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Editor's Report

In this edition of the *Chronicle*, we are pleased to offer three original articles that together cover antitrust issues relating to the pharmaceutical industry in the United States as well as healthcare issues in the United Kingdom:

- The first article, by **Joel Cohen** and **Tina Wang** of Davis Polk, discusses recent antitrust enforcement developments in relation to pharmaceutical product reformulation.
- In our second article, **Frank Qi** of Ropes & Gray discusses recent merger enforcement in the pharmaceutical sector where pipeline divestitures have been required.
- The third article, by **Bill Batchelor** and **Victoria Yuan** of Baker & McKenzie provides an overview of the application of competition law to the U.K.'s National Health Service and summarizes the first enforcement efforts by U.K. healthcare regulator, Monitor.

As you know, we are always interested in hearing from our Committee members. If there is a topic that you would like to see covered in a Committee program or if you have any other suggestions, please contact the Committee Co-Chairs, Jeff Brennan (jbrennan@mwe.com) or Philip Nelson (nelson.p@east.ei.com).

If you are interested in writing an article for the *Chronicle*, please contact Amanda Lewis (alewis1@ftc.gov).

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Product Innovation or Product "Hopping?" – Differing Assessments of Pharmaceutical Product Development and Marketing Activities

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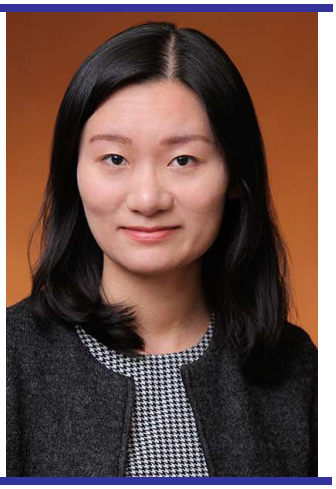

Introduction

It is generally agreed that product development and innovation are pro-competitive. All else equal, the introduction of new and improved products should benefit consumers. That is particularly true in the pharmaceuticals business, where the introduction of new products may improve the health and even extend the lives of consumers. If competitors are unable to keep up, or to develop new products to meet consumer demand, that generally is not a concern of antitrust law.

In certain situations, however, courts have had to grapple with allegations that consumers and/or competitors have come to rely on an older version of a product that has been superseded by a new one. In that setting, the question has been raised whether the transition from old to new is accomplished in a manner that violates the antitrust laws. Years ago, this issue arose in the context of the introduction of new computer platforms that were not compatible with equipment designed for use with a prior version, thus frustrating competitors who had relied on compatibility with the prior version. More recently, the issue has arisen in the complex regulatory world of the pharmaceuticals business. In particular, questions have arisen whether and when the introduction of new drugs (or new formulations or dosages of existing drugs) may frustrate the entry of generic drugs that rely upon the existence of the older product or formulation. The introduction of the new drug (or formulations or dosages of existing drugs) are combined, in some cases, with termination of sales of prior versions. In some circles, the product transitions involved in the pharmaceutical business are referred to, perhaps derisively, as product "hopping."

This article examines the case law that addresses so-called product hopping, culminating (for now) with the Second Circuit's recent decision in *New York v. Actavis*,[1] in which the court took the unprecedented step of ordering a pharmaceutical company to continue selling a product it no longer wished to sell on terms ordered by the district court. The cases raise a number of questions including: (i) whether withdrawal of a product from the market can by itself trigger antitrust liability; (ii) whether and to what extent additional "exclusionary" conduct is required for antitrust liability; (iii) whether the law imposes an affirmative obligation to *facilitate* generic competition; and (iv) whether and how courts should consider the potential for chilling innovation by regulating a company's ability to

[1] 787 F.3d 638 (2d Cir. 2015).

transition to a new product. This article examines these issues.

Background on Product "Hopping"

The Hatch-Waxman Act sought to strike a balance between lowering drug prices (by facilitating entry of generic versions) and incentivizing innovation. Under the Act, a company that develops a new drug is rewarded with exclusivity for a number of years. At the same time, however, certain barriers to generic entry[2] were removed or reduced and generic competitors were incentivized to challenge patents they thought were invalid, unenforceable, or not infringed. In addition, under state substitution laws, pharmacists are permitted or required to substitute a "pharmaceutically and therapeutically equivalent," or AB-rated, generic (e.g., same active ingredient, strength and absorption, form, and delivery method) when filling a prescription, unless the prescribing physician or the patient requests otherwise. Insurance plans and other payors also incentivize generic substitution of brand drugs through various mechanisms, including by assessing higher co-payments for brand drugs for which generic equivalents are available. Thus, once its patent or other regulatory exclusivity period expires, a popular brand drug may be faced with a "patent cliff," (i.e. the loss of a substantial portion of its sales upon entry of generic competition.

