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When Does Sharing Make Sense?:
Antitrust & Risk Evaluation and Mitigation Strategies

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When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies

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I. INTRODUCTION

There exists a new front in the battle to define the precise circumstances under which a monopolist's refusal to deal with a rival constitutes exclusionary conduct that violates Section 2 of the Sherman Act. The latest clash arises in the context of a brand-name drug manufacturer's decision not to sell samples of a patented drug that is subject to certain government-mandated restricted distribution protocols to a potential generic rival seeking to use those samples to conduct bioequivalence testing necessary to develop a generic version of the product.[2] Without access to these pharmaceutical samples, the generic firm may be unable to develop, manufacture, and ultimately sell a generic version of the drug to consumers at a significantly lower price than the branded product.[3]

Against the compelling backdrop of a health care system afflicted by rapidly rising costs, some now argue that the antitrust laws should be used to force brand-name drug companies to share samples of their products with generic rivals to further competition and reduce the cost of prescription drugs.[4] Although significant ambiguity remains about the exact contours of "refusal-

[1] The author is an Attorney Advisor to Commissioner Joshua D. Wright of the Federal Trade Commission. Any views expressed in this article are his own and do not necessarily represent the views of the Commission or any Commissioner.

[2] Some also have argued that the Federal Trade Commission ("FTC") can prosecute such conduct as a standalone "unfair method of competition" under Section 5 of the FTC Act. *See, e.g.*, David Balto, *Can Antitrust Laws Prevent Abuse of FDA Risk Programs?*, LAW360 (Sept. 4, 2013), *available at* http://www.law360.com/articles/468192/can-antitrust-laws-prevent-abuse-of-fda-risk-programs. Although the precise boundaries of Section 5 remain unclear, it is well accepted that Section 5 should not be used to circumvent standards established by the federal courts to evaluate claims under Section 2 of the Sherman Act. *See* Boise Cascade Corp. v. FTC, 637 F.2d 573, 581-82 (9th Cir. 1980) (rejecting a Section 5 claim where there is "well-forged" case law under the traditional federal antitrust laws).

[3] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (finding early generic drugs are offered on average at a 20 to 30 percent discount to the branded products); Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-offs Cost Consumer Billions* 8 (2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (finding generic entry immediately benefits purchasers because of savings from lower drug prices).

[4] There have been at least four cases filed in federal court in the United States challenging such conduct. Mylan Pharm. Inc. v. Celgene Corp., No. 2:33-av-00001 (D. N.J. filed May 3, 2014); Lannett Co. Inc. v. Celgene Corp., No. 2:08-cv-03920 (E.D. Pa. filed Aug. 15, 2008); Accord Healthcare, Inc. v. Acorda Therapeutics, Inc., No. 0:13-cv-60742 (S.D. Fla. filed Apr. 1, 2013); Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D. N.J. filed Sept. 14, 2012). The FTC filed an *amicus* brief in *Actelion Pharmaceuticals Ltd.* opposing the defendant's motion for a

to-deal" law in the United States, it is unlikely that this problem can or should be remedied through the blunt instrument of the antitrust laws. A better approach might be to rely instead on existing regulatory tools that are better tailored to addressing potential problems arising in the pharmaceutical industry. Another option would be to seek Congressional action establishing an appropriate process for the development of generic versions of branded drugs with restricted distribution protocols.[5]

II. REGULATORY AND INDUSTRY BACKGROUND

The potential antitrust issue outlined above stems from the intersection of two aspects of the unique regulatory regime that overlays the pharmaceutical industry:

1. First, in order to ensure that a drug's benefits outweigh its risks, the Food & Drug Administration ("FDA") is authorized to mandate risk management programs known as Risk Evaluation and Mitigation Strategies ("REMS") for certain high-risk pharmaceuticals that raise significant safety concerns.[6] REMS can consist of a variety of safety measures beyond routine labeling requirements, including special training for prescribers and patients, patient monitoring, and restricted distribution through specific certified pharmacies. REMS programs therefore can prevent access to a drug through customary distribution channels, such as wholesale distributors.

   An example of a drug subject to a FDA-mandated REMS program is Thalomid. In the late 1950's and early 1960's, thalidomide was marketed and sold to pregnant women to relieve symptoms of morning sickness. Tragically, it was discovered later that thalidomide led to the death of thousands of children whose mothers had prolonged exposure to the drug during pregnancy, and caused serious birth defects in several thousands more.[7] As a result, the drug was withdrawn from the market. In 1998, the FDA approved thalidomide under the brand-name Thalomid to treat symptoms associated with leprosy and, in 2006, to treat multiple myeloma patients.[8] Significantly, the FDA approved Thalomid only on

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declaratory judgment. Without taking a position on the merits of the underlying case, the FTC asserted that a refusal by a branded manufacturer to sell samples to a generic drug company could, under certain specific circumstances, violate Section 2 of the Sherman Act. Brief for Fed. Trade Comm'n as Amicus Curiae, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D. N.J. Mar. 11, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

[5] For additional discussion about the the issues raised by the application of the antitrust laws to this scenario, *see* Darren S. Tucker, Gregory F. Wells & Margaret E. Sheer, *REMS: The Next Pharmaceutical Enforcement Priority*, 28 ANTITRUST 74 (2014).

[6] 21 U.S.C. § 355-1 (2012). For additional background on the FDA's authority to require REMS, *see* U.S. FOOD & DRUG ADMIN., *FDA Basics Webinar: A Brief Overview of REMS*, http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf.

[7] *See, e.g.*, *The Thalidomide Disaster*, TIME (Aug. 10, 1962).

[8] *See, e.g.*, Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, With Other Uses Seen*, NY TIMES (July 17, 1998), http://www.nytimes.com/1998/07/17/us/thalidomide-approved-to-treat-leprosy-with-other-uses-seen.html; Sheryl Gay Stolberg, *Thalidomide, Once Banned, Is in Demand*, NY TIMES (Nov. 28, 1997), http://www.nytimes.com/1997/11/28/us/thalidomide-once-banned-is-in-demand.html; Sheryl Gay Stolberg, *Thalidomide, Long Banned, Wins Support*, NY TIMES (Sept. 6, 1997), http://www.nytimes.com/1997/09/06/us/thalidomide-long-banned-wins-support.html.

the condition that the drug manufacturer would restrict the distribution of the drug and implement a REMS program to prevent the risk of embryo-fetal exposure.[9]

2. Second, under the Hatch-Waxman Act, generic drug manufacturers can obtain accelerated approval of a generic drug through an Abbreviated New Drug Application ("ANDA") by showing bioequivalence with the branded version of the product.[10] This process reduces the development costs for generic drugs and expedites generic drug approval by allowing generic manufacturers to rely on safety and efficacy studies conducted for the branded product. Significantly, in order to conduct the bioequivalence testing necessary to file an ANDA successfully, the generic drug manufacturer must acquire samples of the branded pharmaceutical.

A REMS program potentially can have significant implications for the ability of a generic manufacturer to develop a generic product, successfully file an ANDA, and introduce the generic product into the market. When a REMS prevents distribution of a drug through customary channels, a brand-name drug manufacturer's decision not to sell a limited quantity of the product directly to a potential generic rival may foreclose the only means for accessing the branded product and theoretically can thwart generic competition.

Recognizing this possibility, Congress granted the FDA the authority to ensure that REMS do not "block or delay approval" of an ANDA.[11] The FDA can enforce this provision through monetary penalties or by withdrawing the branded product from the market.[12] Furthermore, the FDA has the authority to craft procedures that would help make REMS-restricted drugs available to generic drug companies for bioequivalence testing.[13]

III. POTENTIAL ANTITURST IMPLICATIONS OF REMS

Some have asserted that a brand-name drug manufacturer's decision not to provide samples of a REMS-restricted drug to a generic firm so that the potential rival can develop a generic version of the drug represents an anticompetitive "refusal to deal" that violates Section 2 of the Sherman Act. However, the Supreme Court has long held that "the Sherman Act does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal," suggesting that such claims face significant obstacles.[14]

Indeed, although "the high value . . . placed on the right to refuse to deal with other firms does not mean that the right is unqualified," the antitrust laws only require firms with monopoly power to assist their rivals under very narrow circumstances.[15] The Supreme Court has been

[9] *See* U.S. FOOD & DRUG ADMIN., *Thalomid Risk Evaluation and Mitigation Strategy (REMS)* (Nov. 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222649.pdf.

[10] 21 U.S.C. § 355(j).

[11] 21 U.S.C. § 355(f)(8).

[12] 21 U.S.C. § 333(f)(4)(A).

[13] 21 U.S.C. § 355-1(f)(2), (g)(4).

[14] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (quoting United States v. Colgate & Co., 250 U.S. 300, 307 (1919)).

[15] *Id.* (quoting Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985)).

cautious in recognizing such circumstances "because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm."[16] Moreover, compelling firms to share "may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities" and "requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited."[17]

So when do the antitrust laws require a monopolist to assist a rival?

Many have read the Supreme Court's guidance in this area, and chiefly its decisions in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*[18] and *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko*,[19] as imposing a "prior course of dealing" requirement for any successful refusal to deal claim under Section 2. Under this approach, a firm cannot be held liable under the antitrust laws for refusing to deal unless it is first shown that the firm terminated a voluntary course of dealing with the rival. Many lower courts have endorsed this view, requiring plaintiffs to proffer evidence of a "prior course of dealing" to establish that a refusal to deal has the potential to violate Section 2.[20] Under this interpretation, a brand-name drug manufacturer's decision not to provide samples of a REMS-restricted drug to a potential generic rival would not violate Section 2 unless it could be shown that the branded firm terminated an existing supply contract for a REMS-restricted drug. This can be a very demanding requirement as there often may be no "prior course of dealing."

But as others have pointed out, a "prior course of dealing" requirement finds little actual support in either *Aspen Skiing* or *Trinko*.[21] Indeed, central to the Supreme Court's conclusion in *Trinko* that Verizon's refusal to share its telephone network with a local phone service competitor did not violate Section 2 was not the absence of a prior course of dealing, but rather the absence of more general evidence demonstrating that Verizon's conduct was "prompted not by competitive zeal but by anticompetitive malice."[22]

Although a "unilateral termination of a voluntary (and thus presumably profitable) course of dealing" can suggest a "willingness to forsake short term profits to achieve an anticompetitive end," and thus can shed light "upon the motivation of [a firm's] refusal to deal," a prior course of dealing is not the only means for identifying exclusionary conduct that violates Section 2. In fact, in *Otter Tail Power Co. v. United States*, an earlier "refusal to deal" decision that remains good law and is cited favorably by the Supreme Court in *Trinko*, the Supreme Court held

[16] *Id.*

[17] *Id.* at 407.

[18] 472 U.S. 585 (1985).

[19] 540 U.S. 398 (2004).

[20] *See, e.g.*, In re Elevator Antitrust Litig., 502 F.3d 47, 54 (2d Cir. 2007); Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 316 (3d Cir. 2007); Covad Commc'ns Co. v. BellSouth Corp., 374 F.3d 1044, 1049 (11th Cir. 2004).

[21] *See* Christy Sports, LLC v. Deer Valley Resort Co., 555 F.3d 1188 (10th Cir. 2009) ("The critical fact in *Aspen Skiing* was that there were no valid business reasons for the refusal."); Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50 (2012), *available at* http://www.wsgr.com/publications/PDFSearch/creighton-jacobson-fall12.pdf (arguing that a fair reading of the refusal to deal precedent does not compel a prior course of dealing requirement).

