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I. INTRODUCTION

In an earlier article commenting on the District Court decision in the *FTC vs. St. Luke's* litigation,[2] I pointed out that the court recognized that the acquisition of Saltzer by St. Luke's was intended to, and would have had the effect of, improving patient outcomes.[3] The court still blocked the acquisition, however, because it found that there might have been other ways to achieve those improved outcomes and that since St. Luke's had not proven that the acquisition path was the only viable one, it had not chosen the least restrictive alternative. Therefore, St. Luke's had not rebutted the government's *prima facie* case based on the market share of the proposed merged entity.[4]

The Court of Appeals affirmed, stating that while the parties and the court believed that the merger was intended—and indeed would have led to—better patient outcomes, the District Court had correctly found that the huge market share of the post-merger entity created a substantial risk of anticompetitive price increases and that the offered efficiencies were not an adequate defense.[5]

Two rather provocative issues for health care mergers come out of the decisions in this case: (1) The policies and intent of the Affordable Care Act[6] seem to have no effect on the antitrust analysis to be applied in these cases: and (2) High post-merger market shares/HHIs create a presumption of harm that cannot be rebutted except by the nearly impossible task of proving a negative (that there is no less restrictive way to achieve the better patient outcomes). The *prima facie* case has become close to irrebuttable.

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[2] FTC v. St Luke's Health System Ltd., Case No. 1:13 – CV-00116-BLW (D. Idaho January 24, 2014) (hereinafter "District Court Decision"), affirmed, St. Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System Ltd., 2015 WL 525540 (9th Cir. February 10, 2015) (hereinafter "Court of Appeals Decision"). The decisions and other filings are collected at https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa. Citations to the Court of Appeals opinion are to the Westlaw text and pagination.

[3] District Court decision at 3; *see* Bernard, *Patient Outcomes vs. Competition: Squaring the Circle in FTC v. St. Luke's*, 9(2) CPI ANTITRUST CHRON. 5 (September 2014).

[4] *Id.* at 4-5.

[5] Court of Appeals decision at 11.

[6] Patient Protection and Affordable Care Act, P.L. 11-148 (March 23, 2010). *See* Bernard, *supra* note 3, at 2-3 for an overview of those policies.

II. THE POLICY AND INTENT OF THE AFFORDABLE CARE ACT HAVE NO EFFECT ON ANTITRUST ANALYSIS—EFFICIENCIES AS UNICORNS

The case against the merger was straightforward. A market was defined (primary care physician ("PCP") services in and around Nampa Idaho), the market shares and HHIs were computed, and the plaintiff rested, secure in the presumption that such a high market share created such a substantial risk of price increases that it didn't have to prove anything else in order to make out its *prima* facie case. St. Luke's presented a defense, arguing benefits to patient care and implementation of the policies of the Affordable Care Act. The District Court found that (i) even if St. Luke's arguments were correct and (ii) that the merger would increase patient care, those facts did not rebut the plaintiff's case based on market share. The Court of Appeals affirmed. But in so doing, the court has made it virtually impossible to argue successfully not merely for improved quality of care as a defense, but even to argue for overall health costs savings as a defense.

The FTC position is that an argument based on improved quality of care may be legitimate, but that the agency has never actually seen one because (to the FTC) the quality improvements are always "speculative" or the parties cannot prove that the merger is "necessary" to achieve them.[7] On this view a defense based on quality of care really is a unicorn—beautiful to contemplate, but never seen in real life.

In one sense the benefits of a merger are always speculative—they haven't occurred yet because the merger hasn't occurred yet. This applies whether the claimed efficiency is better patient care, or the ability to reduce prices because of economies of scale. It is all "speculative" until it is done.[8] But the idea that the merger must in some sense be "necessary" to achieve the desired result creates an almost impossible burden on the merging parties. What the Court of Appeals decision in this case confirms is effectively a reallocation of the ultimate burden of proof.

On the facts of *St. Luke's* what the parties were challenged to prove is that a merger (which had not yet taken place) would provide benefits not attainable by a series of rather complex contractual arrangements (which had not been negotiated). This is not a situation where a "committed team" had already been assembled in that market and had shown that it could generate the patient quality results sought by St. Luke's.[9] As the Court of Appeals noted: "It is difficult enough in Section 7 cases to predict whether a merger will have future anticompetitive effects without also adding to the judicial balance a prediction of future efficiencies."[10] But the court's answer—to require St. Luke's to present "empirical evidence" to support the need for the merger[11]—is to require a showing that approaches impossibility.