Transitioning patients from an old product (facing current or imminent generic competition) to a new product with a patent or other exclusivity period can extend the commercial life of a product family and mitigate the negative financial impact of a patent cliff. In a common scenario, a company, facing expiration of the original patent or other regulatory exclusivity period, will introduce: (i) a new drug covering the same indication or (ii) a different formulation or dosage of the older drug, whose exclusivity period is expiring. The extent to which the new version offers significant patient benefits compared to the older version can vary, but generally the generic version of the older drug (or formulation) cannot be automatically substituted by pharmacists for a prescription that specifies the new version. Accordingly, if the older brand name drug or formulation is not widely prescribed prior to its patent expiration, a generic manufacturer of the older drug may have difficulty generating sales upon market entry unless physicians decide (absent continued marketing efforts by the brand company) to continue writing prescriptions for the older product.[3]

Legal Development: From Technology to Pharmaceuticals

Technology Cases

In a line of "product redesign" cases stretching back to at least the late 1970s, courts have evaluated allegations that a technology company's design change of a popular product harmed competitors that relied on compatibility with the older product. Some courts initially focused on the question of whether the new product offered additional benefits to consumers, as in the IBM cases.[4] Plaintiffs claimed that IBM, a monopolist in central processing units, redesigned its new models in ways that offered little or no technological improvement in order to undermine competition from manufacturers of previously compatible

[2] An example of a barrier that was removed for generic entrants was the need to replicate clinical testing.

[3] In some cases, the brand company will cease marketing efforts for the older product upon introduction of a new version or formulation of the drug.

[4] *Cal. Computer Prods., Inc. v. Int'l Bus. Machines Corp.*, 613 F.2d 727 (9th Cir. 1979); *Memorex Corp. v. Int'l Bus. Machines Corp.*, 636 F.2d 1188 (9th Cir. 1980); *Transamerica Computer Co. v. Int'l Bus. Machines Corp.*, 698 F.2d 1377 (9th Cir. 1983).

supporting devices, purportedly in violation of Section 2 of the Sherman Act.[5] The evidence adduced at trial showed that IBM's new designs saved costs and improved performance. The Ninth Circuit held that IBM "was under no duty to help…other peripheral equipment manufacturers survive or expand" and that "IBM need not…have constricted its product development so as to facilitate sales of rival products."[6] The court suggested that as long as a monopolist is exercising its "right to redesign its products to make them more attractive to buyers,"[7] whether by price or quality, it should not face antitrust liability for any adverse impact on competitors.

The Second Circuit's 1979 decision in *Berkey Photo v. Eastman Kodak*[8] focused on whether the putative monopolist had "coerced" consumers to buy its new product. The plaintiff challenged Kodak's introduction of a new film that was only compatible with Kodak's new camera and thus allegedly undermined the competitiveness of the plaintiff's cameras. The Second Circuit stated that, while there was sufficient evidence that the redesign of the old film was "not technologically necessary," and that a jury could reasonably find that the new film was an inferior product to the old film, market forces (not the antitrust laws) should determine competitive outcomes, so long as "the free choice of consumers is preserved."[9] The court held that so long as Kodak's "success is not based on any form of coercion," then Kodak need not show that the new product is superior to the old one.[10] The Second Circuit noted, in dicta picked up in subsequent cases, that "the situation might be completely different" if Kodak had ceased producing its old film upon the introduction of the new film, "thereby compelling" consumers to buy the new film and camera model.[11]

The courts have continued to struggle with the proper balance of regulating conduct that may hinder competition, while at the same time avoiding undue interference with legitimate product innovation. In *United States v. Microsoft*, the D.C. Circuit held that Microsoft's redesign of its Windows operating system to integrate its Internet Explorer browser more tightly was anticompetitive, because the redesign did not make Microsoft's product "more attractive to consumers" but instead reduced use of rival products "through something other than competition on the merits."[12] The court observed that Microsoft had no commercial justification for certain of its product changes other than exclusion of competing products.[13] In 2010, in a medical device case, the Ninth Circuit held that a product introduction must involve "some associated anticompetitive conduct" in order to violate the Sherman Act, and that a design change that benefitted consumers should be permissible.[14]

[5] *Cal. Computer Prods., Inc.*, 613 F.2d at 739.

[6] *Id.* at 744.

[7] *Id.*

[8] 603 F.2d 263 (2d Cir. 1979).

[9] *Id.* at 279, 287.

[10] *Id.* at 287.

[11] *Id.* at 287 n.39.

[12] 253 F.2d 34, 65 (D.C. Cir. 2001).

[13] Microsoft redesigned Windows in three ways such that Internet Explorer was non-removable by the user, had commingled code with Windows, and could override user browser selections in certain circumstances. The court found that Microsoft had no justification for the first two actions other than exclusion to protect its operating system monopoly but credited Microsoft's procompetitive justification that it had "valid technical reasons," apparently not challenged by plaintiffs, for the third action. *Id.* at 66-67.

[14] *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp.*, 592 F.3d 991, 998-99 (9th Cir. 2010).

Pharmaceutical Cases

Courts in recent years have addressed antitrust claims challenging the introduction of new pharmaceutical products and reformulations. Plaintiffs in these cases generally have alleged that a defendant's product introduction offered no added benefit to consumers and/or that the defendant employed aggressive tactics to get patients to switch to the newer product, in order to hinder or delay generic competition. In response, defendants generally argued that the new versions of drugs offered benefits to patients, and that companies have a right to decide which of their products to market. As will be seen below, the results have been mixed for branded pharmaceutical companies defending against such claims.