[22] *Trinko*, 540 U.S. at 409.

that the defendant's refusal to carry electricity produced by rival power companies over the defendant's power lines violated Section 2 despite the absence of a prior course of dealing because the defendant did so "solely to prevent municipal power systems from eroding its monopolistic position."[23]

The case law therefore suggests that the relevant inquiry for determining whether a refusal to deal is exclusionary conduct that violates Section 2 is not whether the defendant engaged in a "prior course of dealing" but instead whether the defendant's refusal can only be explained by its negative impact on the rival and the resulting harm to competition.[24]

Moreover, although a "prior course of dealing" screen might be easy to apply, and thus is attractive to practitioners seeking to offer clear guidance to clients and avoid fact-intensive inquiries requiring costly and lengthy litigation, the rule also has the very real potential to distort a firm's incentives away from welfare maximization.[25] For example, a "prior course of dealing" requirement may steer a firm away from a potentially profitable contract for fear that if it later decides to withdraw from the arrangement it might be exposed to antitrust liability. Indeed, cautious antitrust counsel may advise a brand-name drug manufacturer not to supply a REMS-restricted drug to a generic drug company—even if it is in the branded firm's interest—for fear that doing so may obligate the branded firm to provide all REMS-restricted drugs requested by the generic in the future.

A better approach to analyzing whether a brand-name drug manufacturer's refusal to supply REMS-restricted drugs to a generic drug company that wants to develop a generic alternative is to apply the "no economic sense" test.[26] Consistent with *Trinko*, *Aspen Skiing,* and *Otter Tail*, under this approach a refusal to deal could result in antitrust liability only in those rare circumstances where the sole justification for the refusal is the negative impact the conduct could have on the rival and the benefits conferred by eliminating competition. Although less of a bright line than the "prior course of dealing" requirement, the "no economic sense" test remains relatively easy to apply in a vast majority of cases and has the added benefit of better identifying refusals to deal that are likely to be anticompetitive while minimizing the risk to consumers associated with false positives.[27]

Even under the somewhat relaxed "no economic sense" approach, a challenge to a brand-name drug manufacturer's refusal to supply limited quantities of REMS-restricted drugs to a generic drug company would face significant obstacles. As the history of thalidomide demonstrates, REMS-restricted drugs carry an inherent and serious risk that—through either use or misuse—the drug may significantly harm individuals handling or taking the drug. If either the brand or generic product caused such harm, the branded firm likely would face significant

[23] Otter Tail Power Co. v. United States, 410 U.S. 366, 378 (1973).

[24] *See* Creighton & Jacobson, *supra* note 21, at 53.

[25] *Id.*

[26] For a detailed analysis of the benefits of the "no economic sense" test, *see* Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413 (2006).

[27] For a criticism of applying the "no economic sense" test to exclusive dealing cases under Section 2 of the Sherman Act, *see* Jonathan M. Jacobson & Scott A. Sher, *"No Economic Sense" Makes No Sense for Exclusive Dealing*, 73 ANTITRUST L. J. 779 (2006).

expenses in the form of regulatory costs, litigation costs, and harm to the branded firm's reputation. Under such circumstances, it is easy to imagine a brand-name drug manufacturer reasonably opting to forgo the relatively small profits earned from the sale of samples of REMS-restricted drugs in order to maintain exclusive control of the product and be able to limit the likelihood that the drug is used or misused in a way that causes harm.

This calculus likely holds true regardless of (i) how sophisticated the generic manufacturer is, (ii) whether the generic firm promises to indemnify the branded firm, or (iii) whether the FDA has blessed the sale of samples of the REMS-restricted products to the generic manufacturer. This is because, given the significant costs associated with an adverse event, the economic rationale for selling a limited quantity of drugs to a generic drug company (*i.e.*, the profits from the sale of the drugs) will almost always be dwarfed by the probabilistic value of harm even as the probability of harm approaches nearly zero.

It therefore appears that a brand-name drug manufacturer often will be able to present a legitimate business justification explaining why it has refused to supply a generic drug company with a limited supply of its REMS-restricted drug. As a result, even under the "no economic sense" test, it would seem that a branded firm's refusal to provide samples of REMS-restricted drugs to generic rivals ordinarily will not lead to antitrust liability under Section 2 of the Sherman Act. There of course may be exceptions to this more general result, and each case should be evaluated individually, but the antitrust laws do not appear to be the best avenue for furthering generic drug development of REMS-restricted drugs.

IV. CONCLUSION

It seems unlikely, whether analyzed for a "prior course of dealing" requirement or under the "no economic sense" test, that a brand-name drug manufacturer's refusal to sell samples of a REMS-restricted product to a potential generic rival that seeks to develop a generic alternative should constitute exclusionary conduct that violates Section 2 of the Sherman Act. A better approach than relying on the antitrust laws to solve the potential problem created by the unique regulatory framework that overlays the pharmaceutical industry, and a solution that finds support in *Trinko*, is to rely more heavily on the existing tools available to the FDA to help make REMS-restricted products accessible to interested generic companies.[28] Doing so would avoid turning the courts into regulators tasked with crafting and monitoring detailed supply contracts between branded and generic firms. Alternatively, Congress could step in to amend the current regulatory regime and create an appropriate process for encouraging generic development of REMS-restricted drugs.

[28] *Trinko*, 540 U.S. at 412 (holding that antitrust liability under Section 2 was not warranted, in part, because of "the existence of a regulatory structure designed to deter and remedy anticompetitive harm").

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Refusal to Deal Under FDA Imposed Risk Evaluation and Mitigation Strategies (REMS): Economic Considerations

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Refusal to Deal Under FDA Imposed Risk Evaluation and Mitigation Strategies (REMS): Economic Considerations

Robert Maness & Brian Segers[1]

I. INTRODUCTION

The Federal Trade Commission ("FTC"), as part of its ongoing enforcement of perceived anticompetitive abuse of the regulatory and legal structure in the pharmaceutical industry, has turned its gaze to branded pharmaceutical firms' refusal to sell samples of restricted distribution products to firms seeking approval to market generic versions.[2]

The types of restricted distribution arrangements that gave rise to these concerns are relatively new, dating from Food and Drug Administration Amendments Act of 2007 ("FDAAA"). The FDAAA granted the FDA powers to require branded firms to design and implement risk evaluation and mitigation strategies ("REMS") for drugs with potentially serious and significant side effects. REMS requirements include a virtual continuum of potential distribution restrictions including requirements to distribute medication guidelines to patients, monitoring and reporting of adverse events, communication plans to disseminate safety information to healthcare providers, certification and training of healthcare providers and pharmacies, and limited distribution to only registered cites of service.[3] The most severe restrictions include Elements to Assure Safe Use ("ETASU") and Implementation Systems.

REMS restrictions in one form or another became increasingly common in new drug approvals. However, more recently, the FDA has been reducing the number of products with REMS designations. There are currently 65 FDA approved individual REMS and an additional six shared system REMS.[4] While the number of REMS programs has been falling (142 drugs have been released from REMS programs), the severity of REMS restrictions has increased dramatically. Over half (40 of 71) of the existing REMS contains an ETASU requirement.[5] This is

[1] The authors are a Vice President and Associate Principal at Charles River Associates. The opinions expressed herein are those of the authors and do not necessarily reflect those of other individuals within Charles River Associates.

[2] Fed. Trade Comm'n Brief of Amicus Curiae, *Actelion Pharmaceuticals Ltd.*, No. 1:12-cv-05743 (D.N.J. March 13, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

[3] Doyle, et al., *REMS: The New Reality*, CAMPBELL ALLIANCE, http://www.campbellalliance.com/articles/campbell_alliance_REMS_article.pdf.

[4] http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm#information. Last accessed on April 23, 2014.

[5] *Id.*

a stark change from 2009, when nearly 75 percent of REMS programs required only medication guides.[6]

It is these highly restrictive ETASU and implementation system programs that have given rise to antitrust complaints. Highly restrictive REMS programs have resulted in situations where generic manufacturers have difficulty procuring sufficient quantities of samples for bioequivalence demonstration, as required under Hatch-Waxman. Generally, generic manufacturers have no difficulty obtaining samples of branded products through normal distribution channels. In the case of REMS programs with ETASU components, though, some generic firms have been unable to obtain samples through normal channels, such as drug wholesalers, and have requested samples from the branded manufacturers. Branded manufacturers have sometimes refused to provide these samples, citing REMS restrictions, and in at least three cases, generic firms have responded with Section 2 antitrust allegations alleging that the refusal to deal illegally prevents generic competition.[7]

The FTC joined the fray, filing an *Amicus* brief in one of these cases noting that the refusal to provide samples could be a violation of either Section 1 or Section 2 of the *Sherman Act*.[8] In summary, while the FTC acknowledges that the Hatch-Waxman Act sought to strike a balance between encouraging low-cost generic entry and protecting branded firms' incentives for continued innovation, the FTC has focused its attention on the potential for misuse of certain REMS programs to impede generic competition.

The FTC argues that a branded monopolist's refusal to sell drugs under REMS programs to rivals supports "a plausible theory of exclusionary conduct."[9] The FTC further asserts that, contrary to the branded manufacturers' position, anticompetitive refusal to deal does not require a prior course of dealing with competitors. The FTC instead focuses on a profit sacrifice test and essentially argues that because branded firms sell REMS restricted drugs at substantial profit, "refusal to sell to generic rivals may provide evidence of its willingness to sacrifice profitable sales in the short run in order to protect its long-term monopoly profits."[10]

In a companion piece to this one, Jan Rybnicek makes a similar argument that a prior course of dealing, while potentially relevant, is not the determinative factor in a refusal to deal inquiry.[11] Instead, he argues that a "no economic sense" test is a better approach to assessing whether a refusal to deal in the context of REMS restrictions is anticompetitive. In this paper, we discuss some of the economic factors that would come into play under such an approach. Those factors would include a balanced view of the costs and benefits of sharing samples with a generic firm—over and above the potential competition that such sharing could facilitate—as well as a

[6] Doyle, et al., *supra* note 3 at 4.

[7] Private antitrust actions have been brought against Celgene (2008) regarding Thalomid, against Actelion Pharmaceuticals (2012) regarding Tracleer, and against Accord Healthcare (2013) regarding Ampyra.

[8] Fed. Trade Comm'n Brief of Amicus Curiae, *Actelion Pharmaceuticals Ltd.*, No. 1:12-cv-05743 (D.N.J. March 13, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

[9] *Id.* at 9.

[10] *Id.* at 12.

[11] Jan Rybnicek, *When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies*, 4(2) CPI ANTITRUST CHRON. (April, 2014).

balanced view of the role of Hatch-Waxman and antitrust policy in the dynamic competition to develop new drugs.

II. THE DYNAMIC COMPETITION TO DEVELOP NEW DRUGS

The FTC, in its *Amicus* brief, and others commenting on the antitrust claims brought by generic firms in the context of REMS restrictions have noted that the Hatch-Waxman Act sought to strike a balance between consumers' interests in the flow of new and improved products (though incentivizing innovation) and the consumers' interests in low prices through increased generic competition. Despite this acknowledgement that Hatch-Waxman was focused on balancing the incentive to develop new drugs with the interest in increased competition, the FTC (and other commenters) have focused exclusively on static measures of competition in terms of the price effects of generic entry and ignored the other half of the balance that Congress attempted to craft—incentivizing the development of new products and treatments. Indeed, the FTC takes the strong position that an antitrust policy that requires branded manufacturers with REMS restricted products to provide samples to generic competitors cannot alter branded firms' incentives to innovate, but only increase consumer welfare through increased generic competition:

> First, allowing potential generic competitors to purchase product samples from the brand would not undermine the incentive to invest; it would simply maintain the incentive structure Congress created in the Hatch-Waxman Act, under which Actelion retains the ability to exert its patent rights.[12]

This view ignores how REMS restrictions brought about by the FDAAA, which did not exist at the time the Hatch-Waxman Act became law, have affected incentives to innovate. In fact, evidence indicates that some product innovations that have been introduced to the market would likely not have existed but for the restrictive distribution mechanisms that REMS protocols instituted. One analysis of the REMS program notes, "[T]hrough its mandated program to improve drug safety, REMS has provided the ability for the FDA to approve products that likely would have never made it to market."[13]

A case in point is Thalomid, one of the products that has been subjected to antitrust litigation regarding the refusal of the branded seller (Celgene) to provide samples to certain manufacturers seeking FDA approval for generic versions.[14] The active ingredient in Thalomid is thalidomide, a compound with a notorious history around the world. In the 1950s and 1960s, thalidomide was used in a number of countries outside the United States (it was not approved by the FDA at that time) as a sedative and a treatment for morning sickness until it was discovered that it caused severe birth defects and was withdrawn from markets worldwide.

