia, involves the challenge by the Department of Justice to the acquisition of Aetna by CVS. Although the Antitrust Division challenged the merger based on a horizontal overlap in a number of local, standalone Medicare prescription drug markets and accepted proposed divestitures to settle the case, it chose to ignore the much larger vertical aspects of the merger. The vertical aspects of the merger arise from the fact that Aetna is a buyer of important inputs — PBM services and pharmacies — that CVS sells. Competitive harms result from first the risk of “input foreclosure” i.e. the refusal to deal with competing health insurers on terms as favorable as those offered a merged Aetna. The potential harms identified by a number of parties including the American Medical Association, the AIDS Healthcare Foundation, and the California Department of Insurance were that the merged firm would raise the costs of rival insurers by advantaging its Aetna business by reducing the availability of PBM or retail and specialty pharmacy services, or by raising the price of these services to competing health insurers. In addition, the acquisition creates risks of “customer foreclosure” by CVS in that the merger would deprive competing PBMs and pharmacies of the markets for their services. Another notable vertical merger involving the same sector, Express Scripts, the second largest supplier of PBM services, acquired Cigna, the nation’s fourth largest health insurer, was approved by the Department at approximately the same time. To the surprise of some, Judge Leon has ordered a hearing to evaluate the proposed consent decree in the CVS/Aetna consolidation under the Tunney Act public interest standard. While the Justice Department did not allege a vertical theory in settling the case it is possible the court could reject the narrowness of the challenge as not in the public interest.

¹⁶ Jonathan B. Baker, *Exclusion as a Core Competition Concern*, 78 Antitrust L. J. 528 (2013).

¹⁷ Herbert Hovenkamp, *Prophylactic Merger Policy*, 70 Hastings L. J. 45 (2018).

¹⁸ Laurence C. Baker et al., *Vertical Integration: Hospital Ownership of Physician Practices Is Associated with Higher Prices and Spending*, 33 HEALTH AFF. 756 (2014); Richard M. Scheffler et al., *Health Care System: Impacts on ACA Premiums and Outpatient Visit Prices*, 37 Health Affairs (Sept. 2018); James C. Robinson & Kelly Miller, *Total Expenditures in Hospital-Owned and Physician-Owned Organizations in California*, 312 [J]AMA 1663 (2014), <http://jama.jamanetwork.com/article.aspx?articleid=1917439> [<https://perma.cc/4NS2-C3SP>] (noting that groups owned by physicians have lower costs than groups owned by hospitals); Hannah T. Naprash et al., *Association of Financial Integration Between Physicians and Hospitals with Commercial Health Care Prices*, [J]AMA ONLINE FIRST (Oct. 19, 2015), <http://archinte.jamanetwork.com/article.aspx?articleid=2463591> [<https://perma.cc/M4QT-M469>].

¹⁹ *Saint Alphonsus Medical Center-Nampa & FTC v. St. Luke’s Health System*, 778 F.3d 775, 793 (9th Cir. 2015).

IV. CONCLUSION

Forbearance has its costs. In the hospital sector, the government neglected to challenge any horizontal mergers over a period of approximately seven years. During that period, and afterwards, hospital markets across the country became highly concentrated. While not all of the increase is attributable to mergers, the implicit green light certainly contributed to the willingness to merge — an outcome that economic studies reveal has enabled the exercise of significant market power in local areas around the country.²⁰ Likewise the absence of precedent and standards regarding vertical mergers invites entities to test the outer reaches of concentration and potentially impose long term competitive harm.



²⁰ Martin Gaynor & Robert Town, *THE SYNTHESIS PROJECT: THE IMPACT OF HOSPITAL CONSOLIDATION*, (Robert Wood Johnson Foundation 2012).

A STRONGER SECOND COMPETITOR? ANALYZING THE COMPETITIVE EFFECTS OF *THE BETH ISRAEL LAHEY* HEALTH TRANSACTION

BY CORY CAPPS, KAYUNA FUKUSHIMA, TETYANA SHVYDKO & ZENON ZABINSKI¹



¹ Bates White Economic Consulting, Washington, DC. The authors provided economic analysis of the Beth Israel Lahey Health transaction on behalf of the Massachusetts Health Policy Commission. The views expressed by the authors do not represent the views of the Massachusetts Health Policy Commission, the Commonwealth of Massachusetts, or Bates White.

I. BACKGROUND

Could a merger between rival firms create a stronger second competitor to the market leader in a way that strengthens competition and benefits consumers? The answer is theoretically ambiguous, and little if any empirical economic research squarely addresses this question. Recently, however, the Massachusetts Health Policy Commission (“HPC”) analyzed this very issue in its evaluation of a proposed merger of several hospital systems in the Boston area. Specifically, the HPC evaluated whether the new system, Beth Israel Lahey Health (“BILH”), would be able to compete more effectively with Partners HealthCare (“Partners”), the largest and most expensive healthcare system in the region, and thereby reduce overall healthcare costs.

The transaction arose in July 2017, when Beth Israel Deaconess Medical Center (“BIDMC”) and some of its affiliates (together, “Beth Israel Deaconess Care Organization” or “BIDCO”), Lahey Health System (“Lahey”), Mount Auburn Hospital, and their respective physician groups, agreed to merge. Under Massachusetts law, the HPC, an independent state agency established by the Commonwealth’s landmark healthcare cost containment law (Chapter 224 of the Acts of 2012),² may conduct a comprehensive analysis of any transaction anticipated to have a significant impact on healthcare costs or market functioning and may issue a public cost and market impact review report (“CMIR Report”).³ A transaction cannot close until the Commission issues its Final CMIR Report. The HPC cannot directly block a transaction, but if it concludes that a transaction may have harmful effects, the HPC may refer the transaction to the Attorney General’s Office or other state agencies.

The HPC issued its Final CMIR Report in September 2018.⁴ It identified significant competitive overlap between the parties such that the merger would enhance their bargaining leverage with insurers. It estimated that higher post-merger prices could increase spending for inpatient, outpatient, and adult primary care services by \$128 to \$171 million per year and increase spending on specialty services by \$30 to \$60 million per year.⁵

The HPC also evaluated whether the merger would create efficiencies or other benefits for the community that could offset the likely competitive harm. Of particular interest, it looked at whether BILH could reduce healthcare costs by attracting volume away from the more expensive Partners system.⁶ Patients shifting from Partners to BILH would generate immediate savings because BILH was projected to maintain lower per unit prices than Partners after the merger. Moreover, a more attractive and effective competitor to Partners could, potentially, also reduce Partners’ bargaining leverage with insurers, leading to additional savings from lower prices (or lower future price increases) for Partners’ services. The HPC also considered whether the combined entity could more effectively anchor narrow-network health plans, which have been shown to have lower healthcare spending.⁷ Ultimately, the HPC concluded that the potential spending reductions arising from the merger would likely be insufficient to offset projected price increases.⁸

2 Mass.gov, “About the Health Policy Commission (HPC),” <https://www.mass.gov/about-the-health-policy-commission-hpc>.

3 See Mass. Gen. Laws ch. 6D, § 13 (requiring healthcare providers to notify the HPC before making material changes to their operations or governance). See also Mass. Health Policy Comm’n, 958 CMR 7.00: Notices of Material Change and Cost and Market Impact Reviews (Jan. 2, 2015), <http://www.mass.gov/anf/docs/hpc/regs-and-notices/consolidated-regulations-circ.pdf>.

4 Massachusetts Health Policy Commission, “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; and The Acquisition of the Beth Israel Deaconess Care Organization by Beth Israel Lahey Health; and The Contracting Affiliation Between Beth Israel Lahey Health and Mount Auburn Cambridge Independent Practice Association,” (HPC-CMIR-2017-2), pursuant to M.G.L. ch. 6D, § 13, Final Report, Sept. 27, 2018, <https://www.mass.gov/files/documents/2018/09/27/Final%20CMIR%20Report%20-%20Beth%20Israel%20Lahey%20Health.pdf> [Final CMIR Report].

5 Final CMIR Report, 3.

6 The HPC also evaluated the parties’ plans for several initiatives to improve quality and access to care.

7 See Dafny, Leemore S., Igal Hendel, Victoria Marone & Christopher Ody, “Narrow Networks on the Health Insurance Marketplaces: Prevalence, Pricing, and the Cost of Network Breadth,” *Health Affairs* 36 (2017): 1606–14; Dafny, Leemore, Igal Hendel & Nathan Wilson, “Narrow Networks on the Health Insurance Exchanges: What Do They Look Like and How Do They Affect Pricing? A Case Study of Texas,” *American Economic Review* 105 (2015): 110–14. See also Ho, Kate & Robin Lee, “Equilibrium Insurer-Provider Networks: Bargaining and Exclusion in Health Care Markets,” *American Economic Review*, 109 (2019): 473–522; Polsky, Daniel, Zuleyha Cidav & Ashley Swanson, “Marketplace Plans with Narrow Physician Networks Feature Lower Monthly Premiums Than Plans with Larger Networks,” *Health Affairs* 35 (2016): 1842–48.

8 Final CMIR Report, 4.

Based on these findings, the HPC referred the transaction for further review to the Massachusetts Attorney General, who ultimately approved the transaction with conditions.⁹ Under the terms of the settlement, BILH must (i) limit price increases below a cap based on the health-care cost growth benchmark for seven years; (ii) invest \$71.6 million to support healthcare services for low-income and underserved populations in Massachusetts; (iii) participate in MassHealth, the state’s combined Medicaid and Children’s Health Insurance Program; (iv) engage in joint business planning with affiliated safety-net hospitals, including Lawrence General, Cambridge Health Alliance, and Signature Brockton Hospital, for eight years; and (v) retain a third party to ensure BILH’s compliance for ten years.¹⁰ Shortly after the Attorney General’s approval, the Federal Trade Commission (“FTC”) closed its investigation.¹¹

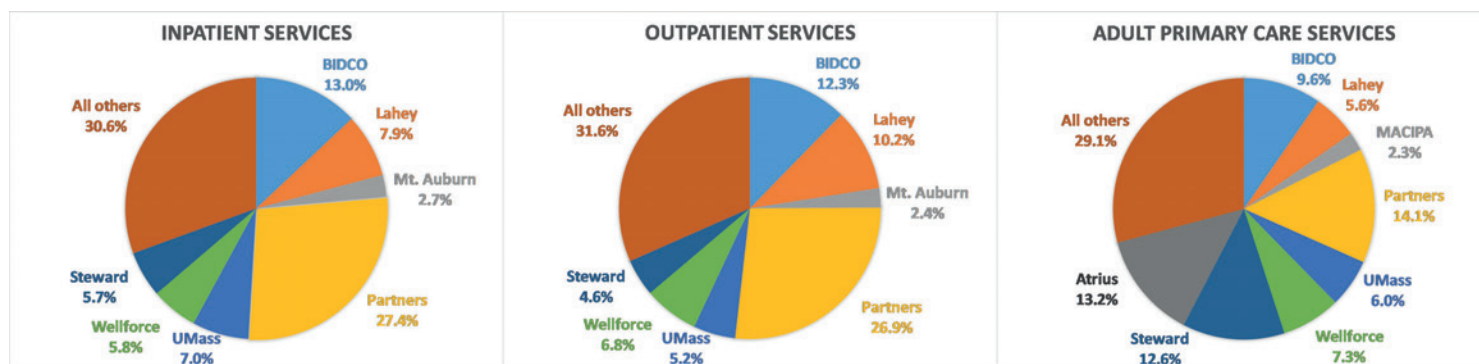
In this article, we review the HPC’s analysis of competitive issues raised by the BILH transaction, with a focus on the potentially pro-competitive effects of creating a stronger second competitor to the market leader.

A. The Parties and the Transaction

The parties signed the agreement to create BILH in July 2017 and closed the transaction on March 1, 2019.¹² The combined system now contracts on behalf of 13 hospitals in the greater Boston area, ranging from academic medical centers to a specialty hospital to community hospitals, as well as over 4,000 physicians.¹³ The transaction gave BILH about a 24 percent share of inpatient discharges statewide, a 25 percent share of outpatient services statewide, and an 18 percent share of adult primary care services statewide.

Partners HealthCare, the largest system in Massachusetts and the parent company of Massachusetts General and Brigham and Women’s hospitals, currently contracts on behalf of 13 hospitals and more than 5,000 physicians in Massachusetts.¹⁴ Statewide, Partners has about a 27 percent share of inpatient discharges, a 27 percent share of outpatient services, and a 14 percent share of adult primary care services. Accordingly, the BILH transaction created a hospital system that is comparable in size and geographic expanse to Partners. The third, fourth, and fifth largest hospital systems — UMass Memorial Health Care, Wellforce, and Steward Health — have between a 5 percent and 7 percent share of inpatient discharges statewide. See Figure 1.

Figure 1. Statewide shares of inpatient, outpatient, and adult primary care services



Source: Final CMIR Report, 45, 47.

9 The HPC also recommended that the Department of Public Health (“DPH”) reconsider its conditions for approval of the parties’ Determination of Need application, and the DPH revised its conditions in response.

10 Assurance of Discontinuance Pursuant to M.G.L. Chapters 93A, § 5 and 93, § 9, *Commonwealth of Massachusetts v. Beth Israel Lahey Health, Inc.* (Suffolk Cty. Super. Ct. Nov. 28, 2018); Mass.gov, “AG Healey Reaches Settlement with Beth Israel, Lahey Health over Proposed Merger,” news release, Nov. 29, 2018, <https://www.mass.gov/news/ag-healey-reaches-settlement-with-beth-israel-lahey-health-over-proposed-merger>.

11 Federal Trade Commission, “Statement of the Federal Trade Commission Concerning the Proposed Affiliation of CareGroup, Inc., Lahey Health Systems, Inc.; Seacoast Regional Health System, Inc.; BIDCO Hospital LLC; and BIDCO Physicians LLC,” Nov. 29, 2018, https://www.ftc.gov/system/files/documents/closing_letters/nid/1710118_bid-mc_commission_closing_statement.pdf.

12 Beth Israel Lahey Health, “Beth Israel Lahey Health Begins Journey to Transform Health Care,” <https://www.bilh.org/in-the-news/2019/2/28/beth-israel-lahey-health-begins-journey-to-transform-health-care>.

13 Final CMIR Report, 26. Beth Israel Deaconess Health System was the second largest system in Massachusetts, with its flagship academic medical center in downtown Boston (BIDMC) and three community hospitals around Boston. Lahey Health was a four-hospital system in northern Boston suburbs. Mount Auburn was a fairly large independent hospital in Cambridge. BIDCO contracting affiliates Anna Jaques Hospital and New England Baptist Hospital also became corporate members of the merged entity; BIDCO members Cambridge Health Alliance and Lawrence General Hospital will continue to contract jointly with BILH without affiliating corporately. Final CMIR Report, 1.