In *Abbott Laboratories v. Teva Pharmaceuticals*,[15] the defendant Abbott twice introduced different formulations and dosage forms of TriCor, an anti-cholesterol and triglycerides drug, and removed each older version from the market before generic entry occurred. According to the court, Abbott re-formulated the drug from capsule to tablet form, and then changed the dosage strength of the tablet form. In addition to discontinuing the older versions, Abbott bought back existing supplies of the older drugs and, perhaps most significantly, it removed the older versions from the National Drug Data File (NDDF), which allegedly prevented pharmacies from filling prescriptions with a generic version of the older drug. The court found that Abbott's actions precluded "free" consumer choice. The court held that plaintiffs did not have to prove that the new formulations had zero benefits, nor that the only purpose of the reformulations was to exclude generics. Instead, plaintiffs had to show that, under the rule of reason, anticompetitive harm from the formulation changes was not outweighed by their procompetitive benefits. Under the facts of that case, particularly given the aggressive efforts purportedly taken to make it difficult, if not impossible, for generics to obtain sales, the court held that plaintiffs had stated a viable claim under Section 2 of the Sherman Act.[16]

Two years later, on a different set of facts, another district court ruled in favor of the brand manufacturer. In *Walgreen v. AstraZeneca Pharmaceuticals*,[17] a D.C. district court dismissed claims against AstraZeneca for ceasing to promote Prilosec, whose patent had expired, and instead promoting Nexium, a drug that allegedly offered no added therapeutic benefit compared to Prilosec. Echoing *Berkey Photo*, the court stated that antitrust law did not require that a new product be superior to existing products. Unlike the defendant in *Abbott Labs*, AstraZeneca had not taken steps to prevent generic substitution by pharmacists. This "critical factor" was missing, the court found. Instead, the court held that AstraZeneca had added a new choice (Nexium), rather than eliminating an existing alternative, and thus the company should not be subject to antitrust liability.[18]

Last year, in *In re Suboxone Antitrust Litigation*,[19] the Eastern District of Pennsylvania found that terminating sales of the older version of a product, combined with alleged disparagement of that product, sufficed for an antitrust claim to survive a motion to dismiss. The court held that, even though the defendant had not purchased existing supplies or changed NDDF codes as in *Abbott Labs*, the withdrawal of the older version taken together with the

[15] 432 F. Supp. 2d 408 (D. Del. 2006).

[16] *Id.* at 421-24.

[17] 534 F. Supp. 2d 146 (D.D.C. 2008).

[18] *Id.* at 151-52.

[19] 64 F. Supp. 3d 665 (E.D. Pa. 2014).

alleged false marketing claims "could plausibly coerce" consumers.[20]

This year, the Eastern District of Pennsylvania revisited this issue, this time with a different result, in *Mylan Pharmaceuticals v. Warner Chilcott*.[21] In that case, the defendant reformulated and introduced different dosage forms of Doryx, an acne drug, and allegedly took other actions, including stopping sales of older products, that the court found were designed "primarily to defeat generic competition," though the reformulations also "provided some benefit to consumers."[22] The court granted summary judgment in favor of defendants. It held that the conduct was not anticompetitive due to lack of exclusionary harm, because the plaintiff, Mylan, was capable of competing effectively with respect to the "old" dosages and formulations for which its generic was approved. In addition, other competing acne medications were on the market (including products with the same active ingredient as Doryx) when the "hops" occurred. Moreover, the court found that Mylan could have chosen to market its own products rather than rely solely on state substitution laws, and also noted "undisputed evidence" that third-party payors continued to promote generic substitution even where the generic versions were not AB-rated.[23] Finally, the court expressed concern that imposing antitrust liability could impede innovation: "The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs."[24] The case is currently on appeal to the Third Circuit.[25]

Finally, *New York v. Actavis*,[26] decided on May 22, 2015, provided the first opportunity for an appellate court to weigh in on product "hopping" in the pharmaceutical context. The Second Circuit held that terminating sales of the older version of a product can be sufficiently "coercive" to state a cause of action, even in the absence of other affirmative acts by the brand manufacturer to undermine generic entry. In doing so, the court sought to draw a sharp distinction between a "soft" switch (in which the old product remains on the market) and a "hard" switch (in which the old product is withdrawn), with the latter being more susceptible to an antitrust claim than the former.

Forest Laboratories (subsequently acquired by Actavis, which recently changed its name to Allergan) had developed a once-daily version of its popular Alzheimer's drug, Namenda, and allegedly took various steps to stop selling its

[20] *Id.* at 682-84.

[21] No. 12-3824, 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015).

[22] *Id.* at *5.

[23] *Id.* at *13.

[24] *Id.* at *16.