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[12] FTC's *Amicus Curiae* brief in *Actelion Pharmaceuticals, Ltd., et al. v. Apotex Inc., et al.*, p. 15. *See also*, Tucker, et al., *REMS: The Next Pharmaceutical Enforcement Priority*, ANTITRUST, 76 (Spring 2014), "Requiring sales of RLD samples would be unlikely to reduce the monopolist's incentive to innovate because generic access to product samples and, ultimately, generic competition was contemplated under the Hatch-Waxman Act."

[13] Doyle, et al., *supra* note 3 at 4.

[14] Complaint, Lannett Co. v. Celgene Corp., No. 2:08-cv-03920 (E.D. Pa. Aug. 15, 2008).

In 1998, the FDA approved Thalomid to relieve complications of leprosy, but only with strict protocols to monitor distribution and educate patients and healthcare providers.[15] Celgene's REMS protocol included restrictions that only registered physicians could prescribe the drug, and only for one-month intervals. Pharmacists were also required to be registered, women of childbearing age had to agree to mandatory pregnancy tests, and both male and female patients had to adhere to birth control methods.[16] Additionally, Celgene was required to develop and maintain a secure patient database to monitor and evaluate the implementation of the ETASU requirements. [17] Approved indications have since expanded to the treatments of multiple myeloma and inflammation. Without these rigid restrictions and monitoring programs, it is unlikely that the FDA would have approved Thalomid.

Importantly, REMS drugs have additional development and marketing costs that are not borne by non-REMS drugs. First, a REMS designation is inherently an indication that there are substantial risks associated with the product. These risks result in increased scrutiny during the FDA review process and the evidence indicates that it takes longer for REMS drugs to receive FDA approval than non-REMS drugs.[18] The detrimental impact on incentives to innovate due to loss of market time from FDA regulatory delays was a key element that the Hatch-Waxman Act sought to address prior to the REMS programs resulting from the FDAAA. To the extent that these delays are longer on average than for other products, the incentives to innovate are already diminished relative to the products envisioned under Hatch-Waxman. Further, rigorous REMS protocols likely limit product demand since they impose additional costs on patients and healthcare providers.

Finally, strict REMS protocols require additional costs to monitor patients and providers, raising the costs of selling these products relative to non-REMS drugs. The branded company would likely continue to shoulder a significant burden for these costs, even after generics entered (see below). These high selling costs also decrease the incentive to innovate, all things equal.

Others have also noted that the current regulatory and antitrust regime has altered the balance struck by Hatch-Waxman in favor of increased generic competition at the expense of incentives to innovate.[19] The Supreme Court has recognized that forcing companies to share "may lessen the incentive for the monopolist, rival, or both to invest in those economically beneficial facilities…"[20] To the extent that consumers benefit from the dynamic competition to develop new products and new uses for existing products (which they surely do), then an

[15] Although this approval predates the formal changes to the Food & Drug Act in 2007, the basic protocols used in the case of Thalomid are similar to ETASU protocols under REMS.

[16] Although this approval predates the formal changes to the Food & Drug Act in 2007, the basic protocols used in the case of Thalomid are similar to ETASU protocols under REMS.

[17] Risk Evaluation and Mitigation Strategy (REMS) Approval for Thalomid® (thalidomide), Modified November 2013, p. 7. *Available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222649.pdf

[18] Doyle, et al., *supra* note 3 at 3.

[19] Richard A. Epstein, *Branded versus Generic Competition-A Kind Word for the Branded Drugs*, HASTINGS SCI. & TECH. L. J. 459-70 (2011).

[20] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, (2004), p. 407.

antitrust policy that reduces incentives to innovate can reduce consumer welfare unless the gain from the price reductions outweighs the reduction from a reduced flow of new products.

III. THE ECONOMICS OF EXCLUSIVE DEALING AND ITS APPLICATION TO REMS PRODUCTS

Standard economic theory has long recognized that unilateral refusals to deal with rivals and exclusive dealing relationships with distributors can be pro-competitive when such exclusivity is necessary to promote efficient levels of investment in training and reputations. In particular, economic theory has recognized that if one party can free-ride on the investments of another party in training sales staff or customers on product features, that firms would underinvest in such programs, even if those investments increase demand and yield gains in consumer welfare.[21]

The REMS restrictions that have been challenged by generic manufacturers are in many ways akin to exclusive dealing arrangements, where a manufacturer restricts access downstream to prevent free-riding on investments in expanding demand for the product. Establishing REMS protocols entail significant investments to design and implement. One source notes that it can cost manufacturers between $5,000 and $500,000 per month to setup and maintain a REMS protocol, and costs to distributors can range from $5,000 to $1 million.[22]

Branded firms have expressed concerns that, even after generic entry, they would bear the lion's share of the cost in setting up and maintaining REMS protocols that would inure largely to the benefit of generics due to automatic substitution laws. All things equal, the branded company's incentive to maintain such programs would diminish with generic approval, with potentially negative impacts on consumer welfare.

In some cases, the branded companies have patented some elements of the risk management programs and those patents are listed in the Orange Book.[23] In those cases, if those patents were found to be valid, the generic firm would have to either license the protocols or develop non-infringing versions before they could market the product. However, even if the generic manufacturers developed their own versions of the ETASU protocols, branded firms may still face liability, withdrawal of FDA approval, and negative impacts on the firm's reputation. Branded companies that have faced antitrust allegations over refusals to provide samples to generics have noted that generic assurances and even indemnification may not adequately protect them from some or all of these risks.[24]

In all these situations, it may make economic sense for a branded company to refuse to provide samples to a potential generic rival since additional generic sellers add risks and uncertainties, the costs of which are largely borne by the branded company. A review of the refusals to deal for a REMS product under a "no economic sense" test would need to address the

[21] CARLTON & PERLOFF, MODERN INDUSTRIAL ORGANIZATION, 4th ed., pp. 418-428.

[22] Briz, *How Effective are REMS Programs in Increasing Patient Safety?,* Kulkarni Law Firm Blog (October 31, 2012), *available at* https://www.conformlaw.com/blog/how-effective-are-rems-programs-in-increasing-patient-safety/.

[23] The FDA's list of approved drug products with therapeutic equivalence evaluations.

[24] *Lannet Company, Inc. v. Celgene Corporation,* 2011 U.S. Dist. LEXIS 32915, Decided March 29, 2011.

impact of a requirement to deal on the branded manufacturer's incentive to invest in these welfare-enhancing activities and weigh any loss against the gains from lower generic prices.

Finally, branded companies have claimed that their patent rights give them the right to refuse to deal, even if the impact is to delay generic entry. The FTC's response is to assert that this is not true because under amendments to the Hatch-Waxman Act, the generics' use of a patented product in the course of pursing FDA approval is not considered an act of infringement.[25] Even so, it is at least an open question whether an amendment that made the use of a patented product immune to infringement claims also was also intended to take away a fundamental right of the patent holder to determine how (and to whom) to sell its patented product.

IV. CONCLUSION

Branded companies' refusal to supply generic firms with samples of products subject to REMS restrictions is thought by many to be the next front in ongoing FTC efforts to prevent perceived anticompetitive attempts by branded companies to forestall generic competition. Even a monopolist's refusal to deal with a competitor, however, is not necessarily anticompetitive. As a matter of economics, there are pro-competitive, or at least competitively neutral, reasons for such a refusal.

In the context of the pharmaceutical industry, a blanket requirement that branded manufacturers deal with potential generic rivals can reduce consumer welfare by reducing the incentive to develop new products and the incentive to make investments that provide critical information to the marketplace and expand demand. A full investigation of whether these refusals to deal with generic rivals are anticompetitive would have to weigh the welfare-reducing effects of these reduced incentives against the welfare gain from earlier entry of lower-priced generic competitors.

[25] FTC's *Amicus Curiae* brief in *Actelion Pharmaceuticals, Ltd., et al. v. Apotex Inc., et al.*, pp. 17-18.

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Defining "Payments": The First Post-*Actavis* Battleground in Pharmaceutical Reverse Payments

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Defining "Payments": The First Post-*Actavis* Battleground in Pharmaceutical Reverse Payments

Lauren Battaglia[1]

I. INTRODUCTION

In June 2013, the Supreme Court ruled in *FTC v. Actavis* that reverse-payment pharmaceutical patent settlement agreements are subject to rule of reason analysis under the antitrust laws. In doing so, the Court not only rejected both the FTC's position that such agreements should be presumptively unlawful and the position of pharmaceutical manufacturers that such agreements should only be subject to scrutiny where they exceed the scope of the relevant patent, but also left it to the lower courts to develop the details of the framework to be applied. While this outcome did not come as a surprise to many, by declining to adopt either of these arguably simpler approaches, the ruling likely raised as many questions as it answered.

In many ways, before the ink was even dry on the Supreme Court's ruling in *Actavis*, the next front in the pharmaceutical reverse-payment saga was already clear. Parties engaged in reverse-payment related litigation prior to the ruling had already renewed arguments regarding the issue in the wake of the Third Circuit's then-recent ruling in *K-Dur* that reverse-payment patent settlement agreements were presumptively unlawful under the antitrust laws.

With this break from the scope-of-the-patent test, pharmaceutical firms (branded and generic alike) were faced with the prospect of a narrower set of paths through which to fend off reverse-payment suits at early stages of litigation. At the same time, given the intense scrutiny afforded these agreements by the FTC and private plaintiffs over the previous decade, the agreements themselves had already evolved significantly—few involved the simple, otherwise unexplained transfer of large sums of money anymore. Instead, many agreements had begun to provide for a range of ongoing relationships between the settling parties—sometimes limited to the products at issue in the patent litigation and sometimes extending beyond. Given this confluence of factors, it is not all together surprising that the wake of the Supreme Court finally weighing in on the issue has brought the parties back around to the very question of what constitutes a reverse "payment."

Currently a number of courts are actively trying to carve the first contours of the rule of reason analysis called for under *Actavis* by attempting to determine whether scrutiny under *Actavis* is limited to cash payments from a brand to a generic or, if instead, the rule is broad enough to also reach other non-cash forms of consideration.

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II. THE RISE OF NON-CASH FORMS OF CONSIDERATION

As mentioned above, with intensified scrutiny of reverse-payment patent settlements over the past decade, the structure of these agreements has evolved. Instead of payments for the generic's commitment to refrain from entering the market, as early as 2005 the FTC reported that agreements notified to it under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") were including other types of provisions such as "side deals" between the brand and the generic.[2]

These side deals typically take one of the following forms: (1) IP licenses, (2) co-promotion agreements, (3) supply agreements, and/or (4) co-development agreements. It is important to note that each of these types of side-deals typically involve actual cash payments between the parties and, in some instances, where an agreement provides for a combination of different types of side-deals, payments may flow in both directions. However, other types of provisions that have also appeared with increasing frequency do not necessarily contemplate any payments being exchanged between the parties.

In particular, the FTC has reported that increasing numbers of agreements contain provisions whereby the brand commits not to market an authorized generic ("AG") during a first Abbreviated New Drug Application ("ANDA") filer's 180-day exclusivity period. These so-called "No-AG" agreements are typically structured in one of two ways—either as a simple commitment by a brand not to market an AG for a fixed period of time (nor license a third party to do so) or through the grant of an exclusive license to the generic for the AG product, which is exclusive even as to the patentee.