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[7] Speech of Deborah Feinstein, Director, Bureau of Competition, Federal Trade Commission, *Antitrust Enforcement in Healthcare: Proscription not Prescription*, at page 11 (June 19, 2014), *available at* https://www.ftc.gov/system/files/documents/public_statements/409481/140619_aco_speech.pdf

[8] One could argue that all of Section 7 is speculative. It is an incipiency statute. But if you are going to allow speculation to show harm, you have to allow speculation to show benefits as well or else you have drastically altered the allocation and quantum of the burden of proof.

[9] Cf. Court of Appeals decision at 20.

[10] *Id.*at 18.

[11] *Id.* at 20.

There is a deeper issue here than just what happens in Nampa, Idaho. The Affordable Care Act and the Accountable Care Organizations arising under it, come from a different policy starting point that Section 7. The idea is to improve patient care and thereby reduce costs.[12] But the payment structure has not yet begun to change. The economic incentives are still there to try to raise prices for individual services.[13] So let's concede for the sake of argument that a merger such as this may lead to an increase in the cost of PCP services. But that leads to another question—how much of an increase is too much? A 10 percent increase in the cost of PCP services would raise health insurance premiums by about 1 percent (assuming the whole increase was passed through).[14]

More provocatively, what if the entire predicted increase in PCP costs was offset by the predicted savings on hospital costs (something outside of the decision's analysis entirely)? What if the increase in PCP costs resulted in a net savings on health care costs, because of fewer hospitalizations? These are not purely hypothetical questions. Rowena Rosenblum-Bergmans, vice president of population health for the Western Connecticut Health Network stated "What we have seen in other ACOs is that primary care visits go up, and hospitalizations go down."[15]

The importance of this approach should not be disregarded by antitrust authorities and the courts. It is the expressed intent of the Affordable Care Act to drive more usage (and hence more costs) to PCPs, *thereby* saving on hospital costs, *thereby* saving on overall costs. Under the Affordable Care Act, PCP costs cannot be looked at as a stand-alone silo. They have to be viewed in the context of overall health care expenditures.

This is no longer strictly a quality of care argument—it is one based on dollars and cents and phrased in traditional efficiency terms. What we are asking is whether measurable savings, outside of the defined antitrust product market but related to it as a matter of a separate federal law, can be used as a defense against potential price increases within the defined market. The Affordable Care Act demands an approach that treats health care expenditures as interrelated. The Department of Health and Human Services, in supporting the "Next Generation ACO Model," recently defined the goal as

> [T]he "Better, Smarter, Healthier" approach to improving our nation's health care and setting clear, measurable goals to move the Medicare program—and the health care system at large—toward paying providers based on quality, rather than quantity, of care.[16]

Under this approach an increase in cost per unit of care might well be outweighed by a reduction in the number of units of care needed, and/or also might also reduce the need for other medical care (i.e. hospital services) resulting in net cost savings both at the PCP level and in terms of overall healthcare costs. And, as noted earlier, increasing primary care visits (and

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[12] *See*, e.g., Dick Perrefort, *A "seismic shift" in store for Medicare Patients*, CONN. POST B.1(March 5, 2015); *available at* http://www.ctpost.com/news/article/Seismic-shift-in-health-care-delivery-on-tap-6120906.php

[13] *See* Bernard, *supra* note 3, at 3.

[14] *See* Bernard, *supra* note 3, at 4 and sources cited therein.

[15] Perrefort, *supra* note 12, at B.2.

[16] CMS, Next Generation ACO Model Frequently Asked Questions (March 10, 2015), *available at* http://innovation.cms.gov/Files/x/nextgenacofaq.pdf

therefore costs) is indeed expected to lead to such an overall cost saving result. How would this model be accommodated in the current legal analysis?

These are extremely difficult questions to answer. The Court of Appeals handled them by simply ruling that quality of care arguments are ineffective under the Clayton Act: "It is not enough to show that the merger would allow St. Luke's to better service patients. The Clayton Act focuses on competition, and the claimed efficiencies therefore must show that the prediction of anticompetitive effects from the prima facie case is inaccurate."[17] But the prediction of effects is limited to the market as defined. The fair implication of this approach is that the claimed efficiencies must be measured in the same market/silo as the costs. Net overall savings don't count. The parties are left trying to show that the presumption of price increases from the Government's *prima facie* case is inaccurate. It is to the presumption issue that we now turn.