[25] On Sept. 30, 2015, the Federal Trade Commission ("FTC") filed an amicus brief in support of Mylan, arguing to the Third Circuit that the district court had erred in its antitrust analysis. The agency argued that generic companies' investment in marketing would undermine their ability to offer the low prices on which they compete, and that, therefore, state substitution is generics' only "practical or feasible" means of distribution. Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant, at 24-25, in *Mylan Pharm., Inc. v. Warner-Chilcott PLC*, No. 15-2236 (3d Cir. Sept. 30, 2015). The FTC also stated that third-party payors' efforts to promote substitution of newer brand drugs with generic versions of the original drugs have been "generally ineffective." *Id.* at 9. In response to the district court's concern about any impact on the incentive to innovate, the FTC argued that imposing antitrust liability would be unlikely to chill "genuine" innovation because product "hopping" involves "minor product tweaks that have little or no therapeutic value" accompanied by "calculated efforts to damage or destroy the market for the original formulation." *Id.* at 29. In any case, the agency noted, "genuine" innovation can be weighed as a procompetitive justification (though for the act of reformulation rather than ceasing of sales). *Id.*

[26] 787 F.3d 638 (2d Cir. 2015).

older, twice-daily version and switch patients to the newer version. Specifically, it was alleged that Actavis publicly announced (and notified the FDA) that it would discontinue the older version, requested the federal Medicare and Medicaid agency remove the older version from its formulary list, and urged health providers to discuss switching to the newer version with their patients. Actavis eventually established a single supply source, by a mail-order company, with alleged additional restrictions on access by customers. The district court held that Actavis's conduct raised substantial questions that violations of Sections 1 and 2 of the Sherman Act exist. It issued an injunction providing that Actavis must continue to make its older version of Namenda available on the same terms as before it implemented its alleged "hard" switch strategy, until one month after generic entry.[27] Actavis pursued an expedited appeal.

On appeal, Actavis and numerous amici curiae (including antitrust economists and business professors) argued, among other things:

1. Antitrust law does not impose a duty to aid competitors by selling a product solely to help rivals gain market share;

2. Actavis did not engage in the type of exclusionary behavior that was alleged in *Abbott Labs* – it simply ceased selling a superseded product on the ground that a once-daily version was a significant benefit to Alzheimer's patients and their caregivers;

3. The decision to stop selling once-daily Namenda did not foreclose generic competition. As the *Mylan* court found, generics are free to compete by marketing their own products. Moreover, third-party payors (from insurers and health plans to pharmacy benefit managers) will continue to incentivize physicians, patients, and caregivers to switch to cheaper generics;[28]

4. Restricting the flexibility of a drug company to devote its resources toward maximizing the success of a new product (developed over a number of years at significant expense) would undermine incentives to innovate, ultimately reducing consumer welfare; and

5. Antitrust law should not be a "vehicle for enforcing the spirit" of other statutory schemes (e.g., Hatch-Waxman Act or state drug laws).[29]

The Second Circuit affirmed the district court's judgment and upheld the injunction. The court acknowledged, but did not find persuasive, the fact that once-daily Namenda was an improved product that yielded consumer benefits. Instead, the court focused on the fact that Actavis had chosen to stop selling the old product (a "hard" switch)[30] rather than permitting consumers to choose between the old and the new (a "soft" switch), concluding that the former involved the type of "coercion" that triggers antitrust liability. The court found that the purpose and effect of terminating sales of twice-daily Namenda was to "coerce" consumers into

[27] *New York v. Actavis, PLC*, No. 14-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).

[28] Such incentives may take the form of formularies (which impact health plan coverage), tiered-drug structures (which impact patient co-payments), step programs (which require patients to try first a preferred, usually cheaper, drug), and prior authorization (which requires patients to obtain insurer approval before taking a drug).

[29] Amici supporting defendants pointed out that the federal and state drug laws are not geared towards promoting competition, but at achieving certain market outcomes directly through regulation.

[30] The court stated: "Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal." *Actavis*, 787 F.3d at 648.

switching and to foreclose generics' "critical" avenue of competition through state substitution laws. The court then stated that Actavis' argument that imposing antitrust liability would deter innovation lacked supporting evidence; instead, the court credited the argument of amici supporting the plaintiff that immunizing Actavis's conduct "may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations."[31] The court "conclude[d] that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act."[32]

Implications and Policy Considerations

Where does this leave us? As noted above, the case law is a mixed bag. On the one hand, there is support for the proposition that the benefits conferred by the new product – i.e., the significance of the innovation – can be an important part of the analysis and can serve as a counterweight to any concern about impeding generic competition for a superseded product. On the other hand, there is support that such evidence is irrelevant. Similarly, there is support for the proposition that terminating sales of the old product can be sufficient to create an antitrust claim (*Actavis*), but also support for the proposition that termination of sales is not sufficient without substantial *additional* conduct that has the effect of excluding generic competition (*Abbott Labs*).