The FTC reports that 19 of the final settlements reported to the agency in FY 2012[3] and 24.8 percent of the total number of final agreements filed with the agency between FY 2004 and FY 2010 contained this type of provision.[4] Although this type of provision does not involve cash payments between the parties, these provisions may be valuable to a generic first-filer. The FTC has found that the presence of an AG reduces the revenues of the first-filer generic by an average

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[2] *Compare* FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2004, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/050107medicareactrpt.pdf, *with* FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2005, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/fy2005drugsettlementsrpt.pdf.

[3] FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2012, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

[4] FEDERAL TRADE COMMISSION, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, August 2011 at vi, *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

of 40-52 percent during the exclusivity period.[5] Thus, by ensuring that the brand will not compete by means of an AG for some period of time, these "No-AG" provisions are said to protect generic revenues.

III. *FTC V. ACTAVIS*

In *Actavis*, the Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effect," namely that reverse payments can be used by a patentee "to avoid the risk of patent invalidation or a finding of noninfringement."[6] The likelihood of a payment having such effects "depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[7]

Justice Breyer, writing for the majority, reasoned that such a rule is capable of being administered by a court in light of the fact that it will not normally be necessary "to litigate the patent's validity…." because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[8] The Court specifically identified two potential justifications for reverse payments—(1) where the payment "amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement" and (2) where a payment "reflect[s] compensation for other services that the generic has promised to perform"—but also left open the possibility that there may be other justifications.

With these guideposts, the Court left it to lower courts to structure the precise rule of reason framework to be applied in this context in such a way as will "avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question…"[9]

Thus, in the view of the majority, the size and character of the alleged "payment" is central to each of the key aspects of the ruling—it is the metric by which the anticompetitive potential of this type of settlement agreement, as well as the adequacy of asserted justifications, are to be assessed, and is also the "workable surrogate for a patent's weakness" which avoids the need to delve into the merits of the underlying patent litigation, thereby making these cases administrable in practice.[10]

Indeed, the majority states that the size of the payment is "itself a strong indicator of power" to charge higher prices because a patentee making such a payment would likely have the power to bring about the anticompetitive harm of concern in the context of reverse payments. Moreover, the payment may be indicative of intent because it "may…provide strong evidence

[5] *Id.* at 33 (finding that during the exclusivity period "wholesale expenditures on the first-filer's generic drug—a proxy for revenues—were 40 to 52 percent lower, when an AG was present.").

[6] *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223, 2236-37 (June 17, 2013).

[7] *Id.* at 2237.

[8] *Id.* at 2244.

[9] *Id.* at 2238.

[10] *Id.* at 2236-37.

that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[11]

Despite this emphasis on the presence and relative size of a "payment" as critical elements of the Court's core holdings in *Actavis*, the question of what actually constitutes a "payment" in this context appears to be among the questions left to lower courts to determine. The opinion does not directly address the issue. In the few instances where the majority uses something beyond a generic reference to "payment[s]," the Court appears to be referencing monetary forms of payment. For example, in describing the nature of reverse payments, the Court states that "[i]n reverse payment settlements…a party with no claim for damages…walks away with ***money*** simply so it will stay away from the patentee's market."[12] (emphasis added). However this might also be explained by the fact that the only forms of payment alleged in *Actavis* involved actual monetary transfers from the brand to the generic—payments in return for the generic firms promoting the branded drug at issue in the patent litigation to prescribers.[13]

Unfortunately the dissent in *Actavis* also did not provide any further clarity on this point. In a single paragraph, the dissent implies that it understood the majority to only be addressing cash payments while at the same time stating that the majority's logic cannot reasonably be limited to just cash payments. Indeed, writing on behalf of the three dissenting justices, Chief Justice Roberts asserted that:

> [the majority's] logic—that taking away any chance that a patent will be invalidated is itself an antitrust problem—cannot possibly be limited to reverse-payment agreements, or those that are 'large. The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for 'other consideration' and 'alternative arrangements.'[14] (internal citations omitted)

These are the muddied waters that federal district courts and parties in three ongoing private reverse payment suits have recently tried to clarify.

IV. RECENT CASES: *In re Lamictal*, *In re Lipitor*, and *In re Nexium*

So far only three courts have addressed this aspect of *Actavis* to any degree—two U.S. District Courts in the District of New Jersey and one in the District of Massachusetts—only one of which actually decided the issue directly. Careful consideration of the approach taken in each of these cases is particularly useful because even these initial indications already reflect a split among lower courts.

[11] *Id.* at 2235.

[12] *Id.* at 2243; *see also Id.* ("But the dissent appears also to suggest that reverse payment settlements—e.g., in which A, the plaintiff, pays ***money*** to defendant B purely so B will give up the patent fight…") (emphasis added)

[13] *Id.* at 2229.

[14] *Id.* at 2246 (Roberts, J., dissenting)

A. In re Lamictal

In *Lamictal*, the only case so far in which the issue of non-cash payments was actually decided and the most recent word on the issue, Judge William H. Walls held that only payments involving monetary transfers are subject to antitrust scrutiny under *Actavis*.[15] The agreements at issue settled patent litigation between GlaxoSmithKline ("GSK") and Teva Pharmaceuticals ("Teva") related to GSK's epilepsy and bipolar disorder product, Lamictal, which is available in both tablet and chewable forms. Under the terms of the agreement, Teva was permitted to sell generic chewables approximately 37 months prior to patent expiration and generic tablets approximately six months prior to patent expiration. GSK also granted Teva an exclusive license to the relevant Lamictal patents, which was exclusive even as to GSK during Teva's 180-day first-filer exclusivity period.

According to Judge Walls, the first step under the *Actavis* framework is to determine whether an agreement involves a reverse payment and this, in turn, "hinges on what the parties exchanged in the settlement and must include money."[16] Though he did not find that *Actavis* decided the matter expressly, Judge Walls relied heavily upon the fact that in his view "[b]oth the majority and dissenting opinions reek with discussion of [the] payment of money."[17] In particular, he highlighted the dissent in *Actavis* (discussed above) which he characterized as having critiqued "the majority precisely because it drew a line between monetary and non-monetary payments."[18]

More broadly though, Judge Walls concluded that the reasonableness of the settlement agreement further bolstered his conclusion that the agreement was not of the sort that is subject to *Actavis* scrutiny. In this regard, he specifically noted three features of the agreement which in his view counseled against the need for scrutiny in that context: (1) Teva was allowed to enter the market prior to patent expiry, (2) there was no monetary payment from the brand to the generic, and (3) the exclusive license was for a relatively brief period.[19]

B. In re Lipitor

In *Lipitor*, a different federal district court in New Jersey granted plaintiffs leave to amend their complaint following *Actavis* to include allegations of non-monetary forms of payment.[20] The agreements at issue in the case provided for Pfizer's forgiveness of outstanding monetary judgments against Ranbaxy and the grant of a right to market generic Lipitor in at least eleven international markets.[21] In allowing the amendments, Judge Peter G. Sheridan declined to directly decide the substantive question, but did observe that "nothing in *Actavis* strictly requires that the payment be in the form of money…"[22]

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[15] *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-995, 2014 WL 282755 (D.N.J. Jan. 24, 2014).
[16] *Id.* at *5.
[17] *Id.* at *7.
[18] *Id.* at *8.
[19] *Id.* at *9.
[20] *In re Lipitor Antitrust Litigation*, No. 12-2389, 2013 WL 4780496 (D.N.J. Sept. 5, 2013).
[21] *Id.* at *11.
[22] *Id.* at *26.

C. In re Nexium

Judge William G. Young made a similar observation in *Nexium*, a case currently pending in federal district court in Massachusetts, in granting the plaintiffs leave to amend their complaint in light of *Actavis* to include allegations of non-cash payments. The allegations asserted in *Nexium* center around agreements between AstraZeneca and three generic manufacturers—Ranbaxy, Teva, and Dr. Reddy's. Under these agreements, Ranbaxy received an exclusive license and cash payments in return for Ranbaxy's provision of manufacturing and distribution services to AstraZeneca. With respect to Teva and Dr. Reddy's, AstraZeneca forgave significant portions of contingent liabilities faced by the firms.

While conceding that the Court "spoke only to the merits of cash payouts," Judge Young emphasized that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment."[23] Judge Young further reasoned that "a broader interpretation of the word 'payment'" would "serve[] the purpose of aligning the law with modern-day realities."[24]

V. ANALYSIS

As reflected in the split summarized above, the question of whether non-cash forms of consideration are also subject to scrutiny under *Actavis* in the context of pharmaceutical patent settlements is far from decided. However, in the meantime it is worthwhile to consider the potential implications if they are.

First, it will likely result in a far broader range of agreements being subjected to intense scrutiny. It is common ground that value can be transferred between parties to a settlement agreement without the exchange of actual money. Indeed, as Judge Posner observed in an earlier reverse-payment case, "any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."[25] Beyond just agreements involving No-AG provisions, such a rule could also potentially reach agreements where the brand grants the generic a non-exclusive license or agrees to act as a backup supplier of the product in the event of a shortage. Both of these are examples of provisions that likely convey some value to the generic without a cash payment, but can also play a key role in facilitating earlier generic entry when used in connection with a negotiated entry date.

As has been recently observed by industry representatives, this broad interpretation could also potentially sweep in other types of agreements that are widely viewed as pro-competitive, such as shared patented Risk Evaluation and Mitigation Strategies ("REMS") programs. To the extent the licensing of a shared REMS program is viewed as potentially constituting a non-cash form of payment, this could discourage branded firms from granting such licenses which could, in turn, have the effect of slowing generic entry and imposing additional costs on generics.

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[23] *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 12-02409, 2013 WL 4832176, *15 (D. Mass. Sept. 11, 2013).

[24] *Id.*

[25] *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F.Supp. 2d 986, 994 (N.D. Ill. 2003)

Second, such a rule may discourage the settlement of patent litigation by subjecting agreements which may in fact involve no actual payment (even under this expanded standard) to significant economic scrutiny. Whereas the existence and value of a cash payment is clear without further analysis, the value of a so-called No-AG clause or other forms of non-cash consideration in a given context is far less clear. Taking just the example of No-AG clauses, as the FTC itself has found, some branded manufacturers simply do not choose to authorize generic drugs under their NDAs even in the face of generic entry, and others do so only for a subset of their NDA-covered drugs.[26] If a branded firm in fact has no intention to introduce an AG for a particular product, a No-AG clause may still be *perceived* by a generic as having some value (at least as reassurance to the generic), but in reality essentially has none and is costless to the brand. More importantly, in these circumstances the brand and generic cannot be said to be allocating markets because the brand never had any intention to enter the generic market in the first place. In light of this, plaintiffs should bear a relatively significant burden in proving the existence and size of a payment on the basis of non-cash consideration alone.

Thus, as FTC Commissioner Joshua Wright recently observed, this broad interpretation of the scope of *Actavis* will likely prove to be a "boon" for economic litigation consulting firms. Significant economic analysis may be required to determine whether a brand was likely to otherwise market an AG in the circumstances and thus whether the No-AG clause had any value.

[26] FTC Authorized Generic Drugs, *supra* note 4 at 15-17.

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New Jersey District Court Limits *Actavis* to Cash Payments

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New Jersey District Court Limits *Actavis* to Cash Payments

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As with patent infringement litigation in many industries, innovator pharmaceutical companies frequently settle their patent infringement litigation against would-be generic challengers by licensing the alleged infringer to market its generic version of the patented drug before patent expiration. But because generic entry costs an innovator firm far more than it profits the entrant, a license giving a generic challenger a business opportunity consistent with its valuation of its litigation prospects could pose a loss wildly out of line with the innovator's own valuation.