III. HANDLING THE BURDEN OF PROOF

The Court of Appeals laid out the basic "burden shifting" framework for Section 7 cases:

> The plaintiff must first establish a prima facie case that a merger is anticompetitive. The burden then shifts to the defendant to rebut the prima facie case…[I]f the defendant successfully rebuts the prima facie case, the burden of production shifts back to the Government and merges with the ultimate burden of persuasion, which is incumbent on the Government at all times.[18]

According to the Court of Appeals, the District Court held that the government had established its *prima facie* case because of the post-merger St. Luke's (1) market share in the Nampa Idaho PCP market, (2) ability to negotiate higher primary care reimbursement rates with insurers, and (3) ability to charge more ancillary services at the higher hospital billing rate.[19] On market share, the post-merger HHIs were dramatically high, with an HHI of 6,219 and an increase of 1,607. On that basis, the District Court found the merger to be presumptively anticompetitive under the 2010 Horizontal Merger Guidelines.[20] As we will discuss below, this finding effectively ended the case.

On reimbursement rates, the District Court found that St. Luke's "would likely" use its post-merger power to negotiate higher PCP reimbursement rates from insurers. The Court of Appeals held that this was not clearly erroneous.[21] In so doing, it held that this prediction was a finding of fact. This is significant, since the District Court's finding that St. Luke's would raise prices in the hospital-based ancillary services market was given no such deference. The Court of Appeals held that absent an express finding of market power in the ancillary services market "it is difficult to conclude that the merged entity could easily demand anticompetitive prices for such services."[22] The documents cited by the District Court "merely" stated that St. Luke's hoped to increase revenue from ancillary services, not that it planned to charge higher prices.[23]

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[17] Court of Appeals Decision at 20.
[18] *Id.* at 12 (internal citations omitted).
[19] *Id.* at 14-15.
[20] *Id.* at 15.
[21] *Id.*
[22] *Id.* at 16.
[23] *Id.*

It is difficult to see any difference between a hope to increase primary care physician services reimbursement, and a hope to increase revenue from ancillary services. The only ways to increase revenue on the system as viewed by the courts here are to increase reimbursement or increase the volume of services. And this applies both to PCP services and to ancillary services. Yet, as to ancillary services, the Court of Appeals does not treat the District Court conclusion as a finding of fact all, and certainly does not apply the deference of the "clearly erroneous" standard to it. This would be a fascinating issue to pursue if the Court of Appeals hadn't made it clear in the next section of its opinion that no findings as to future prices actually were required at all.

This conclusion may seem somewhat surprising, but it flows naturally from the Court of Appeals' analysis. Regardless of any other facts, to the Court of Appeals "The extremely high HHI on its own establishes the prima facie case."[24] The HHI is a calculation. It is not a finding of fact as to something that has occurred as the result of the merger. It is a calculation of market concentration that leads to an inference of power to raise prices or reduce output. It is worth noting, again, that there is no evidence of actual price changes in the record—whether increases in PCP costs or net savings from increased quality of care—on the record.

So how can a defendant rebut the *prima facie* case created solely by the HHI, especially when the defense/justification for the merger is overall cost savings (going beyond the product market as defined for HHI purposes) and/or better patient care? The strong suggestion from this case is that you cannot rebut the case on the numbers, that the *prima facie* case is in fact an irrebuttable presumption of harm that the transaction violates Section 7. The efficiencies defense, whether in terms of patient care or overall health care cost savings, is reduced again to our unicorn.

The Court of Appeals noted that "However, none of the reported appellate decisions have actually held that a Section 7 defendant has rebutted a prima facie case with an efficiencies defense..."[25] The court went on to state that it remains "skeptical" about efficiencies defenses in general, stating that it is "difficult enough" trying to predict whether a merger will have future anticompetitive effects, without trying to balance a prediction of future efficiencies.[26] Perhaps realizing that this is an extreme position, the court backtracked a bit and assumed that rebuttal of the *prima facie* case is possible, but then required proof that the merger was not, in fact, anticompetitive.

This effectively shifts the ultimate burden of proof and the risk of non-persuasion to the defendant. If the defendant can prove that the merger is not anticompetitive, what does it mean to say that the burden then shifts to the Government? What would the Government have to prove?

The fact that this is effectively a shift of the ultimate burden of proof is further supported by the court's assertion that the defendant must show that any economic efficiencies cannot readily be achieved without the concomitant loss of a competitor (i.e. without the merger).[27] The

[24] *Id.* at 16.
[25] *Id.* at 18.
[26] *Id.*
[27] *Id.* at 19.