14 Final CMIR Report, 26–27.

B. Competitive Rationale for the Merger

Among the stated rationales for the merger, the parties aspire to “create a large, lower-cost health network that can compete with Partners HealthCare.”¹⁵ Because the new system would be lower priced than Partners, post-merger growth in its patient volume could reduce healthcare spending. This potential is real, because it has been well-documented that Partners is, by a substantial margin, the most expensive healthcare system in Massachusetts — in 2016, its commercial inpatient services prices were 25 percent to 40 percent above the state average, depending on the payer.¹⁶ However, growth in volume at the new BILH entity would not unambiguously reduce overall healthcare spending because, based on the HPC’s analysis, the BIDCO-owned and Lahey hospitals are not generally priced below Boston area hospitals other than Partners.¹⁷

II. HPC’S ANALYSES OF POTENTIAL BENEFITS AND POTENTIAL HARMS

A. Bargaining Leverage and Price Effects

To analyze the likely competitive effects of the BILH transaction, the HPC relied on well-established tools of hospital merger enforcement. Since the early 2000s, economists have analyzed hospital competition using a two-stage model that matches the industry-specific circumstances that determine hospital prices.¹⁸ Courts have accepted the two-stage model of competition in multiple recent provider merger challenges won by the FTC.¹⁹

In the first stage, insurers negotiate with hospitals over the terms, including price, for inclusion of the hospitals in the insurers’ provider networks. In the second stage, patients choose the hospital at which to receive care when the need arises. Patients will primarily choose among in-network hospitals, because doing so generally entails substantially lower out-of-pocket costs. A hospital’s bargaining leverage in negotiations with insurers in the first stage is derived from the incremental profits to the insurer, whether from higher enrollment or higher premiums, from including the hospital in its network.²⁰ The value that enrollees derive from inclusion of a hospital in a plan’s network is referred to as the willingness-to-pay (“WTP”) for that hospital. That is, the WTP for a hospital is defined as the difference between the value of a network that includes that hospital and one that does not.²¹

15 McCluskey, Priyanka D., “Beth Israel and Lahey Health Sign Final Agreement to Merge,” *Boston Globe*, July 13, 2017, <https://www.bostonglobe.com/business/2017/07/13/beth-israel-deaconess-and-lahey-health-sign-final-agreement-merge/IZWtE3YWeQZyRvaWGYXxAO/story.html>.

16 Final CMIR Report, 32–33. Partners outpatient services prices were 5 percent to 35 percent above the state average.

17 Final CMIR Report, 33–34 (“The BID-owned system is consistently the second-highest priced system for inpatient services, and Lahey is generally comparably priced to Steward Health Care System (Steward) and Wellforce. . . . BIDCO, Lahey, and MACIPA [Mount Auburn Cambridge Independent Practice Association] generally have low to moderate physician prices compared to other eastern Massachusetts physician groups, and they are consistently lower-priced than Partners and Atrius.”).

18 Vistnes, Gregory, “Hospitals, Mergers, and Two-Stage Competition,” *Antitrust Law Journal* 67, no. 3 (2000): 671–92.

19 See Opinion, *Saint Alphonsus Med. Ctr.—Nampa Inc. v. St. Luke’s Health Sys., Ltd.*, No. 14-35173 (9th Cir. Feb. 10, 2015), at n.10 (“This ‘two-stage model’ of health care competition is ‘the accepted model.’” Citing John J. Miles, 1 Health Care & Antitrust L. § 1:5 (2014)). *Complaint, In re Evanston Northwestern Healthcare Corp.*, No. 9315 (2004). See also *United States v. Rockford Mem’l Corp.*, 717 F. Supp. 1251, 1266-78 (N.D. Ill. 1989), *aff’d*, 898 F.2d 1278 (7th Cir. 1990); *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014); *St. Alphonsus Med. Ctr.—Nampa Inc. v. St. Luke’s Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015); *FTC et al. v. Advocate Health Care et al.*, No. 15 C 11473 (7th Cir. Oct. 31, 2016); and *FTC et al. v. Penn State Hershey Medical Center et al.*, No. 1:15-cv-2363 (3d Cir. June 2016). For a summary of these cases and a discussion of implications, see Capps, Cory, Laura Kmitch, Zenon Zabinski & Slava Zayats, “The Continuing Saga of Hospital Merger Enforcement,” *Antitrust Law Journal*, forthcoming.

20 See Gowrisankaran, Gautam, Aviv Nevo & Robert Town, “Mergers When Prices Are Negotiated: Evidence from the Hospital Industry,” *American Economic Review* 105, no. 1 (2015): 172–203; Capps, Cory, David Dranove & Mark Satterthwaite, “Competition and Market Power in Option Demand Markets,” *RAND Journal of Economics* (2003): 737–63; Town, Robert & Gregory Vistnes, “Hospital Competition in HMO Networks,” *Journal of Health Economics* 20, no. 5 (2001): 733–53.

21 For example, if a network that includes a given hospital is worth \$10 million to a health plan’s customers and one that does not is worth \$8 million, then the WTP for that hospital will equal the difference, \$2 million.

The inclusion of a hospital that is valued highly by a significant number of patients and for which there is no close substitute will generally increase the attractiveness of a health plan's network and increase plan enrollment. As a result, such a hospital will have a high WTP and be able to command high prices from insurers. In contrast, inclusion of a hospital for which a close substitute hospital is already part of the network or is available to be added will contribute less to the overall attractiveness of the health plan; such a hospital will have lower WTP and will not be able to negotiate as high a price. For this reason, a merger of substitute hospitals for which other close substitutes are unavailable will increase both their WTP and their ability to negotiate higher prices. Economic research has shown that hospitals and systems with higher WTP values can charge higher prices and earn higher profits.²²

The HPC employed WTP analysis to measure the BILH transaction's likely impact on the new system's ability to negotiate higher prices with commercial payers. First, the HPC used a model of patient hospital choice to estimate the WTP for hospitals in Massachusetts. Second, it established the relationship between WTP and prices in commercial networks for those hospitals. Finally, it used the choice model to predict the change in the parties' WTP and the implied price increase.²³ The HPC found that the estimated change in WTP implied predicted price increases of between 5.0 percent and 7.8 percent for inpatient services, which mapped to an annual commercial spending increase of between \$37.9 and \$59.2 million compared to pre-merger spending for those services.²⁴

The HPC also considered retrospective analyses of prior acquisitions by the parties. Their past transactions, which entailed lower competitive overlap and lesser competitive concern, showed no evidence of significant price increases post-merger. As stated by the HPC, "[a]s Lahey and BIDCO have grown by affiliating with or acquiring new community hospitals, their prices have not generally risen relative to competitors, and their spending has grown at generally the same rate as the rest of the market based on current available data."²⁵ In the BILH transaction, the HPC concluded that the greater competitive overlap between the merging parties implied a higher risk of price increases than in previous transactions.²⁶

B. Care Retention and Redirection

The price increase predicted by the WTP model is an all-else-equal measure of the extent of competition eliminated by a merger. Specifically, the standard WTP analysis does not incorporate other factors that might reduce inpatient spending, such as care retention and redirection, more viable narrow-network products, or dynamic effects of intensified competition between Partners and BILH. Accordingly, the HPC further evaluated whether the price increases predicted under the baseline WTP analysis could be offset if BILH were to become a more effective competitor to the higher-priced Partners.

The most direct mechanism by which healthcare spending could fall would be for BILH to shift volume away from Partners.²⁷ BILH could attract volume from Partners by increasing retention of existing BILH primary care patients, increasing the attractiveness of the system for patients through enhanced branding, or recruiting new physicians to the system. The HPC considered potential cost savings from each of these mechanisms. But several factors could attenuate or eliminate such savings. First, BILH could draw volume from lower-priced hospitals as well as from Partners, in which case the relative magnitude of each shift would determine the effect on overall spending. Second, if BILH were to increase its prices, then the per patient savings from attracting patients from Partners would shrink while the per patient spending increase from attracting patients from lower-priced hospitals would grow.²⁸ The HPC also evaluated these potential offsets to savings.

22 Capps, Dranove & Satterthwaite (2003) and Town & Vistnes (2001). Related research by Professor Katherine Ho of Columbia University has established that having a network of hospitals with higher WTP increases the demand for a health plan. Ho, Katherine, "The Welfare Effects of Restricted Hospital Choice in the US Medical Care Market," *Journal of Applied Econometrics* 21, no. 7 (2006): 1039–79; Gaynor, Martin, Kate Ho & Robert J. Town, "The Industrial Organization of Health-Care Markets," *Journal of Economic Literature* 53, no. 2 (2015): 235–84.

23 Final CMIR Report, 50.

24 Final CMIR Report, 51. The HPC also estimated spending increases of \$78.9 million to \$100.0 million for outpatient facility services and \$11.5 million for adult primary care services. Final CMIR Report, 52. The parties contended that HPC's price prediction did not take into account the Massachusetts regulatory environment, including the healthcare cost growth benchmark for healthcare providers (Chapter 224 of the Acts of 2012). In response, the HPC stated that the price prediction is based on price data from after the implementation of the benchmark, and that the benchmark is not intended to function as a price cap for individual providers. Final CMIR Report, Exhibit B at 12.

25 Final CMIR Report, 3.

26 Final CMIR Report, note 123.

27 BILH could also achieve additional cost savings by shifting patient volume within BILH away from BIDMC and Lahey Medical Center to less expensive BILH hospitals. The HPC estimated that this could generate about \$2 million to \$3 million in annual savings. Final CMIR Report, 61.

28 Final CMIR Report, 57–59.

Retention of Existing BILH Patients. The HPC analyzed non-BILH hospital utilization by the parties' existing patients. It estimated that, assuming BILH's projections of post-merger patient retention could be achieved, increased retention of existing primary care patients would reduce spending by \$2.5 million to \$4.6 million annually for inpatient and outpatient services, after accounting for predicted post-merger price changes.²⁹

Brand Enhancement. The HPC used the same hospital choice model that underlies the WTP analysis to predict the hospitals from which BILH, with an enhanced brand, would draw additional patients. It found that 56 percent of new commercial inpatient volume would likely come from Partners, 13.5 percent from Wellforce, 9.7 percent from Steward, and the remainder from other hospitals.³⁰ Again, relying on the parties' projected post-merger volume increase, the HPC estimated that enhanced branding could lead to \$1.1 million to \$2.5 million in net post-merger savings after incorporating likely post-merger price increases.³¹

Physician Recruitment. To evaluate the effect of BILH recruiting new primary care patients through physician recruitment or brand enhancement, the HPC compared the total medical expenses ("TME") for the parties' physician groups with that of other groups in the parties' service areas. It found that, on average, the parties' patients had \$32 per member per month lower TME than patients of other groups. To achieve cost savings sufficient to offset the projected price increases, the HPC estimated the parties would need to attract 333,000 to 443,000 new patients. This is approximately the total patient population of the largest three commercial payers in the area, which is an implausibly high number.³²

Discussion. Overall, the HPC concluded that any plausible shifts in volume from Partners to BILH would be insufficient to offset likely post-merger price increases by the parties.³³ One factor that limits savings from volume shifts is that savings accrue only on marginal (i.e., redirected) patients, whereas a post-merger price increase would apply to all of the system's patients. As a result, for shifts in volume to achieve meaningful net savings, the total number of patients who change providers post-merger must be large. In addition, increased attractiveness and utilization of BILH would likely make it more difficult for health plans to exclude the combined system from their networks, which would further increase the system's bargaining leverage and potential post-merger price increases (over and above the effect of internalized substitution as measured by the WTP analysis).

An open question, however, is the effect an enhanced BILH would have on the bargaining leverage of *other* systems, particularly that of Partners. At present, the economic literature provides little direct guidance. At one end of the spectrum, BILH might become a second "must-have" system in the area behind Partners, solidifying its bargaining position without significantly chipping away at Partners' market power. At the other end, if BILH were to become a true substitute for Partners, the merger could diminish or remove Partners' must-have status.³⁴ The parties, of course, argued that the latter is more likely.³⁵

²⁹ Final CMIR Report, 58–59.

³⁰ Final CMIR Report, 59. The WTP analysis relied on a choice model that predicts patients' choices of hospital based on hospital and patient characteristics. The model included a "hospital fixed effect" specific to each hospital that captures unobserved hospital characteristics, such as brand, that are valued by patients. To study the effect of enhanced brand, the HPC increased the fixed effect of the parties' hospitals by an amount sufficient to generate a specified amount of additional volume (e.g. 10 percent). Predictions derived from the model with the increased BILH fixed effects identify the hospitals from which additional patients would likely come. Final CMIR Report, note 204.

³¹ Final CMIR Report, 59–60.

³² Final CMIR Report, 60–61.

³³ Final CMIR Report, 62.

³⁴ Shaked & Sutton provide a theoretical discussion of how quality differentiation between firms can weaken price competition between them and, conversely, how reduced quality differentiation can intensify competition. A more attractive BILH could reduce differentiation and thereby increase the price competition faced by Partners. Shaked, Ayner & John Sutton, "Relaxing Price Competition through Product Differentiation," *Review of Economic Studies* 49, no. 1 (1982): 3–13.

³⁵ From its review of past hospital mergers in other markets, the HPC did identify one instance in which a merger of smaller competitors may have enhanced competition with the market leader. OSF HealthCare's Saint Francis Medical Center ("SFMC") had long been the market leader in Peoria, Illinois, and was included in nearly all commercial insurance networks, while its rival, Methodist Medical Center ("MMC"), was included in fewer networks. After MMC acquired two smaller hospitals in the area and affiliated with a larger regional system, UnityPoint Health, BCBS of Illinois terminated its contract with SFMC and replaced it with MMC. Ultimately, SFMC was added back to the network, presumably at a price lower than what had led to the termination. It is possible that the strengthening of MMC enabled to become a more effective substitute for SFMC. Final CMIR Report, 65 at n. 226.

To measure the potential effects of an enhanced BILH on bargaining leverage and prices, the HPC considered how a 10 percent increase in BILH's volume (consistent with the parties' expectations) would change WTP for all Boston-area hospital systems. It found that the decrease in WTP for Partners would generate about a 0.7 to 1.1 percent decrease in Partners' prices and savings of \$8.8 to \$13.8 million. The decrease in WTP for the other systems would lead to price decreases implying predicted savings of \$3.1 to \$4.9 million. However, the enhanced brand of BILH would allow it to negotiate higher prices, increasing inpatient spending by \$14.9 to \$23.3 million. Thus, the HPC concluded that an enhanced BILH brand would only generate overall savings if BILH agreed to cap post-merger price increases.³⁶

A relevant question from an antitrust perspective is whether these effects are merger specific. The answer will depend on the merger under consideration. In general, there may be certain investments with returns to scale that would be profitable for a larger system to undertake, but not for a smaller system. For example, marketing expenditures to grow a system's reputation are likely to benefit every hospital in the system. A larger system, then, may benefit more from a marketing campaign with a fixed budget. Even when such investments can be identified, a full antitrust analysis would also consider whether an alternative affiliation short of a merger could facilitate the same outcome.