Faced with this series of mixed messages, risk-averse pharmaceutical companies and their counsel may look to *Actavis* as not only a decision by the highest court to evaluate product "hopping" (thus far), but also the one that goes farthest toward a rule of presumptive illegality if a product withdrawal can be said to "force" patients to switch to the new product and thereby blunt generic competition. A strong argument can be made that such a rule is bad public policy. A company considering expending substantial sums on innovation with respect to a product nearing patent expiration (clearly something to be encouraged) would have to include in its calculus the possibility that it will be forced to carry the superseded product beyond what is commercially sensible in order to facilitate competition that might undermine the value of the new product and thus the company's return on investment. (Indeed, Forest had undertaken significant clinical testing to obtain FDA approval for the new once-daily labeling of Namenda.)[33] Additionally, it should not automatically be assumed that, as some claim, an *Actavis*-type rule enforces the "competitive spirit" of the drug laws, even if it were appropriate for antitrust law to do so. As noted above, the Hatch-Waxman regulatory scheme sought to achieve a compromise between lowering price and incentivizing innovation. It is not necessarily clear that condemning in this way product "hopping," which does not contravene the letter of the drug laws, strikes a proper balance between drug innovation and price competition or properly facilitates price competition without impeding

[31] *Id.* at 659.

[32] *Id.*

[33] *See, e.g.*, Forest Laboratories, Inc., "Forest Announces U.S. Availability of New Once-Daily NAMENDA XR" (June 13, 2013), *at* http://investor.frx.com/press-release/business-development-news/forest-announces-us-availability-new-once-daily-namenda-xr ("The efficacy and safety of NAMENDA XR was established in a randomized, double-blind, placebo-controlled trial of 677 outpatients on a stable dose of acetylcholinesterase inhibitors (AChEl). AChEIs are a different class of prescription drugs often used in combination with NAMENDA for the treatment of moderate to severe Alzheimer's disease.").

innovation. Such arguments may persuade courts to consider these issues in the future, but for now, *Actavis* is a case that must be reckoned with.

It is tempting to read *Actavis* for the simple proposition that a "hard" switch (ceasing sales of the superseded product at or prior to the expiration of its exclusivity) is always illegal, while a "soft" switch (keeping the superseded product available as a choice for consumers) is always legal. As with most simplifications, that is not quite right. While directionally a hard switch is more likely to create a competitive impact than a soft switch under the reasoning of *Actavis*, that will not always be the case. For example, one can imagine a hard switch that does not involve any "coercion," as in *Mylan*, where there were a number of competitive alternatives and generics had the ability to compete with respect to the same product in different formulations. On the other hand, one can also imagine a "soft" switch in which the old product continues to be offered but only on such unfavorable terms as to be considered to have effectively been withdrawn from the market. Beyond that, there is ample authority for an argument that, despite some of the broader language in *Actavis*, a "switch" to a new product should not be unlawful absent affirmative conduct, beyond a decision to stop selling a superseded product, that blunts or eliminates generic competition.

The bottom line is that, absent further clarification from appellate courts or the Supreme Court, each situation will have to be evaluated on its specific facts. The factors that likely will be taken into account will include the following: (i) whether the existing product will remain available for sale (and on what terms), (ii) whether the company has taken any steps that could be viewed as hindering the ability of generics to sell their product based on an old brand product's New Drug Application, and (iii) the extent to which consumers will have alternatives if they decide not to purchase the new product. In our view, the analysis may, and should, also include the extent to which the new product represents a meaningful advance in technology, and involved a substantial investment in innovation, as a pro-competitive counterweight to any purported reduction of competition from generics for the superseded product.

Pipeline Divestitures in Pharmaceutical Mergers: An Overview

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Introduction

An explosion of deal activity has reverberated through the pharmaceutical industry over the last two years. Industry observers tallied 36 pharmaceutical transactions valued at over $1 billion each in 2014, compared with only 17 such transactions in 2013. This frenzied M&A pace has carried over into 2015. The first two quarters of this year witnessed the closing of 74 pharmaceutical and biotechnology transactions valued at a total of $194 billion, and an additional 125 transactions valued at a total of $125 billion were announced in the second quarter.[1]

In lockstep, there has been a palpable increase in the number—and perhaps intensity—of the Federal Trade Commission's ("FTC") antitrust enforcement actions in this space. Like previous pharmaceutical merger waves, this latest aggressive spending spree has been driven at least partially by the need to acquire or combine R&D pipelines and capabilities to offset impending losses of exclusivity on blockbuster drugs. In many instances where drug pipelines are being acquired, the FTC has determined that divestiture remedies are necessary to prevent potential or future competition from being harmed by the proposed transaction. This is likely to come up in one of two ways: (1) where one firm has a product in the market and another firm is actively engaged in R&D in the same space; and (2) where neither of the firms has marketed products, but both are engaged in R&D efforts to address the same medical need.

Merging parties navigating this territory will find, for a variety of reasons, little case law analyzing the FTC's remedial requirements in pharmaceutical potential competition cases.[2] But the wealth of FTC consent decrees to which one can refer proves extremely instructive. In addition, the FTC has published extensive guidance on the characteristics of divestiture

[1] Pharmaceutical and Life Sciences Deals Insights Quarterly Q2 2015, *available at* https://www.pwc.com/us/en/health-industries/pharma-life-sciences/publications/assets/pwc-pharma-deals-insight-q2-2015.pdf.