District Court held that St. Luke's failed to produce "empirical evidence" that the merger was necessary to produce the claimed benefits, and the Court of Appeals found that not clearly erroneous.[28] But surely this requires too much. In fact, it is difficult even to conceive of what such "empirical evidence" might be. If there were no merger, but rather a network of contracts among all of the primary care physicians to share risk and reward, this would be a loss of competition too. Are we presuming that the *ex-ante* state of the market was perfectly competitive, or that an atomistic market is by definition the most competitive and that therefore any increase in concentration leads to increases in costs?

By refusing to allow consideration of any other factors beyond economics and limiting that consideration to a single silo'd market, the FTC and the courts are not simply ignoring the policies of the Affordable Care Act, they are in fact relying on the unexpressed presumption that the markets for health care services behave the same way as the markets for widgets: that more providers means lower costs. There is evidence that this is an invalid, or at least unproven, presumption in health care.[29] The assumption that health care is a traditional commodity for antitrust analysis deserves exploration rather than simple acceptance.[30]

IV. CONCLUSIONS

There are two major lessons from the Court of Appeals decision in this case.

1. In cases such as this, the presumption raised by a high HHI is effectively irrebuttable. Any attempted rebuttal must be on purely economic terms, must be limited to the metes and bounds of the market set out, and must demonstrate by empirical evidence that the proposed transaction is the least restrictive alternative to reach the desired outcome.
2. Policies and values that are not immediately reducible to dollars and cents in the defined product market are irrelevant, even if those values are set out in more recent statutes (such as the Affordable Care Act).

It is important to note that these conclusions, and this limited view, have not always represented the law. Back in 2001 Genzyme and Novazyme merged. They were the only two companies doing research on a particularly difficult, and fatal condition, Pompe disease. At the time, there was no treatment available for the disease.[31] The merger took place in 2001, and the investigation was closed in 2004 with no action taken. The question that ultimately proved to be decisive was whether allowing the merger made it more or less likely that an effective treatment for Pompe disease would be discovered and brought to market.

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[28] *Id.* at 20.

[29] Some 36 states still have Certificate of Need laws, allowing the government to determine if there is a need for a new facility before allowing it to be built. The concept is that more facilities could lead to higher costs and duplication of services. The idea is to coordinate the provision of services. The understanding was that more providers could result in higher, rather than lower costs. *See* National Conference of State Legislatures, Certificate of Need: State Health Laws and Programs (updated July 2014), *available at* http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx. *See* generally Bernard, *supra* note 3, at 2.

[30] Indeed it is the thesis of this article that such an assumption is not accurate. *See* text accompanying notes 12-16, *supra*.

[31] For a description of the case, *see* Bernard, *Innovation Market Theory and Practice: an Analysis and Proposal for Reform*, 7 (1) COMPETITION POL'Y INT'L 159, 176-178 (Spring 2011).

Under the approach taken by the FTC and the courts in St. Luke's such considerations would have been treated as irrelevant. A merger to monopoly would have been deemed to create a presumption of illegality. It would be impossible to prove that there was no possible less restrictive alternative. And the fact that the merger in fact did increase the chances of finding an effective medical treatment for Pompe disease would be disregarded since it is not reducible to dollars and cents, and it would be extraordinarily difficult to product empirical evidence in advance that the merger would increase the chances of medical success. If that were the approach applied, it would have been a very bad choice. In April 2006 the FDA approved the first treatment for Pompe disease. It was made by Genzyme.[32]

My point is not that the facts of St. Luke's are on a par with those in Genzyme. I only want to suggest that by allowing such a strong presumption of illegality based solely on market share in a tightly defined silo, and by so severely limiting the possible defenses (even those in strictly economic terms), the FTC and the courts risk creating a structure where the expressed concerns and policies of the Affordable Care Act are deemed to be outside of the range of proper consideration in these cases. The need to consider a broader range of factors, and a broader range of potential costs and cost savings, was pointed out in the *St. Luke's* case by a group of hospitals that provide care to low income persons.[33]

Antitrust has had to be reconciled with other values in the past. In the recent financial crisis, mergers in the financial sector were allowed (even encouraged) that never would have passed traditional antitrust analysis.[34] Other factors not only were taken into account, they were deemed to be decisive. Perhaps the Affordable Care Act policies need to be taken more seriously in our antitrust analysis today, and not simply treated as a unicorn.

[32] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108645.htm .The combined research program produced a successful result that neither company seemed close to achieving by itself.

[33] Amicus Brief of America's Essential Hospitals, *available at* https://www.ftc.gov/system/files/documents/cases/140619stlukeessentialamicusbrief.pdf .

[34] *See* Bernard, *U.S. Antitrust 2025: How Have We handled the Bulletproof Cartels?* CPI ANTITRUST J. (December 2010).