C. Anchor for New Insurance Products

The parties also argued that the geographic reach of the new system would allow it to anchor new tiered- or narrow-network insurance products. In general, economic research has shown that narrow-network plans commonly have lower premiums, which can benefit consumers.³⁷ These plans may achieve lower costs by excluding higher-priced hospitals from the network or by placing them on a lower tier, steering patients to less expensive providers. Hospitals may also be willing to accept lower prices from a narrow-network plan if inclusion generates sufficient additional volume.

A free rider problem could limit the effectiveness of the latter mechanism, however. A hospital in a narrow-network plan will have an incentive to lower its prices if doing so results in lower plan premiums that attract new enrollees to the plan and thus additional volume for the hospital. However, including multiple competing hospital systems in a narrow network dilutes this incentive because each system individually bears the cost of decreasing its prices, but all systems collectively share the additional patient volume that stems from increased enrollment. A merger between these hospitals could help internalize the volume benefits of cutting prices, making price decreases more likely.

The HPC investigated whether the creation of BILH could enhance competition through more effective narrow-network products. It observed that the three largest commercial payers in the Boston area already offer plans that include BIDCO and Lahey and exclude Partners, but that these products tend to have low enrollment.³⁸ For a new narrow-network product to draw significant volume away from higher-priced providers, it would need to offer lower premiums than existing narrow-network products. Post-merger, the combined BILH system theoretically would have a greater incentive to lower its prices for narrow-network products. If such price decreases materialized and were effective, they could also lead rival hospitals and health plans to respond by lowering their own prices and premiums. However, when asked, the parties stated that they did not intend to lower prices post-merger.³⁹ Accordingly, the HPC concluded that price decreases were unlikely to be realized.

III. CONCLUSION

The HPC identified mechanisms by which the formation of BILH could lead to higher prices and increased healthcare spending, as well as mechanisms by which BILH could reduce healthcare spending. It used economic analysis to quantify the mechanisms, spending-increasing and spending-decreasing alike, that were amenable to quantification. The HPC generally found that the likely net effect was to increase spending. However, while it recognized the potential benefits of creating a stronger competitor to the market leader, Partners, the HPC was not able to fully quantify the spending decreases that might result were that to occur. As noted, this is in large part because the economic literature does not provide significant guidance into the circumstances under which eliminating existing competitors while simultaneously creating a closer second competitor to a market leader will increase competition and lower spending, much less by how much. Based on the final outcome, the Massachusetts Attorney General appears to have concluded that this potential benefit, in conjunction with BILH's price growth cap and other commitments, was sufficient for the Commonwealth to allow the merger to close.

³⁶ Final CMIR Report, 67.

³⁷ See *supra* note 7.

³⁸ Final CMIR Report, note 221.

³⁹ Final CMIR Report, notes 223, 224.

This naturally leads to the question of the implications for other healthcare transactions, particularly those in which conduct remedies are on offer. While it is difficult to be certain, the BILH outcome appears largely specific to the institutions and market circumstances in Massachusetts. As one example, the weight placed on creating a stronger competitor to the market leader in this instance is unlikely to imply that mergers *generally* will go unchallenged or be solvable via conduct remedies if they do not involve the market leader. Moreover, Massachusetts' agencies have a long track record of collecting claims and other data and using those data to monitor and report on provider pricing. Other states may be less able to monitor and track prices, which could make price restrictions less effective and less attractive.

Indeed, the FTC's recent history shows that its enforcement decisions can go either way. Just three years ago, the FTC strongly (but unsuccessfully) opposed an effort by another state to allow a hospital merger to proceed under a conduct remedy.⁴⁰ Here, the FTC issued a statement upon closing its investigation of the BILH transaction, stating, "The assessment of whether to take enforcement action was a close call. However, based on Commission staff's work and in light of the settlement obtained by the Massachusetts AG, we have decided to close this investigation."⁴¹ Thus, the FTC found that the facts, economic analysis, and remedies sufficiently outweighed the risk of harm, but not by a large margin.

40 Letter from Alexis J. Gilman, Assistant Director, Bureau of Competition, Federal Trade Commission, to Cynthia H. Dellinger, Assistant General Counsel, West Virginia Health Care Authority, and Douglas L. Davis, Assistant Attorney General, West Virginia, *RE Cabell Huntington Hospital Inc.'s Application for Approval of Cooperative Agreement* (Apr. 18, 2016), https://www.ftc.gov/system/files/documents/public_statements/945863/160418virginiahealthcare.pdf.

41 See *supra* note 11.

WHEN PROVIDERS MERGE, IS KAISER A COMPETITOR?



BY DOUGLAS ROSS, JAMES HARLAN CORNING, DAVID MAAS & DOUGLAS LITVACK¹



¹ The authors are with Davis Wright Tremaine LLP in its Seattle and Washington, D.C. offices. The firm represented a physician group in recently concluded litigation (discussed in the article) brought by the State of Washington to reverse acquisitions of two physician groups on the Kitsap peninsula. Defendants argued that Kaiser Permanente physicians should be included in the relevant geographic markets at issue in that case. The authors also have represented, and on an ongoing basis represent, physicians and hospitals making the same argument in matters under investigation by the FTC and other antitrust enforcement agencies.

I. INTRODUCTION

When providers — whether hospitals or physicians — propose to merge, an important initial question to consider is who else competes with the merging providers in the relevant market. If the merging parties have no or few competitors, they may be able to raise prices above pre-merger levels. If they face vigorous competition from other market players, however, the ability of the merging parties to raise prices may be constrained, such that the proposed merger poses little or no threat to competition.

According to the Horizontal Merger Guidelines issued by the Department of Justice and the Federal Trade Commission, “[a]ll firms that currently earn revenues in the relevant market are considered market participants.”² So, if two groups of adult primary care providers in a properly defined relevant geographic market propose to merge, all other adult primary care providers in that market are considered market participants and should be included in market share calculations.³ Similarly, if an acute-care hospital proposes to acquire another such hospital in the same relevant geographic market, all other acute-care hospitals in the market should be included before market shares are calculated and the effect of the acquisition on competition is judged.⁴

II. KAISER PERMANENTE: A VERTICALLY INTEGRATED HEALTH SYSTEM

But what should courts and antitrust enforcers do when some of the providers in the relevant geographic market where a provider merger has been proposed are part of the Kaiser Permanente system? Kaiser Permanente is a vertically integrated system that combines health care coverage (often simply referred to as health insurance) with a delivery network of hospitals, physicians, and other providers. Kaiser’s model has been very successful: it provides health care for over 12 million people in eight states through 23,000 employed physicians and more than 730 medical centers and facilities.⁵ But Kaiser largely operates a “closed” network. Physicians, employed by regional Permanente Medical Groups, provide services on an exclusive basis to members in the Kaiser Foundation Health Plan. Facilities, owned by Kaiser Foundation Hospitals, are exclusively available to those members who need hospitalization.⁶ Individuals who receive their health care coverage through other commercial insurers, such as a regional Blue Cross or Blue Shield plan, UnitedHealth, or Aetna, don’t have the option to obtain care from a Permanente doctor or a Kaiser hospital.

Kaiser Permanente’s closed structure has led some enforcers to argue that its physicians and hospitals should be ignored when a merger of non-Kaiser providers takes place in the same relevant market. In recent cases brought by California and Washington, the attorneys general of those states have made precisely this argument. Last year, California sued Sutter Health, a 24-hospital system in northern California, claiming the system’s contracting practices violate the Cartwright Act, the State’s antitrust law.⁷ California’s complaint claims Kaiser Permanente should be excluded from the relevant market because Kaiser is a closed system that does not make its provider network available to other commercial insurers or to self-funded employers. California (and the other plaintiff in the litigation, UFCW & Employers Benefit Trust) filed a motion in March 2019 (which, as of the date of this article, has not yet been decided) to exclude the opinion of Sutter’s expert economist that Kaiser and Sutter compete in the same antitrust market.⁸

2 U.S. Dep’t of Justice & Fed. Trade Comm’n, HORIZONTAL MERGER GUIDELINES § 5.1 (2010).

3 For example, in the FTC’s challenge to the acquisition of a physician group in the greater Boise area, the court focused on the adult primary care market in Nampa, Idaho. It included all adult primary care providers in Nampa in its market calculation when it found that the combination of eight providers employed by St. Luke’s with the 16 providers in the Saltzer medical group was unlawful. *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke’s Health Sys., Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL 407446 (D. Idaho Jan. 24, 2014), *aff’d*, 778 F.3d 775 (9th Cir. 2015).

4 See, e.g. *F.T.C. v. ProMedica Health Sys., Inc.*, 3:11 CV 47, 2011 WL 1219281, at *11-*12 (N.D. Ohio Mar. 29, 2011).

5 Kaiser Permanente, *At a Glance*, available at <https://ataglace.kaiserpermanente.org/> (last accessed April 6, 2019).

6 In certain markets, Kaiser contracts with non-Permanente physicians to provide specialty medical services not provided by Permanente-employed physicians. Kaiser also contracts with non-Kaiser hospitals and hospital systems in markets where Kaiser does not maintain its own hospital facilities. For example, in Seattle (where Kaiser does not have a hospital), it contracts for most inpatient care to be provided at Swedish Medical Center, a community hospital open to all.

7 Complaint, *California v. Sutter Health*, No. CGC-18-565398 (filed Mar. 29, 2018), available at <https://www.courthousenews.com/wp-content/uploads/2018/03/Sutter-California-COMPLAINT.pdf>. After the complaint was filed the case was consolidated with *UFCW & Employers Benefit Trust v. Sutter Health*, No. CGC 14-538451. The motion was noted for hearing on April 30; trial is scheduled for August 12, 2019.

8 Notice of Motion and Motion to Exclude Expert Opinion of Dr. Gowrisankaran that Kaiser and Sutter Compete in the Same Antitrust Market, *UFCW & Employers Benefit Trust and California v. Sutter Health*, No. CGC 14-538451 (filed Mar. 8, 2019).

The State of Washington made a similar argument in its just-concluded litigation challenging two transactions into which CHI Franciscan Health entered in 2016.⁹ The State claimed the transactions lessened competition in the markets for adult primary care physician services and orthopedic physician services. The State moved to exclude testimony from CHI's expert economist because he included Kaiser physicians in both markets.¹⁰ Both the State of Washington's expert economist and CHI's economist relied on the now-familiar "two-stage" competition model to analyze the competitive effects of the transactions. This model was described succinctly by the Seventh Circuit when it upheld the FTC's recent challenge to the proposed merger of Advocate Health Care Network and NorthShore University HealthSystem:

In the first [stage], which is highly price-sensitive, insurers and hospitals negotiate to determine whether the hospitals will be in the insurers' networks and how much the insurers will pay them. Gregory Vistnes, *Hospitals, Mergers, and Two-Stage Competition*, 67 *Antitrust L.J.* 671, 674–75 (2000). In the second stage, hospitals compete to attract patients, based primarily on non-price factors like convenience and reputation for quality. . . . Concerns about potential misuse of market power resulting from a merger must take into account this two-stage process.¹¹

According to the State,

[P]ayers cannot contract with Kaiser-employed physicians for healthcare services because Kaiser-employed physicians are exclusively contracted with Kaiser. . . . [S]ince Kaiser-employed physicians do not compete with other [market] physicians to be included in other payer's plans, they should not be included in the markets for orthopedic and adult PCP services . . .¹²

In the State's view, then, if the only other primary care physicians in a market in which two groups of primary care physicians merge are Kaiser Permanente doctors, the merger is unlawful because the Kaiser Permanente doctors do not constrain the ability of the merging doctors to raise prices. And, in a similar situation where two hospitals merge and the only other hospitals in the market are Kaiser hospitals, a similarly minded enforcer presumably would argue that the Kaiser hospitals do not constrain the ability of the merging hospitals to raise prices.

III. IS IT SENSIBLE TO EXCLUDE KAISER AS A MARKET PARTICIPANT?

The Merger Guidelines assert that vertically integrated firms must be included in the relevant market, "to the extent that their inclusion accurately reflects their competitive significance."¹³ What is the competitive significance of Kaiser providers located in the same market where non-Kaiser providers plan to merge?

The issue arose 20 years ago, when two hospitals in Oakland and Berkeley, California, sought to merge.¹⁴ The district court held that a Kaiser hospital in Oakland was part of the relevant product market for the purpose of assessing the merger:

All forms of acute inpatient care, however, are substitutes for the services offered by defendants because they all accomplish the task of delivering acute inpatient services to patients in the Bay Area. . . . Although Kaiser hospitals may not directly provide services to non-member patients, *they do provide viable substitutes for services offered at other hospitals in the region*; if faced with an anticompetitive price increase, patients may choose to join the Kaiser network for acute inpatient services.¹⁵

9 *State of Washington v. Franciscan Health System et al.*, No. 3:17-cv-05690-BHS, Dkt. No. 1 ¶ 85 (filed Aug. 31, 2017). The State challenged the acquisition by CHI Franciscan of a small group of orthopedic surgeons as a violation of Section 7 of the Clayton Act. *Id.* The state asserted also that CHI Franciscan and a second group — of about 55 physicians in various specialties — violated Section 1 of the Sherman Act when they entered into a transaction by which the group sold its assets to CHI, assigned its leases to CHI, and agreed to see exclusively CHI patients. CHI Franciscan, in turn, was responsible for the group's expenses and for contract negotiation. CHI Franciscan paid the group according to its productivity. The case has settled on so-far undisclosed terms. *Id.*, docket notice dated Mar. 14, 2019 (terminating trial date pursuant to notice from the parties the matter was resolved and ordering dismissal/settlement papers be filed by April 29, 2019).

10 State's *Daubert* Motion to Exclude Portions of the Expert Reports and Testimony of Lawrence Wu, Ph.D., *Franciscan Health System*, No. 3:17-cv-05690, Dkt. No. 177 at 8 (filed Dec. 21, 2018).

11 *F.T.C. v. Advocate Health Care Network*, 841 F.3d 460, 465 (7th Cir. 2016); see also *Saint Alphonsus Med. Ctr.-Nampa Inc.*, 778 F.3d at 784 n.10 (9th Cir. 2015) ("This 'two-stage model' of health care competition is 'the accepted model.'") (citing John J. Miles, 1 *Health Care & Antitrust L.* § 1:5 (2014)).