Consequently, settling some pharmaceutical patent infringement suits requires conveying some value to the generic aside from the license itself, a superficially counterintuitive phenomenon that antitrust plaintiffs have called a "reverse payment" that pays the generic to delay its entry.[2] Over the last 15 years, appellate courts' antitrust reviews of these settlements have ranged from extreme deference to a presumption of competitive harm. Meanwhile, as litigants awaited guidance from the Supreme Court, the nature of the gap-bridging value generics arguably received evolved away from cash payments towards business opportunities.

Finally, in *FTC v Actavis*, the Court held last year that reverse-payment settlements are subject to antitrust analysis (contrary to the majority rule), but must be evaluated under the rule of reason, not (as antitrust plaintiffs had argued) subject to a presumption of anticompetitive harm.[3] Evaluating a settlement that, according to the FTC, had paid two generic firms more than the value of the business services they provided the innovator firm pursuant to the settlement, the Court reasoned that "the likelihood of a reverse payment bringing about anticompetitive effects [is not presumed, but] depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."

Actavis thus gives courts and litigants some guidance on how "reverse payment" settlements will be analyzed.[4] But there remains a fundamental question: exactly what constitutes

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[1] The authors are partners at Mayer Brown LLP. They thank their colleague Joshua Faucette for his contributions to this article.

[2] *See* Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19.2 ANNALS OF HEALTH L. 367-400 (2010, *available at* http://works.bepress.com/bret_dickey/2.

[3] *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

[4] *But see In Re: AndroGel Antitrust Litig. (No. II)*, Case No. 1:09-MD-2084-TWT, Slip op. at 2 (N.D. Ga. Oct. 23, 2013) (anticipating *Actavis*' remand, wondering "how in the heck a trial judge (and a jury) is supposed to apply the *Actavis* decision to an actual case").

a reverse payment? When a settlement provides for value to the generic beyond the grant of a license for the accused generic product, but not for any cash, does *Actavis* even apply?

The first district court decision to address the issue in detail came in the *Lamictal Direct Purchaser Antitrust Litigation* in New Jersey.[5] *Lamictal* involved an antitrust challenge to the settlement of a patent dispute between GlaxoSmithKline ("GSK") and Teva Pharmaceuticals ("Teva") At issue was GSK's patent for lamotrigine, used to make tablet and chewable forms of the anticonvulsant Lamictal. After Teva filed an Abbreviated New Drug Application ("ANDA") for Lamictal in 2002, GSK sued for infringement of its patent, which did not expire until July 2008.

In early 2005, after the district court invalidated Claim 1 of the patent, the case settled, with GSK agreeing to supply Teva with generic lamotrigine chewables for resale by Teva beginning in June 2005, and licensing Teva to sell its generic lamotrigine tablets six months before expiration of the patent (or the additional six-month pediatric exclusivity, if, as it turned out, GSK received it). As is now common in these settlements, GSK agreed not to undermine Teva's head starts by launching its own authorized generic ("AG") versions of the tablets and chewables during Teva's first six months with each product.

Direct purchasers of lamotrigine sued, claiming that the settlement violated the antitrust laws. In December 2012, the district court dismissed the complaint for failure to state a claim, holding that plaintiffs had failed to allege a reverse payment. After *Actavis* came down, the Third Circuit remanded the case to the trial court, and plaintiffs moved for reconsideration in light of the Supreme Court's decision.

In the *Lamictal* court's view, *Actavis* lays out "a three-part test." In the first two steps, the court determines whether there was a reverse payment and, if so, whether the payment was "large and unjustified." If both criteria are met, the court proceeds to rule-of-reason analysis, determining "whether the restraint had anti-competitive consequences and whether those consequences are otherwise justified."

The court found that the first step was enough. Plaintiffs had contended that they had alleged a reverse payment because the settlement "'conferred substantial benefits on Teva'—namely, through the No-AG Agreement." But the court disagreed: "nothing in *Actavis* says that a settlement contains a reverse payment when it confers substantial financial benefits or that a no-AG agreement is a 'payment.'" What *Actavis* "reek[ed] with," in contrast, was "discussion of payment of money;" the court noted pointedly that *Actavis* involved "a payment … of hundreds of millions of dollars to generic manufacturers."

Finding that the Court "considered a reverse payment to involve an exchange of money," and that it is "good jurisprudence that the result flows from the factual source," the court declined to "extend the holding of *Actavis* to the non-monetary facts before it." That the generic firm received a benefit was both obvious and immaterial: "'Without doubt Teva received consideration in the settlement. Otherwise, there would be no incentive to settle.'" *Actavis,* the

[5] *In re Lamictal Direct Purchaser Antitrust Litig.*, Case No. 12-cv-995 (WHW), slip op. (D.N.J. Jan. 24, 2014).

court concluded, meant to "give patent litigants latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring."

The *Lamictal* court left little doubt that the settlement would also survive rule of reason scrutiny. Even within its discussion of why *Actavis* did not apply, the court found "[t]hat Teva was allowed early entry, that there was no payment of money and that the duration of the No-AG Agreement was relatively brief," which "all serve to persuade this Court that the settlement was reasonable … ." And, as an alternative ground for dismissal, the court also concluded that the settlement "would most likely survive" *Actavis*' rule-of-reason analysis, finding that:

- the settlement posed "minimal" potential adverse effects on competition because (a) Teva was allowed six months of early entry, (b) there was no cash payment, and (c) the "duration of the No-AG Agreement was a relatively brief six months;"
- the No-AG agreement's value, though likely larger than the parties' avoided litigation costs, was justified in that it was "reasonably related to the removal of uncertainty" caused by the dispute, and may have reflected "ancillary benefit[s]" to GSK from Teva's licensed sales
- the existence of market power, though undetermined, was not dispositive;
- the "sweep of the settlement" did not connote an attempt to maintain supracompetitive prices and prop up a weak patent; and
- as the court had already found, the settlement "did not involve monetary reverse payments."

Lamictal's fate on appeal is unclear. Although *Actavis* categorically rejected *K-Dur*'s reflexive skepticism towards reverse payment settlements, the Third Circuit might be disinclined to restrain itself further and distinguish between cash and non-cash settlements.[6] In the meantime, the *Lamictal* decision establishes a potential bright-line rule exempting from antitrust scrutiny most patent settlements involving the transfer of only noncash benefits from the patent holder to the alleged infringer.

While, as *Lamictal* shows, rule of reason treatment of noncash settlements may turn out to be deferential in any case, a bright line that rules out even the rule of reason will reduce costs and uncertainty for both innovator and generic firms looking to eliminate uncertainty and get on with their businesses of making and selling pharmaceutical products.

[6] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217–19 (3d Cir. 2012), *vac'd and remanded in light of Actavis sub nom. Upsher-Smith Labs. v. Louisiana Wholesale Drug Co.*, 133 S.Ct. 2849 (2013).

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Courts' Prescription for Reverse-Payment Settlements Still Unknown Almost a Year After *FTC v. Actavis*

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Courts' Prescription for Reverse-Payment Settlements Still Unknown Almost a Year After *FTC v. Actavis*

Ankur Kapoor & Rosa M. Morales[1]

I. INTRODUCTION

Nearly a year after the Supreme Court held in *FTC v. Actavis*[2] that reverse-payment settlement agreements between branded and generic pharmaceutical companies are subject to antitrust scrutiny under the rule of reason, federal district courts are still struggling with such threshold questions as what constitutes a "payment" subject to antitrust challenge and whether only a monetary transfer from the patent holder to the alleged infringer can form the basis of an antitrust claim attacking the competitive effects of the settlement.

II. WHAT IS A "REVERSE-PAYMENT" SETTLEMENT?

Briefly, a reverse-payment settlement is a settlement of patent infringement litigation brought by the holder of a patent(s) covering a pharmaceutical product against a would-be generic competitor in which the generic agrees not to launch its allegedly infringing product for some period of time and the patent holder pays the generic (instead of the allegedly infringing generic paying the patentee for damages, hence the term "reverse payment").[3] The antitrust criticism of reverse-payment settlements is that they are payments in exchange for generics' agreements not to compete and therefore cost consumers billions of dollars in lower-priced drugs.

III. THE SUPREME COURT'S *ACTAVIS* DECISION

In *Actavis*, the Federal Trade Commission ("FTC") challenged patent infringement settlements between Solvay Pharmaceuticals, the patent holder of the branded low-testosterone drug AndroGel®, and various generics including Watson Pharmaceuticals (as Actavis was then known). Per the settlements, the generics would receive monetary payments ($19 – $30 million

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[2] 133 S. Ct. 2223 (2013).

[3] The generic is not liable for damages because typically the patentee has sued the generic, not for launching the generic drug, but for the statutorily infringing act of seeking "paragraph IV" FDA approval that contains a certification by the generic that the patent(s) covering the drug is invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The branded-drug manufacturer has 45 days from the paragraph IV filing date to sue the generic contender. *Id.* § 355(j)(5)(B)(iii).

per year for Watson) and "delayed licenses" to begin manufacturing generic AndroGel® five years before Solvay's patent expired.[4] Solvay also received certain marketing and drug supply services.[5]

The U.S. Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal of the FTC's challenge prior to discovery, pursuant to Federal Rule of Civil Procedure 12(b)(6). The Eleventh Circuit held, under what has been called the "scope-of-the-patent" test, that reverse-payment settlements were lawful "absent sham litigation or fraud in obtaining the patent" and "so long as [the settlement's] anticompetitive effects fall within the scope of the exclusionary potential of the patent."[6] The Eleventh Circuit upheld dismissal of the FTC's complaint because the FTC had not alleged sham litigation or fraud in obtaining the patent and because the agreements to delay generic competition to five years before patent expiration fell within the temporal scope of the patent.

The Supreme Court reversed and rejected both the "scope-of-the-patent" test applied by the Eleventh Circuit (as well as the Second and Federal Circuits) and the FTC's proposed "quick-look" or "presumptively-unlawful" test which would have shifted the burden to the defendants to show a pro-competitive justification sufficient to overcome the settlement's presumptive illegality.[7] Instead, the Court acknowledged that some reverse-payment settlements might be reasonable and lawful and, recognizing the complexity of these settlements, the majority held that the rule of reason must apply to reverse-payment settlements, and required courts to weigh their pro-competitive justifications against their anticompetitive effects.[8]

Beyond holding that the rule of reason governs reverse-payment settlements, the Supreme Court offered little guidance in analyzing them. The Court suggested only that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" and that a "large" payment indicates that the patentee possesses some degree of market power.[9] But what is a "large" reverse payment? Does "large" mean a large dollar amount or large relative to the patent holder's expected future profits?

Also, what is an "unexplained" payment? Does the mere presence of some consideration received for the payment, in the form of goods, services, or intellectual property, suffice? Or must the consideration be reasonable under some still unknown standard? And although the Court rejected the Second, Eleventh, and Federal Circuits' holdings that reverse-payment settlements were lawful absent sham litigation or fraud in obtaining the patent, the Court did not foreclose inquiry into the strength of the patent(s), stating only that "it is normally not necessary to litigate patent validity to answer the antitrust question."[10]

In dissent, Chief Justice Roberts presciently warned that, with no clear rules, the majority opinion portends much confusion among district courts in crafting the proper rule-of-reason

[4] 133 S. Ct. at 2229.
[5] *Id.*
[6] *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312(11th Cir. 2012).
[7] *Actavis*, 133 S. Ct. at 2237.
[8] *Id.* at 2230-31.
[9] *Id.* at 2235-36.
[10] *Id.*

analysis for reverse-payment settlements. The questions posed above, and one even more fundamental question, have yet to be answered.

IV. ONE YEAR LATER, AND STILL AT THE BEGINNING: WHAT IS A PAYMENT?

In January 2014, the U.S. District Court for the District of New Jersey dismissed an antitrust challenge to a reverse-payment settlement in *In re Lamictal Direct Purchaser Antitrust Litigation* because there was no cash payment flowing from the patent holder to the would-be generic competitor, narrowly interpreting *Actavis* as imposing a "bright-line" requirement of a cash payment. The court therefore held that it was unnecessary to engage in the requisite rule-of-reason analysis to determine the settlement's anticompetitive effects (if any).