[2] *See, e.g.*, Dissenting Statement of Commissioner Joshua D. Wright, *In the Matter of Nielsen Holdings N.V. and Arbitron Inc.* (FTC File No. 131-0058), September 20, 2013 (describing how merging parties frequently acquiesce the FTC consent decrees even where they believe no competition harm exists because the "alleged relevant product market is small relative to the overall deal size").

remedy proposals that are sufficient to address the alleged competitive harm in mergers.[3]

Two "environmental factors" today put the spotlight more squarely on divestitures. First, the FTC is under enormous pressure, both mission-driven and political, to put a check on pharmaceutical industry consolidation and rising drug prices. This has led the agency to take aggressive approaches in "substantive" antitrust law; in other words, the agency is more likely to determine that a merger will diminish competition and require divestiture. This enforcement posture is coupled with a key second factor: recent highly publicized remedy failures in Hertz-Dollar Thrifty and Albertsons-Safeway. Now, more than ever, the FTC is especially focused on getting its remedies right and will tolerate zero risk in approving divestiture packages. Indeed, the FTC is currently conducting a retrospective analysis of the effectiveness of remedies in 90 merger consent orders spanning 2006-2012, updating and expanding upon the last comprehensive divestiture review in 1999.

Thus, with parties' interests focused on getting the broader deal through, and extremely high scrutiny on the FTC to get it right, we are likely to see more, deeper, and broader consent decrees than in years past. In many ways, this shift is difficult to measure empirically from the outside: non-parties are not privy to the discussions with FTC staff regarding what needs to be divested and to whom. In light of this context, this article reviews the FTC's divestitures requirements and examines how key components apply in the pharmaceutical pipeline divestiture context.

Potential Competition and Pipeline Divestitures

Regularly through both consent decrees and recently in a litigated case, the FTC pursues potential competition cases across industries. The typical situation involves harm to competition where "actual potential competitors" that otherwise were poised to enter the market are acquired. "Perceived potential" competition is a theory that an incumbent firm perceives another firm as a potential entrant and thereby refrains from charging higher prices that could induce the potential competitor to enter the market.

Although the majority of antitrust merger analysis can best be described as a predictive exercise, it is generally difficult to determine whether a firm constitutes a potential competitor in a relevant market.[4] But in important ways, the pharmaceutical industry, more so than many other industries, is well-suited for potential competition analysis. Because the required FDA approval process for new drugs takes many years to complete and is relatively transparent when compared to entry in other industries, the FTC often is able to determine which firms are most likely to enter a relevant market during a specific time period. Informed on the drug's approval posture and timeline (often with the assistance of the FDA, third parties, and the parties' own SEC filings), the FTC can readily identify firms in the drug regulatory "pipeline" that may constitute potential entrants to the product market at issue.

[3] *See* Negotiating Merger Remedies, Statement of the Bureau of Competition of the Federal Trade Commission, January 2012, *available at* https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf; and Frequently Asked Questions About Merger Consent Order Provisions, *available at* https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/merger-faq.

[4] *See, e.g., Federal Trade Commission v. Steris Corporation et al.*, No. 1:15-cv-1080 (N.D. Ohio, Sept. 24, 2015) (finding that the acquired firm would not have probably entered the U.S. contract sterilization market within a reasonable period of time in competition with the incumbent despite mixed evidence).

To be sure, even though the FDA's approval process may provide a greater degree of predictability than usually is possible in other industries, predictions about pharmaceutical entry are far from perfect. A recent study of the investigational compounds of the top 50 pharmaceutical firms from 1995-2007 revealed that only 7.1% of the 1,442 compounds ultimately received approval, and less than 12% of compounds entering Phase I studies ultimately receive approval.[5] The likelihood of success, however, increases in later stages of development. Indeed, about 62% of drugs entering Phase III progress to the NDA/BLA submission, and of those submitted, about 90% ultimately receive approval.[6]

Whether a specific pipeline asset is likely to enter the market (thereby triggering the FTC's enforcement tripwires), however, remains a case-by-case, fact-intensive inquiry. A prototypical pharmaceutical potential competition case involves a merger between an alleged monopolist or firm with market power that holds the only (or one of the few) effective drug for a particular disease and a firm with a late-stage potentially competitive compound. Here, assuming other factors support an enforcement action, the FTC would allege that the existing monopolist would have significantly diminished commercial incentives to continue R&D on the newly acquired pipeline compound because all of that new (eventual) drug's sales would be diverted from the monopolist's existing drug. Alternatively, the monopolist-acquirer would develop and commercialize the acquired pipeline compound, but pricing competition between the two products would be eliminated via the transaction. In this scenario, the FTC would likely require the divestiture of either the monopolist's existing drug or the acquired pipeline assets to restore competition feared lost.

A close cousin of the prototypical potential competition case involves acquisitions of intellectual property where neither firm is currently in the market. Here, the FTC's concerns center on reductions in R&D, resulting in decreased innovation efforts in markets with few or no competitive therapies. Even though the competitive dimensions at stake here are rivalries in innovation (as opposed to classic price competition), the FTC may still require remedies where substitutes for the innovation assets are far and few between.