12 See *supra* note 10.

13 Horizontal Merger Guidelines § 5.1.

14 *California v. Sutter Health System*, 84 F. Supp. 2d 1057 (N.D. Cal. 2000), *aff'd*, 217 F.3d 846 (9th Cir. 2000).

15 *Id.* at 1068 (emphasis added). In an odd move, the district court opinion was later amended to state there was no dispute over the fact that the Kaiser hospitals belonged in the relevant market, 130 F. Supp. 2d 1109, 1119-1120 (N.D. Cal. 2001), despite the fact that the court's initial decision shows the issue was hotly contested by the parties.

While the precise Kaiser issue appears not to have arisen again in any of the decided cases, the district court's decision to include Kaiser when considering the Sutter merger was cited with approbation in the Areeda & Hovenkamp treatise.¹⁶ Other decisions involving vertically integrated firms support this result. The Ninth Circuit, in *ITT v. GTE*,¹⁷ squarely held that "captive sales" cannot be excluded from the relevant market. In that case, the district court found that GTE's acquisition of telephone operating companies threatened competition in the sale of telephone equipment. It did so based on an alleged "submarket" that excluded purchases of telephone equipment by members of the Bell System from their affiliate, Western Electric. The Ninth Circuit held this was error: "vertical foreclosure in itself does not justify defining a customer market to exclude 'captive' sales."¹⁸

The Ninth Circuit has applied this principle specifically to health care services. In *Morgan, Strand, Wheeler & Biggs v. Radiology, Ltd.*,¹⁹ radiologists argued that because osteopathic physicians referred only to osteopathic radiologists, and University physicians referred only to University radiologists, both sets of radiologists should be excluded from the relevant product market in which plaintiffs competed. The Ninth Circuit concluded that, even if referral patterns were "quite fixed, or exclusive" among these providers, *all* radiologists were part of the same market.²⁰ The Court affirmed the entry of summary judgment, concluding that the radiologists failed to present evidence of the product market.²¹

Morgan, Strand is also discussed with approval in the Areeda & Hovenkamp treatise. The authors state that "the integrated firm's ... output belongs in the market," and "[p]recisely the same reasoning applies when the [integrated] firm provides through employees a service in competition with independent service providers."²²

By the same logic, Kaiser should be included in any market where it provides the same physician or hospital services as those provided by the merging parties. As Areeda & Hovenkamp wrote, with specific reference to the district court's decision to include Kaiser when analyzing the merger of Suter and Summit, "each provision of services by Kaiser reduces in like amount the provision of services by other hospitals; further, Kaiser compete[s] with alternative health care arrangements in the signing up of members."²³ Because patients and employers who use other providers (and insurers) could shift to Kaiser in response to a price increase by those providers (which will manifest itself in their premiums), it should make sense always to include Kaiser in the relevant market when considering a provider merger.

While the issue remains open in the courts, several health care researchers have asserted Kaiser should be considered in a market analysis. For example, in the wake of an assignment undertaken in 2013 on behalf the California Department of Justice to consider the effects of a proposed hospital affiliation in the Bay Area, two consultants with Health Management Associates prepared a paper detailing the model the firm used to analyze the merger.²⁴ Their assignment required them to confront the question whether Kaiser should be considered in the analysis. They acknowledged that "non-Kaiser enrollees do not access Kaiser hospitals and that Kaiser enrollees do not access non-Kaiser hospitals," but noted that "Kaiser's strong market power in California affects the bargaining process between a non-Kaiser hospital and another commercial insurer through insurer competition for enrollees" and so they included Kaiser hospitals in their model.²⁵ They explained that "while a Kaiser hospital may not be a viable immediate choice for a non-Kaiser patient, if it has high utility to the patient it may be that they would choose Kaiser during the next re-enrollment, and therefore we believe including Kaiser hospitals in the model is justified."²⁶

¹⁶ Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ("ANTITRUST LAW"), Vol. IIA, ¶ 535e, n.19. (4th ed. 2013).

¹⁷ 518 F.2d 913, 930-931 (9th Cir. 1975), *overruled on other grounds*, *California v. American Stores, Inc.*, 495 U.S. 271 (1990).

¹⁸ *Id.* at 931.

¹⁹ 924 F.2d 1484 (9th Cir. 1991).

²⁰ *Id.* at 1489-90.

²¹ *Id.* at 1489.

²² ANTITRUST LAW, Vol. IIA, ¶ 535e, n.19.

²³ *Id.*

²⁴ Lisa Maiuro and Paul Niemann, "Evaluating the Effects of Hospital Consolidation: How Sensitive is the Discrete Choice of Econometric Model in Identifying Hospital Competitors?" (Aug. 2015), available at <https://www.chcf.org/wp-content/uploads/2017/12/PDF-EvaluatingEffectsHospitalConsolidation.pdf>.

²⁵ *Id.* at 19. The authors relied on research by Kate Ho and Robin Lee that showed "most hospitals negotiate lower prices when Kaiser is present." *Id.* The Ho and Lee paper appears in *Econometrica*, Vol. 85, No. 2 p. 379-417 (Mar. 2017).

²⁶ *Id.*

IV. BUILDING A CASE FOR KAISER'S INCLUSION IN THE RELEVANT MARKET

In the absence of binding case law requiring that Kaiser's doctors and hospitals be considered as market participants when non-Kaiser providers merge, courts and enforcers will treat the issue as an open one. Lawyers urging the inclusion of Kaiser as a market participant will be expected to marshal facts specific to the market under scrutiny to support this result. What facts would be helpful — or harmful — to the argument? In general, advocates of Kaiser-as-a-market-participant will want to show that Kaiser competes with other commercial insurers for members who obtain health care in the relevant market. If non-Kaiser providers in that market merge, and attempt to raise prices to the commercial insurers through whom they obtain their patients, the necessary result will be that those insurers must raise premiums. But this puts the insurers at risk of losing members, who can switch to Kaiser at the next open enrollment period. And once those members have switched to Kaiser, they are lost to the non-Kaiser providers whose price increase started this chain of events.

More specifically, a convincing narrative would seek to establish as many of the following facts as possible:

- A trend over time showing an increase in Kaiser's share of the health care coverage market compared to commercial payers. If Kaiser has increased its share in a geographic market by a substantial amount (at the expense of non-Kaiser commercial plans), this would be consistent with a theory that subscribers switch from non-Kaiser commercial products to Kaiser. The larger Kaiser's share, the stronger the argument.
- Evidence of particular subscribers who switched. In Washington's challenge to the CHI Franciscan transactions discussed above, for example, defendants planned to introduce evidence at trial of patient switching, including testimony from Franciscan physicians that they often lost patients to Kaiser — and sometimes regained those same patients when commercial insurers narrowed the difference between their premium costs and Kaiser's.²⁷
- Evidence that many employers offer their employees a choice between Kaiser and a non-Kaiser commercial plan. To the extent evidence could be gathered on how many employees choose one compared to the other, and how that has changed over time (and perhaps in response to differing employee contribution payments) the evidence could be very persuasive. The ability of a party undergoing a merger review to access this information is limited, however. Only if the government challenges a merger do parties ordinarily have the ability to subpoena employers and brokers. In the absence of subpoena power, employers or brokers might be approached and interviewed to see if they would provide some of this information informally.
- Documents in a merging providers' files, created in the ordinary course of business, showing that providers consider Kaiser to be a competitor. Similarly, documents (perhaps e-mails in the payer negotiating files) that show commercial payers put pressure on providers to control costs to stem the tide of subscribers exiting commercial plans for Kaiser should be very persuasive.

Kaiser, as a vertically integrated organization, can directly realize the cost savings that result from controlling utilization of its services, and is incentivized to develop patient-centric models of care that emphasize prevention and early intervention. Kaiser can pass these cost savings to its members (and their employers) in the form of reduced premiums and out-of-pocket costs. These reduced costs, in turn, allow Kaiser (both as an insurer and delivery system) to capture more share, allowing Kaiser to achieve further cost savings through efficiencies. Available evidence supports the conclusion that Kaiser is good at lowering costs. Kaiser's health insurance exchange products in California are priced at or below the offerings from Blue Shield, Anthem, and Health Net.²⁸ Kaiser offers a strong brand, high clinical quality, and loyal customers. Kaiser is consistently one of the top-rated health plans according to the NCQA.²⁹ Kaiser's Medicare Advantage plans consistently score highly according to CMS's STAR ratings.³⁰

²⁷ Defendants' Pre-Trial Memorandum, at 34 (Case 3:17-cv-05690-BHS, Dkt. 249) (filed Feb. 27, 2019). The case settled before trial however. *Supra* note 8.

²⁸ For example, Kaiser has consistently offered insurance products through Covered CA (whereas some firms have exited) and Kaiser offers some of the lowest priced products available there. See Covered California's Health Insurance Companies and Plan Rates for 2018, available at https://www.coveredca.com/newsroom/PDFs/CoveredCA_2018_Plans_and_Rates_8-1-2017.pdf.

²⁹ Available at <http://healthinsuranceratings.ncqa.org/2018/search/Commercial/CA>;
<http://healthinsuranceratings.ncqa.org/2017/search/Commercial/CA>;
<http://healthinsuranceratings.ncqa.org/2016/search/Commercial/CA>;
<http://healthinsuranceratings.ncqa.org/2015/search/Commercial/CA>.

³⁰ Available at <https://www.medicare.gov/find-a-plan/results/planresults/plan-details.aspx?pp=planlistbynameorid>.

The pressure Kaiser places on non-Kaiser providers in a market may have additional effects, beyond forcing non-Kaiser providers to keep prices they charge insurers at levels that will not incentivize their patients to drop those insurers and switch to Kaiser. Kaiser's prowess as a competitor may motivate mergers or other innovative joint ventures. If two health care systems have hospitals and affiliated physicians in different cities and towns across a broader geographic area where Kaiser provides coverage for a substantial segment of the population, the systems may be motivated to merge or form a joint venture so they can better control costs and work together, perhaps also with a like-minded payer in the region, to develop a Kaiser-like vehicle that can better manage care and compete more effectively with Kaiser. Several years ago, for example, eight well-known systems spread across a broad swath of southern California (including among them Cedars-Sinai, UCLA, and Huntington Memorial) joined with Anthem Blue Cross to form Vivity — a narrow network, low-cost product designed specifically to offer integrated care in direct competition with Kaiser.³¹

V. CONCLUSION

The fundamental issue that antitrust counsel for providers and the antitrust enforcement agencies alike must confront is whether the presence of Kaiser providers in a market constrains the ability of merging, non-Kaiser providers to raise prices. In two separate enforcement actions, California and Washington have argued that because commercial payers can't switch from non-Kaiser providers to Kaiser providers immediately in the event of a price increase by the non-Kaiser providers, the two-stage competition model requires the exclusion of the Kaiser providers from the market. If non-Kaiser hospitals and physician groups adopt the State enforcers' theory that Kaiser providers don't compete with them — and raise prices in that belief — they likely will suffer economically during subsequent open enrollment periods when commercially insured individuals switch from commercial health care coverage to Kaiser to take advantage of lower premiums and out-of-pocket costs. This reality can be a powerful constraint on providers' ability profitably to raise price. Rote application of the two-stage competition theory to exclude Kaiser from the competitive calculus when two providers merge in a market where Kaiser has a strong presence would be a triumph of theory over fact. The two-stage competition model may work well to explain how competition operates in markets dominated by commercial insurers, who stimulate providers to compete against each other to be included in the insurers' networks. But in markets where Kaiser is strong, ignoring Kaiser ignores the competitive reality faced by providers. It would seem better economics to adjust the two-stage competition theory to account for the reality of Kaiser's competitive effects on providers, than to ignore that reality so as to preserve the simplicity of the theory. After all, it was an economist who first said, "when the facts change, I change my mind."³²

31 See, e.g. Modern HealthCare, "How Anthem's Vivity venture is faring in Southern Calif. showdown with Kaiser?" (Oct. 23, 2015), available at <https://www.modernhealthcare.com/article/20151023/NEWS/151029953/how-anthem-s-vivity-venture-is-faring-in-southern-calif-showdown-with-kaiser>.

32 But who that economist was remains a subject of dispute. Some accounts suggest that John Maynard Keynes said it first; others credit Paul Samuelson. See Quote Investigator, "When the facts change, I change my mind. What do you do sir?," available at <https://quoteinvestigator.com/2011/07/22/keynes-change-mind/>.

UNCERTAINTY IN PHARMACEUTICALS MARKETS



BY HENRI PIFFAUT¹



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I. INTRODUCTION

In a number of industries, competitive constraints come mostly from outside the market. Think of markets where access is dependent on the grant of an exclusive right via a concession, or some digital platform markets where network effects create exclusive ecosystems. That is also the case in most pharmaceutical markets, where patents protect the position of an operator. I say “most,” because the intensity of competition between molecules depends on the regulatory design. The common feature of all these markets is the presence of an incumbent that earns some rents and that has to internalize the constraints coming from outside of the market. How incumbents deal with outside constraints is currently the subject of intense scrutiny: Big tech is accused of nipping emerging platforms in the bud; big pharma of proceeding with killer acquisitions against emerging competitors or pay for delay deals with possible generic entrants; etc. All these markets share a common feature which is the uncertainty of where, or when, the threat to the market position may come. This begs the question of how such uncertainty should be addressed in a competition law assessment. This article seeks to answer that question by focusing on the pharma markets and pay for delay, but many of the developments could be equally applicable to other markets.

II. THE CONTEXT: PAY-FOR-DELAY CASES ARE ABOUT UNCERTAINTY

In most pharma markets there are barriers to entry in the form of IP. It is a legitimate effort from incumbents to protect their past investments and use existing laws and regulations to make rivals’ efforts to enter more uncertain and therefore costly. Candidate entrants may try to work around IP barriers or challenge them. Either way, the success of the efforts is uncertain and will depend on findings by courts. The outcome of court cases cannot be safely predicted, not because they are random, but because the court relies on mechanisms that enables it to combine information from both parties, and possibly experts. Each party on its own does not have access to complete information. The courts aggregate and interpret information, and adjudicate under the applicable law. Before a court reaches its decision, each party can only make its best estimates of the outcome of disputes based on assumptions, private and public information, and internal decision processes. It follows that in pharma markets successful, or even profitable, entry by generic companies is, by definition, uncertain and companies’ actions, whether they are contemplating entry or monitoring possible efforts to enter, are based on incomplete information and best estimates of the outcome of future events.

Intuitively, it does not sound good for competition that an incumbent pharma company would either buy a candidate entrant, purchase assets that had been developed to prepare an entry (killer acquisition), or agree, against compensation, with a candidate entrant that the latter will not enter (a pay-for-delay agreement). However, all these decisions are shrouded in present and future uncertainty, whereas competition law’s role is to deliver legal certainty and objective, *in concreto*, assessment. This article argues that the EU competition law concept of potential competition seems to be the right prism through which to address these possible theories of harm. It examines how potential competition has been applied and reconciled with the prevalent uncertainty to pay for delay transactions in the pharmaceutical industry; it also looks at how this translates for showing restrictive object or effect in a context of uncertainty.