Just a few months earlier in September 2013 in the same district, however, a different judge took a less restrictive view of *Actavis* in *In re Lipitor Antitrust Litigation*. The *Lipitor* court treated as an open question the issue of whether an antitrust complaint could meet the "plausibility" pleading standard under *Bell Atlantic Corp. v. Twombly* where no major cash payment was involved in a reverse-payment settlement between Pfizer and Ranbaxy that allegedly unlawfully delayed generic entry of Pfizer's super-blockbuster Lipitor. Instead, Pfizer had agreed to drop its patent-infringement suit against Ranbaxy based on Pfizer's patented blood-pressure medication, Accupril, in exchange for a $1 million payment by Ranbaxy (Pfizer's claims were allegedly worth significantly more) and for Ranbaxy's dropping its action against Pfizer over Lipitor. Nevertheless, the court granted the plaintiffs leave to amend their complaint to include allegations of non-cash payments while noting that "nothing in *Actavis* strictly requires that the payment be in the form of money."

In *In re Nexium Antitrust Litigation*, the U.S. District Court for the District of Massachusetts gave *Actavis* its broadest application and denied that defendants' motion to dismiss the complaint. The court read *Actavis* as sweeping in non-monetary payments, stating that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction." The court applied *Actavis* to the brand-name manufacturer's agreements to forgive patent infringement damages in other cases and to agreements not to launch the brand-name manufacturer's own authorized generic in competition with the generic manufacturers.

In February 2014, the court administratively stayed the *Nexium* case to draft an opinion setting forth its reasoning for granting some of the defendants' motions for summary judgment on the ground that there was insufficient evidence of a "large, unjustified reverse payment" under *Actavis* and also for denying other motions for summary judgment on that same issue. A month later, the court granted two of the plaintiffs' motions for reconsideration and reopened the case for the limited purpose of allowing further briefing on, *inter alia*, the existence of a reverse payment. An opinion is expected this fall.

V. A CALL FOR REASONING IN A RULE OF REASON

As Chief Justice Roberts stated in the dissent in *Actavis,* and as many commentators stated when the Supreme Court decided *Actavis*, much if not virtually all of the guidance on the antitrust analysis of reverse-payment settlements is being left to the district courts. Divergent post-*Actavis* district-court views about what exactly constitutes a "payment," and whether cash is

required, demonstrate that district courts, almost a year after *Actavis*, are still struggling even to begin to find their way to a consistent and coherent approach to analyze the competitive effects of reverse-payment settlements within the challenging patent and regulatory environment of this important public health issue.

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The *St. Luke's-Saltzer* Antitrust Case:

Can Antitrust and Health Care Reform Policies Converge?

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The *St. Luke's-Saltzer* Antitrust Case: Can Antitrust and Health Care Reform Policies Converge?

Monica Noether[1]

I. INTRODUCTION

Earlier this year, a federal judge sided with the Federal Trade Commission ("FTC") and the Idaho Attorney General and enjoined the acquisition of a physician practice that included 16 adult primary care physicians ("PCP"s) by a hospital that already employed eight adult PCPs. The ruling was based only on the alleged lessening of competition attributable to the horizontal overlap in adult PCP services, despite the transaction's obvious concomitant vertical implications.

Notwithstanding its small scale, this case has attracted considerable national attention in health care antitrust circles as it raises policy questions that are fundamental to the pressures facing the health care industry in the era of reform.

II. BACKGROUND

The acquisition involved St. Luke's Health System (St. Luke's) and Saltzer Medical Group (Saltzer) and the physicians they both employ in the city of Nampa, Idaho. Nampa, a city of about 85,000 residents, is located approximately 20 miles west of Boise.

St. Luke's operates seven acute care hospitals with almost 900 beds combined, all in Idaho. Its largest, flagship facility is in Boise. It also operates a full-service emergency department (limited to outpatient services) in Nampa itself. St. Luke's has exclusive arrangements with approximately 500 physicians (both affiliated and employed) across southern Idaho and eastern Oregon. It has acquired all of its adult PCPs in Nampa since 2011.

Saltzer was the largest multi-specialty physician group in Idaho, including 41 physicians at the time of its acquisition. These physicians were primarily located in Nampa, although some also practiced in the surrounding area.

The acquisition of Saltzer by St. Luke's was completed in December 2012 after Judge B. Lynn Winmill denied St. Luke's' competitors, St. Alphonsus Health System and Treasure Valley Hospital, their preliminary injunction to enjoin the transaction. These private plaintiffs had alleged vertical foreclosure, arguing that the proposed transaction would harm competition by blocking physician referrals, but the Court found that the transaction would not cause

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irreparable harm.[2] Judge Winmill relied on assertions by the defendant that it would take time to "scramble the eggs," and that therefore the transaction could be subsequently undone if the full review of the merits indicated this was in the consumers' best interests.

Subsequently, the FTC and the Idaho Attorney General entered the fray, filing a complaint in March 2013 that focused purely on the horizontal overlap of adult PCPs in Nampa. The cases were consolidated, and a full trial on the merits spanned four weeks in the fall of 2013. On January 24, 2014, Judge Winmill found for the plaintiffs and ordered that St. Luke's divest the entire Saltzer Medical Group.

III. ISSUES

Judge Winmill clearly recognized the complexity of the issues that he was asked to address in this case.

> ….Americans spend more on health care than the next 10 biggest spenders combined…yet we lag behind many of them on quality and patient outcomes….[The experts] advocate moving away from our present fee-for-service health insurance reimbursement system that rewards providers…for billing high volumes of expensive medical procedures. A far better system would focus on…rewarding successful patient outcomes and innovation….It will require a major shift away from our fragmented delivery system and toward a more integrated system where primary care physicians supervise the work of a team of specialists, all committed to a common goal of improving a patient's health.

The Court also noted "the Acquisition was intended by St. Luke's and Saltzer primarily to improve patient outcomes. The Court is convinced that it would have that effect if left intact, and St. Luke's is to be applauded for its efforts to improve the delivery of health care in the Treasure Valley."[3]

While recognizing the need for integrated provider systems, however, Judge Winmill did not accept defendants' arguments (nor the views of many other consolidating providers nationwide) that such integration is most effective when accomplished through ownership. He found that "there are other ways to achieve the same [beneficial] effect," i.e., he disputed the merger specificity of the likely efficiencies.

The extent to which ownership is superior to looser affiliations in facilitating achievement of the goal of delivering higher value care through greater provider coordination was the key issue of this litigation. The Court's decision reflects the tension that many providers articulate between what they perceive as conflicting directives to, on the one hand, coordinate effectively across an entire care delivery team, and to, on the other, continue to compete as atomistic providers.

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[2] Saint Alphonsus Medical Center – Nampa, Inc., Treasure Valley Hospital, Limited Partnership, Saint Alphonsus Health System, Inc., and Saint Alphonsus Regional Medical Center, Inc. v. St. Luke's Health System, Ltd. Case no. 1:12-CV-560-BLW. Memorandum and Order, December 20, 2012.

[3] Saint Alphonsus Medical Center – Nampa, Inc., Treasure Valley Hospital, Limited Partnership, Saint Alphonsus Health System, Inc., and Saint Alphonsus Regional Medical Center, Inc. v. St. Luke's Health System, Ltd. Case no. 1:12-CV-560-BLW. Federal Trade Commission; State of Idaho v. St. Luke's Health System, Ltd.; Saltzer Medical Group, P.A. Case No. 1:13-CV-00116-BLW. Memorandum Decision and Order. January 24, 2014.

The St. Luke's case raises a second issue that has also been echoed in several other settings nationwide. This concern involves the cost-increasing byproduct of a regulatory policy that reimburses hospital-based services at higher rates than "comparable" services provided outside the hospital setting. This long-standing Medicare reimbursement policy, mimicked by many private payors, led the Court to conclude that an effect of the transaction would be to "raise rates for ancillary services (like x-rays) to the higher hospital-billing rates." While such a change may have nothing to do with any merger-related increase in market power, this case highlights an increased focus on the extent to which such differential reimbursement rates are justified.

In the remainder of this article, I discuss each of these issues in greater detail in the context of the current health care reform debate.

IV. WHAT EXTENT OF INTEGRATION IS REQUIRED TO FULLY ACHIEVE THE BENEFITS OF "VALUE-BASED CARE"?

A variety of forces have led to substantial horizontal and vertical consolidation of the health care industry over the last several years. While much of the credit (or blame) has been attributed to the passage of the Affordable Care Act in 2010, and the associated creation of federally-sponsored Accountable Care Organizations, increasing private sector concern over continued growth in health care spending has played at least as significant a role.

Efforts to "bend the cost curve" advocate replacing traditional "fee-for-service" reimbursement of health care providers with mechanisms that "pay for value" and organize around population, rather than individual, health goals. Such efforts rely on integrated provider delivery systems that place incentives on their provider participants to coordinate to ensure that high-value care is delivered to a patient population. Under this paradigm, individual providers are not paid more simply for delivering more services, but rather they are compensated only if the services they deliver contribute cost effectively to maintaining the health of the population that they serve.

Physicians, among other providers, are responding to these pressures by affiliating with larger organizations, particularly hospitals. Physicians seek larger organizations to absorb the risk of becoming responsible for the cost of maintaining or restoring their patients' health. At the same time, hospitals recognize that physicians serve as the gatekeepers for all the services that their patients consume. There are conflicting reports on the proportion of physicians employed by hospitals, but all accounts indicate that it has been increasing in the last several years and likely exceeds 25 percent of all practicing physicians.[4]

Health reform initiatives directed toward improving quality while reducing the rate of cost growth require scale for at least three reasons:

[4] *See*, for example, Elisabeth Rosenthal, *Apprehensive, Many Doctors Shift to Jobs with Salaries*, N.Y. TIMES (February 13, 2014), *available at* http://www.nytimes.com/2014/02/14/us/salaried-doctors-may-not-lead-to-cheaper-health-care.html; Robert Kocher & Nikhil Sahni, *Hospitals' Race to Employ Physicians—The Logic behind a Money-Losing Proposition*, 364 (19) N. ENGLAND J. MEDICINE 1790-1793 (May 12, 2011); Beth Kutscher, *Making physicians pay off*, MODERN HEALTHCARE (February 22, 2014), *available at* http://www.modernhealthcare.com/article/20140222/MAGAZINE/302229986/making-physicians-pay-off.

1. In order to control costs effectively while delivering high quality care, all members of a care team must face a common incentive to provide the most cost-effective, high quality bundle of services to each patient in their care. This implies that compensation schemes must cause each provider to recognize itself as a cost center, rather than a revenue center.
2. Related to the first point, providers must be responsible for all treatment costs, regardless of whether or not they reflect efficient care patterns or not. However, given that reimbursement adjustment methodologies designed to account for severity differences across patient populations are imperfect, it is important to mitigate the financial risk caused by a few very sick "outlier" patients through the "law of large numbers."
3. Care coordination across a variety of providers and settings requires a health data information technology that links clinical information with cost data from all providers in the system and permits usage of the data to measure resources and outcomes. The fixed costs associated with installing and operating such a system can total many hundreds of millions of dollars and therefore depend on sufficient scale to be affordable.[5]

The ultimate question raised in the St. Luke's case is the extent to which common ownership or employment to create scale and align financial and quality incentives is necessary to address these factors, or whether looser clinical affiliations are sufficient to achieve the same objectives. Testimony at the trial focused extensively on the evidence relating to this question, and both sides presented well-known quality experts to opine on the topic.