Remedies Requirements: Divesting and Licensing Pipeline Assets

In pharmaceutical transactions, the probable anticompetitive effects alleged by the FTC frequently originate from a limited subset of products relative to the overall deal. Many marketed products or pipeline assets are usually being acquired, and the competitive concerns emanating from the offending overlaps can typically be structurally resolved—either via a divestiture or licensing arrangement—because the merging parties' goals and motivations behind the transaction can still be met absent these products. In a broad sense, the structural remedies requirements of the FTC do not differ greatly where the divested assets are existing business/products or pipeline assets that have yet to commercialize. But remedies analysis, like antitrust in general, is a fact-intensive process, and the requirements can differ in some respects. The agency has made no secret that it generally prefers the divestiture of an autonomous, on-going business unit that comprises at least the entire business of one of the merging parties in the relevant market. In pharmaceutical transactions, such divestitures are often infeasible, as discrete pipeline assets

[5] Tufts Center for the Study of Drug Development, Cost of Developing a New Drug, November 18, 2014, *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

[6] *Id.*

almost never constitute autonomous going concerns.

The FTC's Approach: Divestiture Must Replace But-For Likelihood of Entry

In a potential competition or innovation markets case, where a remedy is more likely to involve the divestiture or out-licensing of pipeline assets,[7] the FTC will usually seek to ensure the facilitation of successful competitive entry. This is especially challenging in the pharmaceutical industry, where, despite greater predictability in late stages, even the most promising Phase III compounds routinely fail to win approval and commercialize. Should the divested assets fail to materialize into an actual competitive product, even a thorough post-mortem analysis might not be able to determine whether the causes of failure were the immutable characteristics of the assets or marketplace, or something avoidable if only a divestee-buyer had sufficient assets or a different divestee-buyer was selected. In recognition of these concerns, the FTC has tremendous latitude in crafting hybrid structural and behavioral remedies to ensure the sufficiency of the remedy, such as being able to couple divestitures with interim supply agreements, personnel obligations, and other forms of assistance from the divesting party to ensure the maximum speed and probability of entry by the divestee. What assets are sufficient will also depend significantly on the identity and means of the divestee-buyer.

Fundamentally, the FTC wants to ensure that the divestee-buyer must be willing and able to enter the market with the divested or out-licensed assets. Willingness is about commercial incentives, and this is usually not a concern as long as the parties' proposed divestee-buyer is an independent entity without other commercial entanglements with the parties that could theoretically reduce its incentive to push R&D and eventual commercialization.[8] Ability can be broken down into two categories: (i) divestiture/licensing of all assets necessary for the divestee-buyer to be an effective, long-term competitor; and (ii) a determination of whether the purchaser itself is capable of advancing the divested assets into a competing product.

Key Divestiture Components

Core Components

In pharmaceutical pipeline divestitures, the FTC will automatically assume that the following key components would be necessary in any approvable package: (1) access to key inputs such as a drug's API; (2) R&D capabilities; (3) intellectual property, whether owned or licensed; (4) know-how, trade secrets and other technology; (5) access to or perhaps divestiture of key technical personnel; (6) manufacturing facilities or supply agreements, if necessary; and (7) marketing and distribution capabilities. Given a finding of probable competitive harm, the FTC will assume assets in their pre-merger form represent a faster or more likely path to entry than other potential entrants into the market. The FTC will do everything possible to ensure that the set of assets continue on its development path with a full head of steam – and avoid any possibility of delay that may cause the advancement to languish.

Any deviation from the standard divestiture components requires specific justification by the parties. The onus is on the parties to explain to

[7] In an overlap created by the acquiring party's marketed product and the acquired party's pipeline assets, there is, of course, the possibility that the merging parties would prefer to divest the marketed product. This may be true where the pipeline assets have greater commercial value or opportunity in the long run even though they are not yet on market.

[8] One can imagine a situation where the divestee-buyer has important relationships with the merging parties in other product markets that could theoretically reduce the firm's incentives to compete aggressively against the merging parties.

the FTC specifically why no divestiture of presumptively important assets would be necessary to maximize the divestee's likelihood of success of short-term entry and long-term success. One can imagine a scenario where the FTC would not require divestiture of manufacturing facilities if the divestee already boasts facilities or third party manufacturing relationships capable of integrating and manufacturing the future product. The same can be true of R&D assets – perhaps the divestee already has directly relevant R&D assets and capabilities that would negate the need for wholesale divestiture. But throughout the process, the parties must convincingly show that the divestee-buyer does not require these assets. Perhaps more importantly and credibly, the divestee-buyer must agree that it does not need to acquire these assets in the divestiture.

Out of Market Assets

The FTC's power and flexibility in obtaining a sufficient remedy can even extend to *out of market* assets.[9] Here, the divestiture package may encompass assets relating to relevant product or geographic markets *outside* of the market(s) where competitive harm is probable. As long as the FTC has determined these assets are necessary for the divestee-buyer to compete as effectively as the divesting party would have but-for the transaction, these assets may be required to go in the divestiture package.