There have been four pay-for-delay cases decided on the basis of Article 101 since 2012: *Lundbeck*,² *Fentanyl*,³ and *Servier*⁴ by the European Commission, and *Paroxetine*⁵ by the UK authorities. All but *Fentanyl* are under appeal. A fifth one, *Cephalon*, is currently in an administrative phase.⁶

A typical strategy of originator companies when facing the end of the patent protection on a molecule is to raise IP barriers against generic entry by applying for patents to block several alternative routes for producing a bioequivalent medicine, for example by protecting a number of processes of manufacturing the molecule or by patenting certain salts, crystalline forms, etc. Despite this, given that the compound itself is no longer protected, generic companies may retain various possible routes to market: They can try to avoid the IP protection by inventing around the incumbent’s patent, get into the market “at risk” (i.e. be ready to face a court action by the incumbent), clear the IP barrier in advance through interaction or judicial process, etc. For instance, reflecting these parameters, the *Lundbeck* decision (para. 635) lists eight routes to market.

2 Commission decision of 19.06.2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement (AT.39226 – *Lundbeck*). Judgment of the General Court of September 8, 2016, Case T-472/13, under appeal.

3 Commission decision of 10.12.2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (AT.39685 – *Fentanyl*).

4 Commission decision of July 9, 2014 relating to a proceeding under Article 101 and Article 102 of the Treaty on the Functioning of the European Union (Case COMP/ AT.39612 – *Perindopril (Servier)*); Judgment of the General Court of December 12, 2018, *Servier SAS and Others v. European Commission*, Case T-691/14, under appeal.

5 Decision of the UK Competition and Market Authority of 12.02.2016 (*Paroxetine* – Case CE-9531/11).

6 Case COMP / AT.39686 where the Commission sent a Statement of Objections on 17.07.2017.

The same *Lundbeck* decision quotes internal documents that use language that reflects vividly the context of decisions under uncertainty that originator and generic companies face when they have to make choices between entering, litigating or negotiating. “It is like a poker game We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards But we have a large pile of \$\$\$ at our side We call it – “the art of playing a l[o]sing hand slowly” Our strategy Our objective: To create a window of opportunity for the Ciprex switch Focus on EU and particularly the northern European markets – the generic markets Three main tactics: – Influencing the authorities – Patent defence, mainly process patents – Deal making.” (*Lundbeck* decision, para. 804)

In those cases, prior to entering into the agreement, the generic company had developed a process to produce the molecule. The generic company was technically able to enter the market but there were uncertainties on the outcome of entry because of legal and commercial risks. To make its decision on whether, and how, to enter, the generic company would rely on both private and public information in order to reduce and model uncertainty. Typically, the generic company future profits will depend on its own performance, general uncertainty surrounding competitive conditions, actions of originator and outcomes of possible court procedures.

On the other side, the originator knows that its patent protecting the molecule will lapse on a given date. Beyond that, the originator may be aware of efforts by some generic companies (based on public or private information) to enter the market. There is uncertainty as to whether these efforts to enter will translate into actual entry or not; and related to this, there is uncertainty on the outcome of a possible IP dispute.

The uncertainty of the outcome of patent court cases is perhaps best described by this quote in the UK litigation concerning a Servier patent:

[The ‘947 patent] is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. . . . The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest. It is right to observe that nothing Servier did was unlawful. It is the court’s job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably (*Servier* Decision, para. 1132)

This Court decision came a year after the European Patent Office OD had confirmed on first instance the validity of the same patent.

If any generic would enter the market, profits would drop significantly. This means that the originator company has a very strong incentive to challenge the generic efforts by arguing that they infringe some of its patents even though they are perceived as possibly invalid. In that regard, the pharma sector enquiry found that whilst the originator companies initiated the majority of the cases, generic companies won 62 percent of the patent litigation cases and in 46 percent of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favorable to the generic company, or settlements which appear to be favorable to the generic company.⁷

Once the originator perceives the threat of entry, it adapts its behavior to potential entry. For it to be able to make a self-assessment of the legality of its behavior, it should be able to base its decision on information that is known to it: Knowns, as well as known-unknowns. There is no reason to make a separation between the two categories. Any business decision is based on both. Typically, there are objective processes in place within the organization to deal with the information available and a best judgment is applied on the outcome of these processes. In other words, it is inevitable that in situations of uncertainty, companies’ decisions are a mix of subjective and objective determinations. One cannot ask the originator company to second-guess information that it does not know but the generic knows.

It follows that prior to any agreement, there are knowns (end of patent protection, generic’s ability to produce), known-unknowns (who will prevail in case of dispute before a court, commercial success, evolution of general factors such as overall demand, evolution of economy, etc.), and unknowns. In order to make the best possible decisions, each party will try to gather as much and as complete information as possible. There are always some elements that will be random (i.e. unpredictable). The gathered information can be private or public (say at least shared with the other party). The judicial process makes the information, as much as possible, complete and shared, and on that basis courts interpret and apply the law.

⁷ Pharmaceutical Sector Inquiry Report of 08.07.2009.

III. EVIDENCE IN TIMES OF UNCERTAINTY: SUBJECTIVITY RATHER THAN WAIT-AND-SEE

A common thread in pay-for-delay cases is how to objectively prove a restriction of competition based on evidence that reflects the uncertainty at the time of the agreement. It would be easy, but wrong, to use later evidence when the fog of uncertainty has dissipated, as it would be equally wrong to reject evidence based on perception of the parties. I will illustrate this by looking at how the concept of potential competition has been applied to pay-for-delay, then at the value of the transfer that changes the incentive to compete for the generic company, and finally at a proper test for a restriction by effect analysis.

A. Potential Competition

How should a competition agency acknowledge these uncertainties and the incompleteness of information? When, and on the basis of what evidence, is the competitive constraint exercised by a generic company that is making efforts to enter strong enough to be considered as “potential competition”? There are three possible options. First, the agency could rely on each party’s expectations in order to determine competition constraints from operators not in the market. Second, the agency could refuse to consider any internalization of uncertainties by the parties and rely only on knowns. Third, the agency could consider that the existence of uncertainties does not allow to conclude that the generic is a potential competitor, in other words that the knowns are not enough. I now discuss these three options.

Option two appears overly extensive or restrictive, depending on whether the ability to produce the molecule is enough. In fact, the only know that would remain in that option would be that the active pharmaceutical ingredient (i.e. the molecule) is no longer protected, but with no view allowed on whether that could translate into market entry. That would lead to numerous type one and type two errors.

Option three amounts to excluding potential competition as soon as there is a dispute (and in effect any other uncertainty such as commercial risk). There are two major weaknesses to this approach. First, is that it provides an incentive for the originator to challenge before the courts. It puts in the hands of the originator the power to decide whether a generic is not a potential competitor. Second, there is no limiting principle. Unless there would be a convincing way to separate various types of uncertainties, any type of uncertainty should be excluded. Intuitively, that cannot be right, given that the very nature of competition is to deal with uncertainty. In that case, the only possible potential competitor that could be considered under competition law would be the one about to enter, a split second before entry. This is underlined by the Technology Transfer Guidelines that state that it is in the interest of the parties to deny the quality of potential competitor.⁸

Let us turn now to option one. The fact that the information about the originator and generic companies’ perceptions is observable and verifiable makes the criteria operant. It remains to be seen if they correspond to the competition reality, or, in situations where these criteria would be met but the generic company would not be a potential entrant, if it would be bluffing the originator. That does not seem likely. The judicial process is organized to identify bluffers, so the originator could proceed with the litigation in order to call the bluff, and if it appears not to be a bluff, then still has the option to offer a settlement. From the generic perspective, this appears a high-risk strategy, given that preparations for market entry entail costs and investment in reputation. Bluffing is also incentivized by the possibility of pay for delay.

The two recent General Court decisions in *Lundbeck* and *Servier* make a distinction between possibilities and intentions. Possibilities are assessed on the basis of a “*faisceau d’indices*” that aims at establishing that the candidate potential entrant has the ability to enter the market. This is the essential factor according to the *Lundbeck* judgment, a purely theoretical possibility of market entry is not sufficient (para. 101). An undertaking cannot be a potential competitor if its entry into a market is not an economically viable strategy (*Lundbeck*, para. 100). The intention to enter is an optional and complementary factor. According to the *Servier* judgment (para. 382), the intention to enter in a market is neither necessary to establish the existence of potential competition on the market nor liable to challenge it; it remains that, when established, it is likely to confirm the ability to enter. What matters is a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive (*Lundbeck*, 102).

The *faisceau d’indices* to establish the possibility to enter included the following findings in both the *Lundbeck* and *Servier* cases: Significant investments and efforts already made by the generic undertakings in order to prepare their entry to the market which resulted in (access to) capacity of production and stocks; obtention of a marketing authorization, or having taken the necessary steps to obtain one within a reasonable period; existence of non-infringing routes to the market; no conclusion by a Court of infringement; a non-negligible possibility that some of the secondary patents (for production process, formulation etc.) might be declared invalid; occurrence of entry at risk; evidence of expected profits; and the significant transfers of value through the agreement.

⁸ Section 2.4 of the Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, pp. 3–50.

In fact, the joint reading of these two Court decisions leads to the following test for potential competition:

1. Considering its production capacities, commercial arrangements, and regulatory approvals, does the entity have the capacity to enter the market within a reasonable time period?
2. Are there any exogenous objective reasons that would lead to insurmountable barriers to entry, such as final court decisions that would take a stance on infringement or validity? (*Servier*, para. 321).
3. Would the entry be economically viable? (However, it does not need to be the most profitable return on investment, see for instance *Servier*, para. 340).

These first three steps provide real, concrete possibilities. They concentrate on showing the ability to enter. There is no need to show incentive to enter which would require more than economic viability. They can be complemented by an examination of the intentions of the parties for instance in terms of entry or conflict over infringement or validity. But, they must not.

Then comes the question of the type of evidence that can prove that these three steps are met. First, from a temporal perspective, it is the evidence available at the time of signing the agreement. This can be illustrated or clarified by recourse to posterior evidence, but such *ex post* evidence cannot disprove the test. Second, the issue arises of the nature of the evidence. Since the questions asked in the test are concrete, their answers call for objective evidence to support them. Judging the profitability of future entry requires to make some assessment of risk factors linked to litigation or commercialization. In *Lundbeck* (para. 141), the Court tries to square the necessary subjective nature of such prediction with a level of objectivity of the evidence:

The Commission therefore did not err in relying on objective documents reflecting the perception that the parties to the agreements at issue had of the strength of Lundbeck's process patents at the time those agreements were concluded (see inter alia recital 669 of the contested decision) in order to evaluate the competitive situation between those parties, it being noted that subsequent evidence may also be taken into account provided that it is capable of clarifying those parties' positions at the time, confirming or challenging their arguments in that respect as well as allowing a better understanding of the market concerned. In any event, that subsequent evidence cannot be decisive in the examination of the potential competition between the parties to the agreements at issue.

This approach makes sense because it corresponds to the reality of human organizations. On the other hand, the *Servier* judgment (para. 384) categorizes such evidence as showing the intention of the parties and therefore not necessary to prove potential competition.

I think there is an argument to be made that such anticipations, when made by experts, do not amount to subjective intentions, but rather form objectively informed predictions. This is similar to predictions that the Commission may make of the effects of a proposed merger on the markets. However, in pay-for-delay cases, the very fact that the parties signed an agreement is likely to be sufficient evidence that given a capacity to enter, it would likely be profitable. That was acknowledged in both the *Servier* and *Lundbeck* cases.

B. Value Transfer and Incentive

Turning now to the restriction of competition analysis, I will first recall the test applied in the *Servier* and *Lundbeck* cases to focus on the third condition, which deals with a change in incentives for the generic company against a payment by the originator, and conclude that it is appropriate to treat these as restrictions by object. Finally, given the reasoning followed by the General Court in *Servier*, it is useful to review the test and type of evidence to rely on to assess effects.

To state the obvious, any elimination of a credible threat of entry is likely to release a competitive constraint on the originator company. If an agreement leads to absence of possible entry, the competitive situation with the agreement is always worse than that without an agreement. In that instance, the evidence of intentions of the parties is irrelevant as the object is clear from the agreement itself: For a potential competitor to withdraw from competition. This was the case of both the *Servier* and the *Lundbeck* agreements. Since the competitive situation is always worse with such an agreement, it seems appropriate to label this as a restriction by object.

The test applied by the Commission in both *Servier* and *Lundbeck* beyond showing, first, that the generic company is a potential competitor, and, second, that the agreement leads to the abandonment of its efforts to enter, calls for a third condition to be met: That a transfer of value would change the incentives of the generic company to enter. This raises two questions: First, since the test addresses incentives, does that involve examining the parties' intentions? And, second, is that test superfluous if in any event the agreement bars entry?

From the generic company perspective, assuming it meets the potential competitor test, if the value transfer would exceed any level of profit it could have expected to make (even if none of the risks would materialize), it would be profit maximizing to stop its efforts and sign the agreement. If the value transfer exceeds the expected profits discounted by the risks incurred (commercial, litigation, etc.) at the time of the agreement, there is again no incentive to earn this money by continuing the efforts to enter the market and confronting risks inherent to competition, and it is profit maximizing to sign the agreement. Such an assessment does not require an examination of the intentions of the generic company prior to the agreement, but, based on its assessment of risks, does confirm that the payment cancels any possible profit out of entering. In that sense there is no subjective element, but for the part of putting a value on the risks. The third scenario is when the value transfer is greater than zero but below the expected profits linked to entry. In that case, there is a need to explain why there are no incentives to enter any more. It could be that investing the same efforts in an adjacent market would bring more profits when including the value transfer for instance. This is again an assessment based on the generic company's expectations and not its intentions.

It is not superfluous to examine the link between payment and incentives. The payment shows that there is a distance between the agreement and a settlement based on the merits of the parties claims on infringement and validity. It shows that the generic company expected to make a profit out of its efforts, most likely out of entry in the market. If there was no transfer of value, it would not make economic sense to consider the generic company as a potential entrant since it did not need any financial prompting to undertake not to enter.

It follows that when the three *Servier/Lundbeck* conditions are met, it is highly likely that the competitive conditions are worse than without the agreement. In other words, a qualification as a restriction by object is justified.