This question has its roots in fundamental economic theory relating to the trade-offs of "making versus buying" or "owning versus contracting." It was first raised by Ronald Coase in his 1937 article, *The Theory of the Firm*.[6] A substantial subsequent literature notes that when transaction costs of contracting are high, either because there are too many contingencies to anticipate or articulate in writing the contract, or because monitoring and enforcement of the contract are difficult, then internal organization (making or owning) is more likely. Such situations are most likely to result, all else constant, when products are specialized, market conditions are changing, and information is imperfect.[7] Many would say that these are all conditions that describe the health care sector.

Judge Winmill clearly believed that integration of physicians and hospitals short of merger is sufficient to achieve the benefits of coordinated care. However, many providers appear to believe that, while affiliations can help, they can accomplish much more through complete ownership. Plaintiffs cited Chicago-based Advocate Healthcare as the poster child for a system

[5] Costs for a large health care system to fully implement an integrated health data system can cost up to $1 billion. *See*, *Epic Challenge: What The Emergence of an EMR Giant Means For the Future of Healthcare Innovation*, FORBES (June 9, 2012), *available at* http://www.forbes.com/sites/davidshaywitz/2012/06/09/epic-challenge-what-the-emergence-of-an-emr-giant-means-for-the-future-of-healthcare-innovation/#./?&_suid=139828115743601117460735829352, and *Will Neal Patterson make Americans Healthier?* FORBES (June 8, 2012), *available at* http://forbesindia.com/printcontent/33028.

[6] Ronald Coase, *The Theory of the Firm*, 4 ECONOMICA 386-405 (1937).

[7] *See*, JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION, 21-34 (1988) or DENNIS CARLTON & JEFFREY PERLOFF, MODERN INDUSTRIAL ORGANIZATION, 17-24 (1994) for summaries of this literature.

that successfully reduced costs through a collaboration with independent physicians where they jointly shared risk for a patient population.[8]

However, it is important to note that while Advocate works with independent affiliated physicians in its Advocate Physician Partners program, it also employs over 1,000 physicians,[9] and the CEO of Advocate noted, "the secret sauce is alignment—and financial incentives toward alignment get physicians' attention."[10] Also in Chicago, Northwestern Memorial HealthCare recently acquired the 900-physician Northwestern Medical Faculty Foundation, even though the group had already been historically affiliated with the hospital system. This move suggests that Northwestern, the health system, believed that greater control of the affiliated physician group was worth the cost.

Other evidence also supports the greater effectiveness of the employment model. The Catalyst for Payment Reform, a non-profit group representing employers, recently compared the extent of commercial payments that were "value-oriented" nationwide with those in California, which has long been recognized as ahead of the rest of the country in terms of integrated delivery. Nationwide in 2013, the percentage of commercial payments received by providers was less than 11 percent, with less than 6 percent of payments based on financial risk contracts, while in California, 42 percent were value-based, almost all of which were at risk.

It is likely not coincidental that Kaiser Permanente, an integrated health plan-provider organization that owns the hospitals it uses and whose physicians are effectively employed by Kaiser[11] covers 40 percent of all privately insured lives in the state,[12] and most of the rest of California's physician population is organized into large groups of employed physicians. As defendants noted, in other parts of the country, providers such as Intermountain Healthcare, Geisinger Health System, Mayo Clinic, or the Cleveland Clinic—which each employ hundreds, if not thousands, of physicians—are all frequently cited as exemplars of cost-effective, high quality integrated delivery systems.[13]

It also appears that the propensity of physician groups to take on risk-based reimbursement contracts is associated with compensation mechanisms that do not reward volume. A recent study of 21 large physician groups found that those that earned a larger proportion of their revenue from risk-based contracts were more likely to pay their physicians by salary or performance metrics (e.g., efficiency, quality) while those that received primarily fee-for-service payments tended to rely more on individual productivity based compensation

[8] Trial Transcript, November 7, 2013, page 3677.

[9] Advocate Medical Group, *available at* https://amgdoctors.com/about-us/.

[10] *Inventing the Future of Healthcare: Top CEOs on the Real Work of Transforming the Healthcare Industry*, (2013).

[11] Technically, California prohibits the corporate practice of medicine. As a result, Kaiser physicians are employed by the Permanente Medical Group, which contracts exclusively with Kaiser Permanente.

[12] CALIFORNIA HEALTHCARE FOUNDATION, CALIFORNIA HEALTH PLANS AND INSURERS: A SHIFTING LANDSCAPE (March 2013).

[13] Trial Transcript, November 7, 2013, p. 3783.

systems.[14] This pattern illuminates the importance of organizational structures that facilitate compensation arrangements that foster incentives to deliver value.

In sum, rigorous, controlled studies do not exist at this point in time to demonstrate conclusively that ownership is more effective than contracting in organizing providers to deliver the "value-based care" that health care reform envisions. But those that participate in the industry clearly sense that strong alignment across the continuum of providers is necessary.

V. HIGHER REIMBURSEMENT OF HOSPITAL-BASED MEDICAL SERVICES

Judge Winmill's second concern regarding the acquisition of Saltzer by St. Luke's related to the regulatory effect that physician services provided under the auspices of a hospital are reimbursed at higher levels by the Medicare program, and by many private payors, than when they are provided by independent physicians. Higher reimbursements for services delivered in the hospital setting are defended by the higher overhead costs that hospitals must incur, the necessity that services be available 24-7, and the greater average severity of the patients they treat. However, in recent years, both the Medicare Payment Advisory Commission and the Office of the Inspector General have recommended that the differential be reduced, if not eliminated.[15]

Judge Winmill's concern over regulatory-sanctioned rate increases resulting from mergers is shared in the review of several other recent transactions. The Connecticut Attorney General, for example, recently issued a report examining "hospitals' ability to engage in provider-based billing" as a result of their acquisition of physician practices.[16] Similarly, the Massachusetts Health Policy Commission expressed concern that one result of Partners Healthcare System's acquisition of South Shore Hospital could be that the affiliated Harbor Medical Associates would begin to charge facility fees.[17]

It is true that when hospitals acquire physician groups, these acquired physicians can in certain circumstances claim higher reimbursement rates than when they were independent. But this is not the result of enhanced market power accruing from the acquisition. Rather, as noted earlier, in the case of Medicare, it is based on established payment policy. When private payor contracts also contain provisions for higher reimbursement rates for services delivered in a hospital-affiliated setting, any immediate rate increase results from transferring the acquired

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[14] Robert Mechanic & Darren Zinner, *Many Large Medical Groups Will Need to Acquire New Skills and Tools to be Ready for Payment Reform*, 31 HEALTH AFFAIRS 1984-1992 (2012).

[15] Department of Health and Human Services Office of Inspector General, *Medicare and Beneficiaries Could Save Billions of CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, A-05-12-00020 (April 2014); MEDICARE PAYMENT ADVISORY COMMISSION. REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY, Ch. 3 (March 2014).

[16] State of Connecticut Attorney General George Jepsen, *Report of the Connecticut Attorney General Concerning Hospital Physician Practice Acquisitions and Hospital-Based Facility Fees* (April 16, 2014).

[17] Commonwealth of Massachusetts Health Policy Commission, *Review of Partners HealthCare System's Proposed Acquisitions of South Shore Hospital* (HPC-CMIR-2013-1) and Harbor Medical Associates (HPC-CMIR-2013-2), *Final Report* (February 19, 2014) *available at* http://www.mass.gov/anf/docs/hpc/20140219-final-cmir-report-phs-ssh-hmc.pdf.

physician group to the existing hospital contract. It does not reflect the exercise of market power in negotiating a new contract.

In fact, this situation is identical to one in which one hospital is acquired by another hospital that has existing higher rates, and the two hospitals are combined into a single license number that moves both onto the acquiring hospital's existing payor contracts. In this situation, the price increase is contractually sanctioned for the remaining duration of the contract, and, again, does not reflect the exercise of market power, since both contracts were negotiated before the acquisition occurred. Only when the contract is renegotiated can market power, if it exists, be exercised, but this is a separate concern relating to the competitive effects of the transaction as a whole rather than to the specifics of the existing contracts.

VI. CONCLUSION

Casual observers may wonder why so much attention and resources have been paid on a transaction involving 24 physicians in a relatively small city. In fact, St. Luke's acquisition of Saltzer epitomizes the fundamental debate raised at the intersection of antitrust policy and health care reform. In the many markets that are not large enough to support multiple scaled integrated delivery systems, how can providers organize and operate in a way that allows them to accomplish the goals of health care reform while at the same time convincing the antitrust agencies that they will not exercise market power?

A recent report authored by several leading health economists and policy makers recommends that:

> the antitrust enforcement framework [be updated] to place greater emphasis on favoring clinical integration activities that are accompanied by financing reforms that move away from FFS payments and place providers at financial risk for quality gaps and higher costs…. Many clinical coordination arrangements or even mergers among high market-share organizations could be considered safer if the merged organizations…implement contracts with payers that place substantial emphasis on reducing overall costs while improving quality and if subsequent performance on these measures improves significantly. We view this as more meaningful evidence on the value of care than analysis that focuses on prices for specific services.[18]

Implementing such a recommendation implies that the antitrust agencies must recognize that significant merger-specific benefits result from many provider combinations, while the merging parties must clearly and concretely articulate that they are using their combination to foster the goals of health care reform.

[18] Engelberg Center for Health Care Reform at Brookings, *Bending the Curve—Person-Centered Health Care Reform: A Framework for Improving Care and Slowing Health Care Cost Growth*, pp. 8 and 31 (April 2013).

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North Carolina Dental: The Supreme Court and State Action Antitrust Immunity

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North Carolina Dental: The Supreme Court and State Action Antitrust Immunity

Jane E. Willis & Amy D. Paul[1]

I. INTRODUCTION

It is well-settled under Supreme Court precedent that antitrust immunity may apply when either (i) a state exercises its legislative authority by passing a regulation or (ii) an actor acts at the direction of the state, even if that action results in anticompetitive effects or harm to the competitive process.[2] A threshold question for application of state action immunity is whether the actor is a state (public) or private actor because this determination drives the level of scrutiny applied to the action at issue. While it may seem simple enough in principle, it is difficult in practice to determine, based on existing case law, whether certain committees or boards, although affiliated with and sanctioned by state and local governments, are public or private actors.

On March 3, 2014, the Supreme Court granted certiorari in the case of *North Carolina State Board of Dental Examiners v. Federal Trade Commission* ("*North Carolina Dental*").[3] As a result, the Supreme Court will have the opportunity to clarify the state action immunity doctrine, including whether an entity is a public or private actor, and provide guidance as to when conduct is exempt from antitrust scrutiny.

II. THE ISSUE: PRIVATE OR PUBLIC ACTOR?

Whether an entity is a public (state) or private actor determines whether a one-part or two-part test applies when determining state action immunity. In *California Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.*,[4] the Supreme Court created a two-part test "to determine whether anticompetitive conduct engaged in by private parties should be deemed state action and thus shielded from the antitrust laws."[5] First, "the challenged restraint must be one clearly articulated and affirmatively expressed as state policy."[6] Second, the conduct "must be actively supervised by the State itself."[7]

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[1] The authors are, respectively, Partner and Associate in the litigation department of Ropes & Gray LLP.

[2] *See* Parker v. Brown, 317 U.S. 341, 351 (1943) (holding that the "Sherman Act makes no mention of the state as such, and gives no hint that it was intended to restrain state action or official action directed by a state").

[3] Case number 13-534, in the U.S. Supreme Court.

[4] 445 U.S. 97 (1980).

[5] Patrick v. Burget, 486 U.S. 94, 100 (1988) (citing *Midcal*).

[6] *Midcal*, 445 U.S. at 105 (internal citations omitted).

[7] *Id.*

If an actor is the state or a public actor, it needs only to satisfy the first prong, which it can do by identifying the state policy that clearly articulates its purpose is to displace competition.[8] The rationale for this reduced scrutiny stems from the comfort that public actors' conduct is "likely to be exposed to public scrutiny," and thus will be "checked to some degree through the electoral process."[9] Some entities such as counties, municipalities, and other substate government entities are deemed to be state actors and thus are not subject to the active state supervision requirement under *Midcal*.[10] When an actor is private, immunity will apply only if the actor can satisfy both *Midcal* prongs.