The legal determination of the value transfer is of a high importance. It must be a transfer that would not take place if there was no agreement, otherwise there would not be a change in the incentives of the generic company. So, for instance, if the value transfer takes the form of a side agreement, the Commission would have to prove that it would not have been signed absent the main agreement. If that is proven, then the overall value attached to the side agreement may have an effect on the incentives of the generic company. The fact that the side agreement was signed at arm's length or not is irrelevant, the whole economic benefit brought to the generic company, even if made at arm's length, is a value transfer. However, the General Court judgment in *Servier* contains statements which could suggest a narrower interpretation such that the value transfer is only established when its terms do not reflect normal market conditions. In my opinion, that appears inconsistent with a proper analysis of the impact on the generic company incentives. Let me add that under EU competition rules, there is no way under Article 101 to balance the possible beneficial effects of the side agreement on another market with the negative effects of the pay-for-delay.

If there is a value transfer and one relaxes the second condition of the test, so that the generic company undertakes not to enter only for an initial period (and not anymore for the length of patent protection) but the originator keeps the freedom to challenge entry of the generic company past this initial period of time, the conclusions remain the same. The agreement does not solve anything and just postpones the problem. The two parties are likely to face the same choice at the end of the initial period but the originator is relieved of competitive pressure meanwhile. Competition conditions are worse with the agreement.

If, on top, the originator undertakes not to challenge entry of the generic company past this initial period of time, the assessment becomes more complex. This is a so-called "early entry" settlement: The generic company receives a payment for not competing, but only for a while, and it may enter before the end of the patent protection under dispute. The existence of a value transfer would suggest that the generic company would derive a profit from not signing and therefore competing on the market during some time in the initial period. Similarly, if the originator company is ready to share part of its profit, that points towards elimination of competition. The same arguments that point towards a restriction by object apply here. However, the context in which the early entry agreement has been signed must be understood. There could be anticipated changes, such as regulatory changes, product hopping that could enhance or decrease the merits of the scenarios, etc.

C. Restriction by Effect

Turning now to the analysis of effects of a pay-for-delay agreement, there are a number of issues to examine: The nature of the effects, the type of evidence that can be used, definition of the counterfactual scenarios, whether effects should have occurred *ex post facto*, etc.

First of all, likely effects should be found at the time of signing the agreement. This is not specific to pay-for-delay agreements but the uncertainty relating to infringement/validity of a patent at time of signing should not be left aside in favor of a later decision by a court on the subject under dispute. The main argument for that is one of legal certainty. A company must be able to self-assess the legality of its actions at the time of the behavior in question. Having to wait for future events to determine the legality of an agreement increases the legal uncertainty: Both the scenario under implementation of the agreement, and that under the but-for, include many more unknowns than a determination based on *ex ante* facts. In addition, if the legality depends on future events, not only would the company be unable to determine with certitude whether its planned behavior is legal, but it would increase the attractiveness of potentially anticompetitive practices. The amount of the fine would be the same whether the determination is made on facts *ex ante* or *ex post*. Since it is less likely that the behavior be found illegal based on unknown future facts, a company will be more likely to adopt an anticompetitive behavior.

The scenario under the pay-for-delay agreement then should include likely events. For instance, if an agreement which, hypothetically, does not amount to a restriction by object excludes a potential competitor, it is important to assess the likely other entrants at the time, even if they face uncertain prospects. Similarly, if an existing dispute over IP rights has non-negligible probabilities of ending with validity or invalidity, both scenarios should be considered.

Counterfactual scenarios, absent the pay-for-delay agreement, must also include likely events. Most of them are equivalent to those that may happen in the presence of the agreement, because they do not depend on whether the potential competitor is in or not. However, some events are agreement dependent. The most obvious one is the possible entry of the potential competitor. As discussed above, a potential competitor must have the (future) ability to enter, but it may not have the incentive to do so. For instance, there might be alternative investments with higher returns. However, for the potential competitor to have an influence on the competitive behavior of the incumbent, its entry must be likely, at least from the perspective of the incumbent. That means that the Commission should prove, not only ability to enter, but also that the potential competitor has the incentive to do so. If contemporary documents would show intent to enter, then that should confirm the existence of the incentive.

The question remains whether the Commission should prove that actual (but future and unsure) entry would have effects on competition or should prove that the threat of entry has effects as well. The latter corresponds to the recent US FTC opinion in the Impax case: “The Commission explained that the U.S. Supreme Court’s Actavis decision held that eliminating the risk of competition through a reverse payment settlement itself constitutes an anticompetitive harm. The Commission found there was ample evidence of a risk that Impax could have launched a generic product before the agreed-upon date, had it not entered into the reverse payment settlement with Endo. The Commission therefore concluded that Complaint Counsel established a prima facie case.”⁹ First of all, if the threat of entry has an effect, it should be enough, since the only reason why it would have an effect is because the incumbent would deem it credible. If the Commission cannot prove that the threat of entry likely alters the competitive behavior of the incumbent, it is probable that the only arguments available would then be one of common sense: If the potential competitor enters, there is one more competitor for a product that before its entry commended high margins, it is therefore likely that entry would lead to a drop-in prices. The argument would remain the same if entry by one or two other players were also possible. That is economics 101.

To summarize,

- By effect restriction should be assessed at the time of the agreement
- Both the scenarios with and without the agreement must account for likely events
- The potential entrant must not only have the ability to enter, but also the incentive (intention to enter proves an incentive)
- Threat of entry or actual entry must have effects on competition outcomes, unless there are many entrants that should be obvious most of the time

The *Servier* decision applied a similar framework of analysis. It argued that each of the generic companies that signed a pay-for-delay agreement with Servier, intended to enter and there were only very few alternative entrants so that their withdrawal from the competitive process had an effect on competition.

⁹ <https://www.ftc.gov/news-events/press-releases/2019/03/ftc-concludes-impax-entered-illegal-pay-delay-agreement>; emphasis added.

If one turns now to the *Servier* court ruling on restriction by effect,¹⁰ the General Court stated that it is not enough to find that the elimination of a potential competitor is likely to have anticompetitive effects, but that the Commission should prove actual effects (*Servier* GC, paras. 1092, 1128). The General Court considers that while *Servier*'s market power and the absence or scarcity of sources of competition may confirm the existence of restrictive effects, this is not sufficient to make likely and concrete the effects of an agreement hindering a competitive threat (*Servier* GC, para. 1180). In particular, in the counterfactual scenario, the Commission should: (i) prove that the potential entrant would likely have entered the market in the absence of the agreement (*Servier* GC, para. 1169) in view notably of events that took place after the conclusion of the agreement and the evolution of its perception of the validity of the patent (*Servier* GC, para. 1170), notably that it would have entered before generic entry actually occurred (*Servier* GC, para. 1203); and (ii) explain what likely effects the potential entrant competitive threat would have had on *Servier*, notably on prices, quantities, quality, diversity of products or innovation, in the absence of the agreement (*Servier* GC, para. 1179).

The test applied by the General Court in *Servier* resembles the one discussed above, but has two important points of tension. First, the GC considers that factual developments that took place after signing the pay-for-delay agreement should be considered. As discussed, this flies in the face of legal certainty and may increase the incentives to behave illegally. Second, the GC calls for proof of likely entry. Likely entry is not the same thing as likely effects. That goes beyond the incentive to enter. It would mean that the Commission would have to prove that generic company is likely to win the patent litigation. This leads to a confusion of powers, asking the Commission to second-guess what a specialized patent court would have said in cases where no court decision would have taken place, because of the pay for delay agreement. Alternatively, when there would have been a court decision, we are back to the first point of tension and the issue of legal certainty.

IV. CONCLUSION

Pay for delay cases raise interesting issues on what consists of a potential competitor and how to assess effects. As in many markets, uncertainty is the hallmark of competition in these cases and what makes the assessment challenging. Both competition authorities and the courts should acknowledge uncertainty, not ignore it nor use *ex post facto* developments to solve it. Specifically, there are lessons to be learned and applied to the digital economy, where one of the main concerns is how to preserve the ability of potential competitors to develop into rivals to the incumbent platforms, while there is very high uncertainty on how they will develop.

¹⁰ The General Court decision is in French, the translation in English is mine.



TO SETTLE OR NOT TO SETTLE? AN ANALYSIS OF THE *SERVIER* PATENT SETTLEMENT CASE AND ITS PRACTICAL IMPLICATIONS

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I. INTRODUCTION

Investigations into patent settlement agreements are still fairly new in the European Union. The European Commission (“Commission”) adopted the Final Report of its inquiry into the pharmaceutical sector in July 2009. Since then, it has published eight reports on the monitoring of patent settlement agreements, and has adopted two infringement decisions (with a third investigation still ongoing). Each of the decisions was appealed and led to a judgment by the General Court (“GC”).

The most recent development is the GC’s judgment in the *Servier* case.² This case is particularly noteworthy because (i) the GC refuted the Commission’s assessment of the product market definition and hence the dominance abuse under Article 102 of the Treaty on the Functioning of the European Union (“TFEU”), which marks the first annulment in many years;³ and (ii) the Commission’s finding that the settlement agreement between Servier and the generic company, Krka, infringed Article 101 TFEU. On the other hand, the GC agreed with the Commission that the agreements between Servier and the other generic companies each restricted competition “by object”. The GC’s analysis in that context raises fundamental questions about the interplay between competition law and intellectual property rights (“IPRs”).

This article reviews the key takeaways from, and the possible implications of, the *Servier* case for the pharmaceutical industry. It focuses in particular on some of the key issues from an IP and regulatory perspective. The GC’s ruling is not final yet as the Commission and all the parties have appealed the findings to the Court of Justice (“CJEU”).⁴ Two other cases are currently pending before the CJEU: the *Lundbeck* case⁵ and a referral from the UK Competition Appeal Tribunal in the *Paroxetine* case.⁶ Although they all involve patent settlement agreements concluded between originator and generic companies, each of these cases presents its own specificities, and parallels can only be drawn to a limited extent.

II. THE FACTUAL BACKGROUND AND CONTEXT OF THE *SERVIER* CASE

On July 9, 2014, the Commission fined Servier and five generic companies (Niche, Matrix, Teva, Krka, and Lupin) for having entered into patent settlement agreements that allegedly violated Article 101 TFEU.⁷ According to the Commission, each of the agreements restricted competition “by object” because they included a value transfer from Servier to the generic company, which allegedly induced the generic companies to settle and refrain from entering the market for a determined period. The Commission also found that the settlement agreements restricted competition “by effect”. The agreements related to perindopril, Servier’s angiotensin-converting-enzyme (“ACE”) inhibitor, used to treat hypertension and heart failure.

In addition, the Commission held that Servier abused a dominant position in violation of Article 102 TFEU through the combination of the patent settlements and the acquisition of an upstream process technology to produce the active pharmaceutical ingredient (“API”) for perindopril, which according to the Commission was non-infringing.

The Commission alleged that Servier put in place an overall strategy that was aimed at excluding its generic competitors and/or delaying their entry into the market. The Commission defined the relevant product market downstream very narrowly, limiting it to the perindopril molecule despite the fact that the therapeutic class of ACE inhibitors included 16 similar molecules, all treating the same therapeutic indication. As a result, it found that Servier was dominant on that market. The Commission also found Servier dominant on the upstream market for the process technology.

Servier (and each of the generic companies) appealed the Commission’s decision (“Decision”) in its entirety. On 12 December 2018, the GC upheld the Decision as to the illegality of the patent settlement agreements, except for the agreement between Servier and Krka, where the GC ruled that it did not restrict competition “by object” and “by effect.” It annulled the Decision in so far as it relates to the product market definition and dominance finding. Servier’s total fine was reduced from €331 million to €228 million.

² Case T-691/14, *Servier and Others v. Commission*, EU:T:2018:922.

³ The last full annulment of an Article 102 TFEU decision on the merits was 15 years ago in the *Atlantic Container* collective dominance case: Joined Cases T-191/98 and T-212/98 to T-214/98, EU:T:2003:245.

⁴ Cases C-201/19 P, *Servier and Others v. Commission*; C-176/19 P, *Commission v. Servier and Others*; C-198/19 P, *Teva UK and Others v. Commission*; C-151/19 P, *Commission v. Krka*; C-144/19 P, *Lupin v. Commission*; C-164/19 P, *Niche Generics v. Commission*; C-166/19 P, *Unichem Laboratories v. Commission*; C-197/19 P, *Mylan Laboratories and Mylan v. Commission*.

⁵ Case C-591/16 P, *Lundbeck v. Commission*.

⁶ Case C-307/18, *Generics (UK) and Others*.

⁷ Case AT.39612, *Perindopril (Servier)*.

III. THE COMPETITION LAW ASSESSMENT OF PATENT SETTLEMENT AGREEMENTS

A. The Legal Test

The GC confirmed the Commission's overall test pursuant to which a patent settlement agreement will restrict competition "by object" if (i) it is concluded between an originator and a generic company that qualifies as a potential competitor; (ii) the originator company makes a value transfer (generally a payment) to the generic company; and (iii) that transfer is made in return for the latter's commitment not to challenge the validity of the underlying patent (non-challenge clause) and/or not to commercialize the generic product (non-commercialization clause).⁸

B. The Role of IPRs

The *Servier* case took place within a particular factual context. The compound patent for perindopril had been filed with the European Patent Office ("EPO") in 1981 and, following the grant of supplementary protection certificates in most Member States, patent protection expired in 2003. However, at the time of the agreements, several process patents were still in place, including patent EP1296947 ("947 patent"), which was at the heart of the dispute and concerned the alpha crystalline form of the perindopril erbumine salt and the process for its preparation.

In a context where the compound patent has expired but several other patents (e.g. process, formulation, *etc.*) remain in place, generic companies that would like to enter the market have several options. They can seek a declaration of non-infringement, file an action of invalidity, or enter "at risk," i.e. launch the product without "clearing the way".⁹ If the originator company brings an infringement action, the generic company can also counterclaim the invalidity of the patent(s). It should be noted that the burden of establishing the invalidity of a patent is not easy. The originator company, on the other hand, can obtain an injunction if there is a sufficiently serious threat that the generic company will enter the market with an infringing product. In the *Servier* case, litigation was ongoing with each of the generic companies, involving the 947 patent but also several of Servier's other process patents. At the time the agreements were concluded, none of the cases had resulted in a final ruling on the merits by a national court; Servier's 947 patent was, however, successfully upheld by the EPO in the first instance. In addition, Servier was successful in a summary invalidity action brought by one of the generic companies (Krka) and was also granted a number of preliminary injunctions against generic companies by the English Patent Court.

The GC acknowledged the importance of IPRs and the value of settlements. It also recognized the presumption of validity of granted patents. However, the GC appears to have taken the position that competition law rules should prevail over IPRs, in this case patent rights. Neither the CJEU jurisprudence nor any rule of law requires that such a preference be given to one set of rules over the other. On the contrary, the CJEU has consistently emphasized the importance of protecting IPRs¹⁰ and the crucial importance to balance competition law and IPRs. This balance is particularly relevant as both serve a common goal, namely promoting consumer welfare.

C. What is Meant by "Potential Competition"

The GC considered that, in order to establish that the generic companies qualified as potential competitors, the Commission had to show that the generic companies had "real and concrete possibilities" to enter the market. In the GC's view, it was sufficient for that purpose that the Commission showed that the generic companies had taken steps and invested in the development, manufacturing, and commercialization of a generic form of perindopril. To rebut the Commission's case, the GC said that the innovative company (i.e. Servier) had to demonstrate that the generic companies were faced with "insurmountable obstacles," preventing them from entering the market.

The GC's analysis is problematic for several reasons, some of which are developed below.

⁸ It is interesting to note that in the *Lundbeck* case, the GC took a number of "additional factors" into account, including: the fact that the value transfer by Lundbeck to the generic companies was allegedly based upon each generic company's expected profit had it entered the market; the fact that none of the agreements contained a commitment by Lundbeck to refrain from infringement proceedings against any of the generic companies after the agreements had expired; and that the agreements did not in fact settle any patent dispute. The GC also held that the commitments by the generic companies went beyond the scope of the contested process patents and thus beyond what Lundbeck could have obtained by successfully litigating.

⁹ Which consists in resolving any patent issues before entering the market either by applying for a revocation of the patents concerned or seeking a declaration of non-infringement regarding the product the generic company intends to launch.

¹⁰ See e.g. Case C-170/13, *Huawei v. ZTE*, EU:C:2014:2391.

First, the GC imposes an impossible task on the innovative company given that e.g. the generic application for a marketing authorization is not a public document which can be accessed by third parties and it is therefore impossible for a third party, such as Servier in this case, to know the details of the difficulties faced by a generic company in the application process.

Further, the GC considered that the mere existence of a patent was not an “insurmountable obstacle” to entry because the generic companies could have entered “at risk”. The GC disregards the scope of patent protection, which provides the patent owner the right to stop any infringing product falling within the scope of the patent from being commercialized in the protected jurisdiction (see e.g. the Agreement on Trade-Related Aspects of Intellectual Property Rights and Directive 2004/48/EC on the enforcement of IPRs).

The GC also disregarded the value to originator companies of obtaining a preliminary injunction or judgment at first instance upholding the validity of the patent. According to the GC, an injunction is temporary and first instance judgments can be overruled on appeal and are therefore not final. Neither one of them therefore rules out generic competition. However, an injunction or a judgment at first instance should be sufficient evidence that the patent concerned is an obstacle to entry for generic companies. Injunctions are a fundamental part of the patent enforcement system. By not recognizing their value, the GC seems to suggest that damages should be the only appropriate remedy for patent infringements. Moreover, if only a final judgment on the merits can rule out generic competition, this would put an impossible burden of proof on the companies given that the whole purpose of a settlement is to end a dispute before a final ruling is issued.

In the *Servier* case, the GC also agreed with the Commission that the technical, regulatory and/or financial barriers to entry that the generic companies were facing did not prevent them from being potential competitors of Servier. The perceptions of the generic companies on the likely outcome of the litigation were only an indication of their intention, not their ability, to enter the market.

D. On the Restriction of Competition “by object”

The GC recognized that non-challenge and non-commercialization clauses included in a settlement agreement can be justified. This is good news, as such clauses are indispensable for the settlement of any patent dispute. Indeed, no company would consider settling a dispute regarding the validity/infringement of a patent if the day after the settlement one party could re-commence legal proceedings invoking the same claims and counterclaims of invalidity/infringement as were settled.

According to the GC, a settlement agreement becomes problematic if it includes a reverse payment inducing the generic company to accept such clauses and limit its efforts to enter the market. It is in that case the inducement, rather than the recognition by the generic company of the validity of the litigious patent, that constitutes the real reason for the restrictions in the agreement. A patent settlement agreement that fulfils these criteria will qualify as a market exclusion agreement, and thereby a “by object” restriction of competition.

On that basis, the GC found that the agreements concluded between Servier and the generic companies (except Krka) infringed Article 101 TFEU. The GC considered that it did not have to examine whether the agreements also restricted competition “by effect”.

The GC’s qualification of the agreements in the *Servier* case as “by object” restrictions also raises a number of concerns. This article will not cover them all, but focuses on a few IP and regulatory aspects.

First, as underlined by Advocate General Nils Wahl in the *Cartes bancaires* case,¹¹ only conduct whose harmful nature is proven and easily identifiable, in the light of experience and economics, should be regarded as a restriction of competition “by object,” and not agreements which, having regard to their context, have ambivalent effects on the market. Patent settlement agreements have no such harmful nature and are fundamentally different from market sharing agreements concluded e.g. in the *BIDS* case,¹² which did not concern IPRs. Although, as previously explained, the GC recognized the presumption of validity of the patents, it did not seem to recognize the value of such patents and the specific context for each of the agreements. Patent settlements, however, are inherently complex and cannot be analyzed in the same way as cartel agreements. The CJEU has explicitly clarified that restrictions “by object” should be reserved to agreements that are inherently harmful to competition.¹³ Out-of-court settlements of patent disputes, which should generally be encouraged, are not inherently anticompetitive and should therefore be subject to a “by effects” analysis.

¹¹ See Opinion of Advocate General Wahl delivered on March 27, 2014 in Case C-67/13 P *CB v. Commission*, EU:C:2014:1958.

¹² See Case C-209/07, *Beef Industry Development and Barry Brothers*, EU:C:2008:643.

¹³ See Case C-67/13 P, *CB v. Commission*, EU:C:2014:2204.

Second, the GC did not recognize the importance for the generic companies of being among the first wave of entrants on the market on the one hand, and the consequences of generic entry for the patent holder on the other. For the generic, it is important to be the first in this situation, or among the first wave of those entering the market, in order to secure a large slice of the initial profit. If the generic company is not within the first wave of entrants (e.g. because it faces regulatory issues), there is little value for it in entering the market afterwards, as competition will have driven prices to the lowest figure capable of covering costs, and thus to a low profit. As a result, the possibility of a “super profit”, available to the generic companies that are part of the first wave of market entries, will be gone. A patent settlement agreement between an originator and a generic company cannot be assessed without taking these factors into account. For example, a generic company that realizes that, for some reason e.g. regulatory difficulties, it will not be able to enter the market on time (namely with the “first wave” of generics), may be inclined to settle rather than continue litigation. It seems odd to prevent such company, once it has decided to settle for its own reasons, from negotiating the best deal possible with the originator (e.g. by negotiating the best possible payment).

Third, other factors such as bifurcation, which exists in many EU Member States and pursuant to which the infringement/invalidity claims of a patent can be subject to different procedures, creating a risk that litigation lasts for a long time and occurs simultaneously in various jurisdictions; or the cost of having to pursue proceedings against several parties and/or across different jurisdictions and the uncertainty of their outcome, have to be taken into account when assessing the context of, and rationale behind, patent settlements.

Fourth, the settlement of one litigation proceeding may have little effect on competition if several parallel litigations are ongoing. For example, if a settlement results neither in delaying generic entry nor in delaying the resolution of the legal proceedings challenging the validity of the patent, it seems rather excessive to characterize it as restriction “by object” simply because it includes a payment. In other words, the context matters as much as the terms of the settlement.

E. The Value Transfer

Despite the above, not all patent settlement agreements including a payment will necessarily be problematic. Indeed, patent settlements *per se* are not an issue, and the GC highlighted that value transfers need to be looked at carefully. According to the GC, a value transfer that covers costs inherent to the litigation is unlikely to be considered an incentive to delay market entry. The GC also clarified that other payments could be legitimate, although it will be up to the parties to show that such costs were inherent to the settlement of the litigation and justify the amounts in question. Although we cannot enter into the specificities of the *Servier* case in this article as the case is under appeal, in assessing whether a value transfer is justified one should look at many factors, including the commercial context surrounding the settlement agreement. For example, considerations such as the desire to avoid costly and time-consuming litigation in multiple jurisdictions, or the purchase of patents, or even to secure a generic distributor in a particular jurisdiction should be considered. The determination of the impact of the value transfer should thus be made on a case by case basis, taking into account all relevant elements which could justify its amount.

Moreover, an amount that is insignificant will not give rise to an inducement not to enter the market and will likely be acceptable, even if not inherent to the litigation.

F. The Krka Agreement

The GC considered that certain agreements will not give rise to a suspicion of a restriction of competition “by object”. This is the case for example where a settlement agreement is accompanied by a license agreement concluded at market conditions and is based on the recognition, by the generic company, of the validity of the patent. Such an agreement will likely escape competition law scrutiny.

On that basis, the GC found that the agreement between Servier and Krka, pursuant to which Krka received a license on the litigious patent in seven European countries, could not be characterized as an illegal market sharing agreement restricting competition “by object”. The GC found that the royalty paid by Krka under the license agreement was consistent with market value and therefore did not consist in a reverse payment. Further, the settlement agreement with Krka was concluded after the EPO had upheld the validity of the relevant patent and the granting of an injunction against Krka by the High Court in the UK. The GC found that this context was a key consideration for Krka to decide to settle, i.e. that the settlement was reached on the basis of the strength of the patent.

The agreement with Krka is also the only one that was subject to a “by effects” analysis by the GC. In its analysis, the GC found that the Commission did not prove that Krka would likely have entered the market earlier with its own generic product, in absence of the agreement. The GC’s test is consistent with previous case law.¹⁴

¹⁴ Case C-382/12 P, *MasterCard v. Commission*, EU:C:2014:2201.

The GC rejected the Commission's theory that the fact that Krka was removed as a competitive threat was in itself sufficient to establish appreciable effects on competition, absent any proof of effects on parameter of competition such as price, quantities, quality, and innovation. It was moreover not established by the Commission that Krka's continuation of the proceedings against the 947 patent would probably, or plausibly, have allowed a faster or more complete invalidation of the patent, given that the challenge of the 947 patent was continued in the UK by Apotex and before the EPO by several other challengers.

IV. THE ANALYSIS OF RELEVANT PRODUCT MARKET UNDER ARTICLE 102 TFEU

The GC considered that the Commission's definition of the relevant market contained several errors. Most notably, when analyzing the competitive constraints on perindopril, the Commission did not sufficiently assess the substitutability of perindopril and other ACE inhibitors in terms of their therapeutic use, underestimated the propensity of patients treated with perindopril to be switched to another ACE inhibitor, and gave too much importance to the price factor.

A. The Importance of Therapeutic Substitutability

The GC disagreed with the Commission's emphasis on price analysis. The Commission concluded that the market should be defined narrowly, and be limited to perindopril in its originator and generic versions, because the different ACE inhibitors did not impact the price of perindopril. According to the Commission, because sales of perindopril were more significantly affected by the entry of the perindopril generic than by the entry of generics of other ACE inhibitors, other ACE inhibitors did not exercise competitive pressure on perindopril.

The GC, on the other hand, considered that all the ACE inhibitors belonging to the same class were substitutable; and that perindopril was subject to competitive pressure from "qualitative" factors other than price, e.g. the promotional efforts by manufacturers of other ACE inhibitors; or the fact that doctors do not usually make prescription decisions primarily based on price but based on therapeutic differences, as well as the patient's profile. The GC's analysis is in line with previous case law.¹⁵

The GC emphasized that when analyzing competition between medicinal products in the pharmaceutical sector it is crucial to take qualitative, i.e. non-price competitive factors, in particular therapeutic effectiveness, into account. Markets must thus be defined following a global analysis, including price and non-price factors.

B. Doctors' Prescribing Behavior

The GC considered that the Commission erred when assessing doctors' tendency to switch patients treated with perindopril to other medicines.

The Commission had found that perindopril was in a market of its own because of doctors' reluctance to switch patients to different medicines. The GC disagreed and held, based on the evidence before it, that such a theory was not established and that the Commission's assessment of the evidence relating to the marketing of perindopril was erroneous. Moreover, the GC considered that the fact that Servier made substantial investments to market perindopril and tried to differentiate it from other ACE inhibitors was a relevant factor showing that perindopril did compete with these other medicines.

In addition, according to the GC, the medical studies, recommendations from international organizations (e.g. the World Health Organisation), surveys of prescribing physicians, responses from producers of other ACE inhibitors, and expert statements, did not prove that there were significant therapeutic differences between ACE inhibitors.

The GC annulled the Commission's product market definition which limited the relevant market to the perindopril molecule only. As a result, it also annulled the Commission's finding that Servier was dominant on the product market as defined in France, the Netherlands, Poland and the UK. The definition of the relevant API technology market (which was based on the product market) was also annulled, and so was the part of the fine imposed on Servier relating to the infringement of Article 102 TFEU.

¹⁵ E.g. Case T-321/05, *AstraZeneca v. Commission*, EU:T:2010:266.

It is noteworthy in this context that the GC carried out a detailed and thorough review of the vast evidence before it. In the end, it conducted a full judicial review of the Commission's market definition and dominance assessment. This shows the importance of internal documents and evidence in proceedings before the GC. Whereas the Commission is increasingly requesting large amounts of documents from companies during investigations and heavily relies on internal company documents to establish its theories of harm, the *Servier* case shows that such documents and scientific evidence are equally important for companies' defense.

V. CONCLUSION

With appeals pending before the CJEU, the final word has not been spoken just yet. In particular, it will be interesting to see how the CJEU, which has always been the protector of IPRs, will strike the balance between such rights and competition law. In addition to the CJEU's judgment in the *Servier* case, the rulings in the *Lundbeck* and *Paroxetine* cases may also provide further clarifications. During the hearing in the *Lundbeck* case on 24 January 2019, it was clear that the CJEU is carefully considering how to assess patent settlement agreements and where to draw the line between legal and illegal agreements.



THE COMMISSION'S PAPER ON THE OBLIGATION OF CONTINUOUS SUPPLY OF MEDICINES AND ITS IMPACT ON PARALLEL EXPORTING ACTIVITIES IN THE EU: A PARADIGM SHIFT?

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I. INTRODUCTION

On May 25, 2018, the Commission held an *ad hoc* meeting with experts from Member States to discuss the problem of medicine shortages in the European Union (“EU”). The outcome of this meeting was a Paper by the Commission on how the obligation of continuous supply established in Directive 2001/83/EC can be used to tackle the problem of shortages of medicine at the national level.² In this paper, I discuss the key content of the obligation of continuous supply, in light of the Commission’s Paper from May 2018, and outline the potentially far-reaching spill-over effects that the Commission’s initiative might have in terms of parallel trade and relations between marketing authorization holders and their wholesale distributors.