A. Background Facts

North Carolina Dental involves a board ("Board") that was statutorily created to regulate the practice of dentistry.[11] The eight-member Board is comprised of six licensed dentists, one licensed dental hygienist, and one consumer member. The dental members are elected by dentists; the hygienist member is elected by dental hygienists. The governor appoints the consumer member. Board members, other than the consumer member, are required to maintain an active dentistry practice while serving on the Board. Thus, a majority of the Board consists of dentists engaged in active practice, elected by other dentists. In addition to the issuance, denial, and revocation of dentistry licenses, it is also granted a broad power to "take other disciplinary measures against a licensee as it deem[ed] fit and proper."[12]

If the Board suspects that an individual is engaging in the unlicensed practice of dentistry, it is permitted to bring an action to enjoin the practice in North Carolina Superior Court or to refer the matter to the District Attorney for criminal prosecution.[13] It does not have the express authority to discipline unlicensed individuals or issue orders.

The case before the Supreme Court concerns the provision of teeth-whitening services. Both dentists and non-dentists provide these services, though non-dentists may do so at a significantly lower price than dentists. The Board opened an investigation into teeth-whitening services provided by non-dentists. As a result of its investigation, the Board took several actions, including sending 47 cease-and-desist letters to 29 non-dentists and sending letters to shopping mall operators encouraging them not to lease kiosk space to non-dentists providing these services. The Board's actions had the result of impeding non-dentists from providing these services and deterring suppliers of teeth-whitening products used by non-dentists from selling such products in North Carolina. These actions threatened the availability of teeth whitening services at reasonable prices to North Carolina consumers.

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[8] How to determine whether the clear articulation prong has been satisfied is an issue that was decided by the Supreme Court in FTC v. Phoebe Putney Health System, Inc., 133 S. Ct. 1003 (2013). The Court held that a state's "grant of general corporate powers to [an actor] does not include permission to use those powers anticompetitively." *Id.* at 1007.

[9] Town of Hallie v. City of Eau Claire, 471 U.S. 34, 45 n.9 (1985).

[10] *See id.* (holding that municipalities must only satisfy the first prong) and *Phoebe Putney*, 133 S. Ct. at 1007 (finding that a state-sanctioned hospital authority was a substate government entity).

[11] N.C. GEN. STAT. § 90-29(b)(2).

[12] N.C. GEN. STAT. § 90-41.

[13] N.C. GEN. STAT. § 90-40.1.

B. The FTC's and the Fourth Circuit's Decisions

In 2011, the Federal Trade Commission ("FTC") issued a Decision and Order that the Board had illegally thwarted lower-priced competition by engaging in anticompetitive conduct to prevent non-dentists from providing teeth whitening services to consumers in the state. In analyzing whether the Board was a public or private actor, it held that the "operative factor" in determining whether a public-private hybrid entity,[14] such as a regulatory body like the Board, was required to meet the active supervision prong was the "degree of confidence that the entity's decision-making process is sufficiently independent from the interests of those being regulated," particularly financial interests.

The Fourth Circuit agreed with the FTC that because the majority of the Board was comprised of market participants (i.e., dentists), who were "chosen by and accountable to their fellow market participants," it was therefore a private actor subject to both *Midcal* prongs.[15]

The court then found that the Board could not satisfy the active supervision prong. The Board argued that certain reporting provisions and "good government" provisions under North Carolina law were evidence of active state supervision. The court disagreed, finding that this type of "generic oversight" was insufficient to satisfy the degree of required state review. Instead, the court held that because the Board sent the cease-and-desist letters without state oversight and without the required judicial authorization from the Superior Court, the active supervision prong could not be satisfied; therefore, the Board's actions were not entitled to antitrust immunity.

III. WHY THIS DECISION MATTERS

Both the Fourth Circuit's decision and the Supreme Court's grant of certiorari have generated considerable interest among the antitrust bar, as well as professionals and companies that participate in regulated industries. Depending on the Supreme Court's ruling, quasi-governmental boards across the country could be emboldened to take similar actions that may be anticompetitive, knowing that they have antitrust immunity just as if a state legislature itself had take the action. The result could be exclusion of competitors from an industry—as is alleged in *North Carolina Dental*—or higher prices, lower output, lower quality, or other reductions in competition.

Notably, this case will mark the second time in two years (*Phoebe Putney* being the first) that the Supreme Court has confronted the ambiguities surrounding state action antitrust immunity. The outcome in *North Carolina Dental* will shape and effect antitrust cases for years to come.

IV. THE SUPREME COURT GRANTED CERTIORARI

In its petition to the Supreme Court, the Board argued that the Fourth Circuit's decision created a "circuit split" on the issue of whether the Board is a state or private actor, and therefore whether a one-prong or two-prong test applies. The split is a result of the perceived tension between the Fourth Circuit's decision to require active supervision in this case and the Ninth and Fifth Circuits' declination to require active supervision in other cases. The Board argued that the

[14] The entity is both public and private because it is established by statute but comprised of private citizens.
[15] 717 F.3d 359, 368 (4th Cir. 2013).

Fourth Circuit's decision was contrary to these precedents, which establish the rule that a state entity's enforcement of an anticompetitive state policy is exempt from antitrust scrutiny—"without regard to the public officials' independence from private interests, method of selection, or supervision by other state entities."[16]

In *Earles v. State Bd. of Certified Public Accountants of Louisiana,*[17] the Fifth Circuit considered the status of Louisiana's state board of Certified Public Accountants ("CPAs"), which had promulgated rules prohibiting CPAs from carrying out their accounting practices while simultaneously selling securities. The court held that the board was a state actor "despite the fact that [it was] composed entirely of CPAs who compete in the profession they regulate," and thus exempt from the active supervision requirement. The court opined that the "public nature" of the board's actions would cause it to not act self-interestedly.

Hass v. Oregon State Bar[18] involved the Ninth Circuit applying the one-prong test to the Oregon State Bar based on several factors, including that there were non-lawyers on the board of governors, that the records were open for public inspection, and that its accounts were periodically audited by the state auditor. The Ninth Circuit took the view there was an electoral "check" on the actions of the board that would hold the board accountable at least to members of the profession.[19]

The grant of certiorari in *North Carolina Dental* comes only one year after the Supreme Court granted certiorari in *FTC v. Phoebe Putney Health System, Inc.*, 133 S. Ct. 1003 (2013). In that case, the Supreme Court decided that a hospital merger in Georgia previously approved by the county hospital authority was anticompetitive and the approval was not entitled to antitrust immunity. The justices voted unanimously that state action immunity applies only when the state legislature has a clearly articulated policy to displace competition and a state's grant of general corporate powers is insufficient to meet this standard.

Phoebe Putney did not provide the Court an opportunity to address the public versus private actor question because the FTC did not challenge the Eleventh Circuit's determination that hospital authorities qualified as "political subdivisions."[20] Given that it was not appropriate to address the issue in *Phoebe Putney*, the Supreme Court may have seen *North Carolina Dental* as the proper case to address this important component of the state action immunity doctrine.

V. HOW THE COURT WILL RULE

The Court's decision in *North Carolina Dental* may further provide guidance regarding the underlying question of whether the determination of state versus private actor is more of a bright-line test or a facts-and-circumstances test. In other words, are there some state-created entities (the Fourth Circuit calls these "quintessential state agencies") entitled to immunity

[16] Petition for Writ of Certiorari, North Carolina State Board of Dental Examiners v. Federal Trade Commission, at 10 (No. 13-534).

[17] 139 F.3d 1033 (5th Cir. 1998).

[18] 883 F.2d 1453 (9th Cir. 1989).

[19] *Hass*, 883 F.2d at 1460 & n.3.

[20] *Phoebe Putney*, 133 S. Ct. at 1011 n.5.

without a showing of active supervision, while others are not? If so, how does one determine what those "quintessential state agencies" are?

In *Town of Hallie v. City of Eau Claire*, the Supreme Court recognized immunity for municipalities—official sub-state entities—without a showing of active state supervision.[21] Without explicitly defining what entities—other than municipalities—may constitute state actors, the Court suggested that its rule may not be limited to municipalities. In a key footnote, the Court stated:

> In cases in which the actor is a state agency, it is likely that active state supervision would also not be required, although we do not here decide that issue. Where state or municipal regulation by a private party is involved, however, active state supervision must be shown, even where a clearly articulated state policy exists.[22]

The Board has urged the Court to expound on the footnote in *Hallie* and rule that state-created agencies, such as the Board, acting pursuant to their grant of power, are engaged in official conduct and, as subdivisions of the state or "substate entities," do not require active supervision. The State asks the Supreme Court to rule that, when dealing with official state agencies, a one-prong test applies, without consideration of how the agency members were selected. Given the facts and circumstances of *North Carolina Dental*, which point so heavily to the conclusion that the Board is a private actor (market participants elected by market participants with only one state-appointed member), a reversal of the Fourth Circuit's decision could well establish a bright-line rule that would insulate these types of boards from investigation by antitrust regulators and for liability for anticompetitive conduct. Such a ruling could, therefore, cause substantial adverse effects on consumers and the general public.

Alternatively, the Supreme Court could endorse a test like that proposed by the FTC, that turns on an inquiry into the facts and circumstances of the individual body, including the selection process for decision makers and to whom they are responsible, when determining whether a state agency or board is subject to antitrust scrutiny. Such an approach would likely result in an affirmance of the Fourth Circuit's decision.

Notably, in *Earles v. State Bd. of Certified Public Accountants of Louisiana*, the government had a greater hand in the selection of the board members. Pursuant to statute, the seven members of the board were chosen by the governor from a slate of candidates proposed by other accountants. Candidates were then confirmed by the state senate. In the original state action immunity case—*Parker v. Brown*—six of the nine members of the State Commission were required to be farmers, and thus were market participants, but the farmer members were appointed by the governor and confirmed by the state senate.[23] In light of these cases, the Supreme Court may agree with the Fourth Circuit that the process for selecting a board's members is relevant to the immunity inquiry. If so, the Court could distinguish the North Carolina Board from those in *Earles* and *Parker* and hold that, if a board's members are elected by market participants (without the intervening choice of state officials), then it is a private actor for purposes of antitrust immunity. This approach would seemingly accord with the holdings in

[21] 471 U.S. 34, 45-47 (1985).

[22] *Id*. at 46 n.10.

[23] The Commission was regulating the terms on which a commodity could be sold.

two other Supreme Court cases—*Midcal* and *Goldfarb v. Virginia State Bar*—both of which emphasized that when a state subdivision like a board has the characteristics of a private actor and takes actions that ostensibly benefit its own members, the two-prong test should apply.[24] This approach would protect consumers from actions by boards that are dominated by market participants whose conduct is unchecked.

VI. CONCLUSION

The fact that the Supreme Court granted certiorari in this case has resulted in substantial interest, not only from the antitrust bar but also from executives in various professions and industries across the country that are regulated by states in a similar manner. The decision will have an important effect not only on antitrust doctrine but also, more practically, on how government entities, such as professional boards, are governed and ultimately on how professions regulate themselves, as well as on how much authority such professional groups have to limit lower cost providers.

Professional licensing boards regulate nearly one-third of the U.S. workforce across 800 different occupations.[25] If the Supreme Court immunizes these boards' potentially anticompetitive actions, the market for these professional services may become skewed by self-interested participants, which will ultimately harm consumers.

[24] Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975) concerned a minimum fee schedule for attorneys. The Supreme Court held this constituted price-fixing that was not immunized by state action because the State did not compel the minimum-fee schedule.

[25] *See* Aaron Edlin & Rebecca Haw, *Cartels By Another Name: Should Licensed Occupations Face Antitrust Scrutiny?*, U. PA. L. REV. (forthcoming 2014).