II. PARALLEL TRADE OF PHARMACEUTICAL PRODUCTS AND EU COMPETITION LAW

Parallel trade of pharmaceutical products can be broadly described as the buying of medicine in a (lower-cost) Member State, and then reselling them in a different Member State at a higher price, thus taking advantage of the price difference between the two Member States. This price arbitrage is enabled by Member States’ regulatory powers over the pharmaceutical sector, which sets it apart from most other traded goods industries.³ As summarized by Advocate General Jacobs in *Syfait*, Member States often limit the prices payable for pharmaceutical products within their national territories with the aim of protecting social insurance budgets. Notwithstanding, some Member States are willing to let pharmaceutical products sell at a higher price than the one charged in other Member States, in what appears to be a recognition of the need to compensate pharmaceutical companies for their research and development (R&D) investments, which are not adequately remunerated by ‘low-cost’ Member States.⁴

The Commission has long considered restrictions to parallel trade of medicine to constitute a serious breach of the competition rules, an approach that is heavily influenced by internal market considerations.⁵ In a nutshell, the Commission finds that: (i) the free movement of products could be frustrated should companies be allowed to erect artificial barriers along national borders; and that (ii) there is no evidence backing the industry’s claim that price discrimination between different Member States is decisive for boosting R&D in the industry.⁶

This view has been partially confirmed by the Court of Justice of the European Union (“CJEU”) in *GSK*.⁷ In this case, the MAH had notified the Commission of a dual pricing system to wholesale distributors under which prices charged for pharmaceutical products destined to parallel exports were higher than those. The Commission considered such dual pricing mechanism to restrict competition by object and effect and therefore refused to grant an exemption under Article 101(3) of the Treaty on the Functioning of the European Union (“TFEU”). GSK appealed against the Commission’s refusal to grant an exemption, alleging an infringement of Article 101(3) TFEU. In its ruling, the General Court (“GC”) upheld GSK’s plea that the Commission had infringed Article 101(3) TFEU. According to the GC, the Commission had failed to take into consideration all the factual arguments and evidence submitted by GSK and to duly substantiate its conclusion that parallel trade did not result in efficiency losses for GSK, since it could not significantly alter its capacity to innovate and invest in R&D.⁸ Moreover, the GC states that the financial benefits stemming from parallel trading accrue to the parallel trader rather than to the health care system or the patient.⁹ For the GC, competition law is only concerned with the potential impact of parallel trade on the final consumer’s welfare; thus, wealth transfers between marketing authorization holders and distributors are of no interest to competition law, if they fail to bring a significant added value for the final consumer.¹⁰

2 European Commission, Directorate-General for Health and Food Safety, “Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018.”

3 Opinion of Advocate General Jacobs in Case C-53/03, *Syfait*, para. 77.

4 *Ibid.* para. 78.

5 MEMO/08/567, Brussels, September 16, 2008, Antitrust: Commission welcomes Court decision on parallel trade in the pharmaceutical sector.

6 Nadia De Souza, Directorate-General for Competition, unit B-2, Competition in Pharmaceuticals: The Challenges Ahead Post AstraZeneca, Competition Policy Newsletter I, 39 (2007).

7 Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GSK*, para. 60.

8 Case T-168/01, *GSK*, para. 303.

9 *Ibid.* *GSK*, para. 135 (quoting the Commission’s Communication COM(1998) 588 final of November 25, 1999 on the single market in pharmaceuticals, Recital 161).

10 *Ibid.* *GSK*, para. 273.

Following an appeal by the Commission against the GC's ruling, the CJEU ruled that an agreement intended to limit parallel trade should, in principle, be considered to be a restriction of competition by object even though it can, theoretically, benefit from an exemption pursuant to Article 101(3) TFEU, taking into consideration the nature and specific features of the sector.¹¹ However, the Court found that the GC had erred in law by demanding the Commission to prove that the agreement between GSK and its distributors is disadvantageous for final consumers, as a pre-condition for a finding of an object restriction.¹² Hence, the CJEU brushed aside the General Court's considerations that dual pricing systems limiting parallel trading should be assessed as restrictions by effect that mitigated or eliminated some of the inefficiencies of parallel trading, and that had a limited (or non-existent) impact on consumers' welfare.

The CJEU also had the opportunity to assess restrictions to parallel trading imposed by marketing authorization holders in light of Article 102 TFEU. In *Sot. Lélos kai Sia* the CJEU was asked whether a dominant company's refusal to meet orders sent by distributors, because the latter were involved in parallel trade, constituted an abuse of dominance or whether it could be justified on efficiency grounds. According to the Court, a dominant company's refusal to supply wholesalers with the purpose of impeding parallel trade constitutes an abuse of a dominant market position, unless justified by objective reasons. However, a Member State's intervention in fixing the prices for pharmaceuticals at the national level cannot, in itself, be regarded as constituting an objective justification for restricting parallel trade.¹³ To reach this conclusion, the Court focused on parallel trade impact on importing countries, claiming that distributors are not the only ones benefiting from this practice. Because parallel trade opens up new alternative sources of supply for buyers in importing countries, it should also be regarded as welfare-enhancing for final consumers in such countries.¹⁴ In the Court's view, such an increase in welfare for final consumers is the result of a downward price pressure created by parallel trade, which creates benefits for social health insurance funds and patients, who will pay a smaller proportion of the prices of pharmaceutical products.¹⁵

The CJEU assessment of parallel trade was, however, mitigated by two important aspects: First, the Court found that marketing authorization holders must be allowed to protect their own commercial interests when confronted with orders that are out of the ordinary in terms of quantity (a criterion that is to be assessed by the national courts). In fact, a market authorization holder cannot be put in a position where the only alternative at its disposal to limit parallel trade is to simply not supply lower price Member States.¹⁶ Second, the Court adamantly recognized Member States' right to take appropriate and proportionate steps to resolve a situation "where parallel trade would effectively lead to a shortage of medicines on a given national market," as long as those steps are consistent with the obligation enshrined in Article 81 of Directive 2001/83 to ensure a continuous supply of pharmaceuticals.¹⁷

This shift in approach to parallel trade reached its pinnacle when the Commission announced on May 17, 2018 the closing of infringement procedures against Poland, Romania, and Slovakia for imposing restrictions on parallel trade. In its press release, the Commission began by reaffirming the lawfulness of parallel trade under EU law. However, the Commission emphasized that Member States may also lawfully impose restrictions on parallel trade, "as long as the measures are justified, reasonable, and proportionate to ensure a legitimate public interest. For example, to ensure an adequate and continuous supply of pharmaceuticals to the population."¹⁸ In this regard, the Commission explicitly acknowledged that parallel trade may in fact represent a critical factor influencing the occurrence of medicine shortages. Furthermore, the Commission explicitly acknowledged that several Member States have been plagued in recent years by a lack of an appropriate and continued supply of medicinal products to pharmacies, resulting in a grave impact on the treatment of patients.¹⁹

11 Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GSK*, paras. 102 and 103.

12 *Ibid.* *GSK*, para. 64.

13 *Ibid.* para. 67.

14 *Ibid.* para. 53.

15 *Ibid.* para. 56.

16 *Ibid.* para. 68.

17 *Ibid.* para. 75.

18 European Commission Press Release - Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia, May 17, 2018.

19 *Ibid.*: "After careful assessment, the Commission has concluded on the need to look for other ways than infringements to adequately solve this complex situation in order to swiftly and efficiently deal with an issue that might have negative impact on the health of European citizens."

III. DIRECTIVE 2001/83/EC AND THE REGULATORY OBLIGATION OF CONTINUOUS SUPPLY OF MEDICINES

Shortly after announcing the closing of several parallel trade infringement procedure cases, the Commission published a Paper on the obligation of continuous supply to tackle the problem of shortages of medicine.²⁰ The Commission's Paper essentially tries to flesh-out the content of the obligation to ensure a continuous supply of the domestic market, which is enshrined in Articles 81 and 23a of Directive 2001/83/EC.²¹

Pursuant to Article 81, marketing authorization holders and wholesale distributors of medicine products placed on a Member State's market must ensure appropriate and continued supplies to pharmacies, and other persons authorized to supply medicinal products, so that the needs of patients in the Member State in question are covered. Additionally, Article 23a establishes that marketing authorization holders must notify the national competent authority at least two months before a product is removed from a Member State's market (either temporarily or permanently).

Building upon these two provisions, the Commission's Paper clarifies that marketing authorization holders must supply distributors (including so-called full-liners, which distribute the total range of medicines), and persons entitled to supply medicines to the public "sufficiently in advance and in adequate quantities to cover demand from patients in a Member State."²² Distributors, on the other hand, are under the obligation of ensuring a continuous supply to pharmacists and, other persons entitled to supply the public, in order to cover the needs of the patients on the territory where the distributor is established. Most importantly, the Paper highlights that distributors can only supply other distributors provided this does not impact their ability to meet the public service obligation ("PSO") of ensuring a continuous supply to the pharmacies and other persons entitled to supply to the public in the geographic area under their responsibility.²³ Thus, the Commission's Paper makes it abundantly clear that the obligation of continuous supply applies both to marketing authorization holders and distributors alike, even though Directive 2001/83/EC appears to state that only (full-line) distributors are subject to PSOs (PSO is the "obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.")²⁴

It should be noted that the legislation of most Member States does not differentiate between different categories of distributors for the purpose of applying the obligation of continuous supply. The replies provided by Member States to the Commission's questionnaire launched in 2017, which underpinned the May 2018 Paper, show that only Belgium, Germany, and France distinguish between two categories of distributors: (i) full-liners, which are linked to PSOs, and (ii) all other distributors (not subject to the obligation of continuous supply). The only other exception seems to be Slovenia, which distinguishes between full-line, contact-line, and short-line distributors. When a distributor is subject to the obligation of continuous supply, national legislation may impose a duty upon marketing authorization holders to supply distributors so that the latter "guarantee a demand-oriented and continuous supply to the pharmacies with which they do business."²⁵ This means that full-liner distributors subject to PSOs may not be required to proactively search for alternative ways of supply.²⁶ Furthermore, certain Member States have strengthened the obligation of continuous supply with the right of distributors to request marketing authorization holders for a supply corresponding to the distributor's market share.²⁷

20 This Paper follows-up on the responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, which are summarized in the PPT by Agnès Mathieu-Mendes: https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd03_en.pdf.

21 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

22 Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018, p. 1.

23 Paper on the obligation of continuous supply to tackle the problem of shortages of medicines – Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018, p. 2.

24 Article 1(18).

25 This is the case of Germany: see European Commission, Health and Food Safety Directorate-General, Summary of Responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, p. 3.

26 E.g. Denmark: see European Commission, Health and Food Safety Directorate-General, Summary of Responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC, p. 4.

27 This is the case of Czech Republic.

In addition to the general obligation of continuous supply, marketing authorization holders must be especially vigilant as regards to products for which there are limited or no alternatives, because their manufacturing process depends on a single facility. This obligation for an additional vigilance/duty of care on the part of marketing authorization holders in ensuring a continuous and adequate supply of medicines also extends to those medicines where a discontinuation of supply could result in public health risks (e.g. critical or essential medicines such as vaccines and medicines for life threatening conditions). Because of the critical nature of certain medicines, Member States may ask holders of marketing authorizations to develop a shortage prevention plan, within the context of their obligation to ensure continuous supply. For instance, in Portugal, Infarmed (the Portuguese sector regulator) has published a notice containing a list of active pharmaceutical ingredients in relation to which the pharmacies must inform the authorities, within 48 hours, of any lack of access to medicines experienced.²⁸ This PSO should, however, be regarded as a secondary safeguard in relation to the more general obligation to ensure a continuous supply that applies both to marketing authorization holders and distributors.²⁹

One important consequence of the Commission's Paper has been the follow-on initiatives by national pharma regulators. For example, on January 8, 2019, Infarmed adopted a Notice that closely follows the Commission's Paper, and which appears to drastically change the regulatory approach to parallel trade. Prior to this Notice, holders of marketing authorizations and distributors were generally not held responsible for shortages in the Portuguese market, as this was considered to be a pure competition law issue. Furthermore, Infarmed had a practice of awarding a blank authorization to distributors, regardless of the geographic market supplied and of the applicability of PSOs. In reality, less than 2 percent of a universe comprising over 600 distributors in Portugal actually supply the Portuguese market and cater for patients in the national territory. Hence, the vast majority of distributors in Portugal have long been off the hook in terms of the applicability of the obligation to ensure supply.

Pursuant to Infarmed's 2019 Notice on the obligation of continuous supply, in order for the sale of medicines to operate seamlessly, it is paramount that the few distributors which actually serve the domestic market are supplied with the medicines necessary to face the pharmacies' demand. Due to the risks posed by a disruption in the supply of medicines, Infarmed stated that marketing authorization holders must supply all distributors that are under the obligation of supplying the Portuguese territory (either nationally or regionally). Thus, holders of marketing authorizations can neither justifiably refuse to supply a distributor subject to PSOs, nor put forward efficiency defenses that could underpin such a refusal. Essentially, Infarmed, by drawing a hierarchy topped by those who favor domestic sales, has imposed on marketing authorization holders the burden of effectively monitoring the destination of the medicines sold to their distributors.

IV. CONCLUSION

Possibly the most important and contentious element of the Commission's Paper on the obligation of continuous supply is that it clearly fleshes-out the relation of subsidiarity between domestic supplies and parallel exports. The Commission's explicit recognition that Member States are permitted to set broad PSOs to ensure a continuous supply of medicines deeply encroaches on the vertical relations between marketing authorization holders and distributors. While such relations were typically subject to competition rules embedded by Internal Market considerations, there has been a noticeable shift towards the strengthening of Member States' rights to regulate such relations and, consequently, discipline parallel trade. Although it is still too soon to ascertain the full impact of the Commission's Paper, some follow on initiatives are already taking place at the national level, with the regulator taking a more active role in disciplining vertical relations with a potential impact on security of supply.

The Commission's Paper does not elaborate on its implications in terms of competition law enforcement. In particular, it is unclear whether the Commission has fully reversed its classic approach to parallel trade cases under Articles 101(1) and 102 TFEU, or if it now applies Article 106(2) TFEU to the obligation of continuous supply and related PSOs, thus setting-aside the application of the competition law rules.³⁰ Should this be the case, it would dovetail with the CJEU ruling in *Sot. Lélos kai Sia*, which recognizes Member States' right to take appropriate and proportionate measures when parallel trade leads to a shortage of medicines.

²⁸ Infarmed Informative Notice number. 235/CD/8.1.6, of November 21, 2012.

²⁹ Infarmed, Informative Notice (Circular Informativa) N.º 012/CD/100.20.200, from January 8, 2019 on Duty to supply the market – responsibilities of the player involved in the medicine value chain (Obrigação de fornecimento do mercado – responsabilidades dos intervenientes no circuito do medicamento).

³⁰ Article 106(2) TFEU reads: "Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in the Treaties, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Union."

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