A recent example demonstrates how this can play out in a pharmaceutical pipeline divestiture. Just this year, the FTC alleged that a Sun Pharmaceutical and Ranbaxy Laboratories combination would likely harm future competition in generic minocycline *tablets* by reducing the number of suppliers of three dosage strengths.[10] Ranbaxy was one of three existing suppliers of generic minocycline, while the FTC alleged that Sun was one of only a limited number of firms likely to sell generic minocycline tablets in the near future. To remedy the elimination of what would have likely been Sun's entry, the FTC not only required that Ranbaxy divest its interests in generic minocycline tablets (the market where competition would be allegedly lessened), but that Ranbaxy also divest its related capsule assets (capsules were not identified as a market where competition would be allegedly lessened). The purpose of including out-of-market capsule assets was to enable the divestee-buyer to obtain FDA approval for a change in API suppliers for minocycline tablets as quickly as Ranbaxy would have been able to absent the transaction. With this, the divestee-buyer would be able to establish the current API supplier of the generic minocycline capsules as the API supplier for its future generic minocycline tablets through a less time-intensive FDA regulatory process because the divestee-buyer would have control of both capsules and tablets, which use the same API from the same API supplier. Without the additional capsule assets, the divestee-buyer would not be able to enter and sell minocycline tablets as quickly as would have Ranbaxy, and competition would not be maintained in the tablet markets. Additionally, the FTC required that the merging parties supply generic minocycline tablets and capsules to the divestee until the divestee established its own manufacturing infrastructure. All of this would take place under the watchful eye of an interim monitor until the divestee eithers successfully obtained FDA approval of the drug, or abandoned manufacturing efforts (after

[9] Recent examples in the non-pharmaceutical context include Polypore's acquisition of rival Microporous and Community Health Systems/Health Management Associates.

[10] "FTC Puts Conditions on Sun Pharmaceutical's Proposed Acquisition of Ranbaxy," January 30, 2015, *available at* https://www.ftc.gov/news-events/press-releases/2015/01/ftc-puts-conditions-sun-pharmaceuticals-proposed-acquisition.

commercially reasonable efforts to obtain FDA approval), or reached five years.

Another potential out of market divestiture in pipeline pharmaceuticals involves therapeutic indications outside of the market at issue. For example, the FTC might determine there is likely to be competitive harm from a transaction where the acquiring firm's drug is indicated to treat the same condition that the acquired firm's pipeline compound is intended to treat. But the pipeline assets might also be undergoing development for several other unrelated indications where there is no anticompetitive overlap. One can think of oncology drugs that might also be used to treat unrelated diseases like Parkinson's or Alzheimer's diseases. Here, a preferable remedy might be licensing instead of divestiture. The merging parties would seek to retain use of intellectual property in the R&D or production of other products outside the relevant product markets at issue. Not surprisingly, the onus will be on the parties to convince the FTC why licensing is sufficient. Licensing instead of divesting the rights may be insufficient if it limits how the divestee-buyer can use the intellectual property and reduces the divestee-buyer's long-term ability to compete. One solution to this issue is requiring the parties divest the intellectual property but agree that the parties can license back rights to the divested intellectual property. But if a more tailored solution like an licensing if intellectual property regarding the overlapping indication is otherwise unworkable, the FTC may require that the merging parties divest the entire pipeline program, ensnaring with it the rights to indications out of the overlapping markets.

Key Characteristics of an Acceptable Divestee-Buyer

Because pipeline assets are particularly susceptible to deterioration while being held up during the pendency of the divestiture process, the FTC has indicated that it will by default require that a divestee-buyer be vetted and selected upfront (*i.e.*, before the parties are permitted to close).

In screening the proposed divestee-buyer, the FTC will want assurances that the firm is capable of transitioning and integrating a discrete set of R&D assets, and also possesses the scientific, regulatory, and commercial capabilities to take the assets through the FDA approval process and get it to market. Many factors can push the FTC to approve a particular divestee-buyer. The first is strong financial fundamentals: the proposed buyer needs to have the financial capability and incentives to acquire, transition, integrate, develop, and ultimately take to market the assets required. The financial conditions of the divestee-buyer are often scrutinized via balance sheets and other financial reports to assess whether it has the financial wherewithal to meaningfully replace the alleged lost competition. The second involves experience. A successful divestee-buyer tends to be a market participant (even a fringe competitor might do) that already has a track record of acquiring and integrating pipeline assets and developing them into marketed drugs. The more one can show the firm is familiar with the markets in question and/or the divestiture process, the more likely the FTC will approve such a divestee-buyer. Third, the divestee-buyer must develop and present to the FTC detailed plans on how it plans to execute all key tasks, including integration, R&D, regulatory approval, manufacturing, and ultimately go-to-market strategies.

Looking Ahead

We can expect to see more consent decrees that require the parties to divest assets sufficient to eliminate the risk that any potential future failure to enter can be traced to insufficient of divested assets or the selection of an improper divestee-buyer. Facing a deluge of

pharmaceutical mergers, and with a strong incentive to minimize if not eliminate the risk of an unsuccessful remedy, the FTC appears more determined than ever scrutinize divestitures packages for sufficiency and divestee-buyers for appropriateness. And because pharmaceutical transactions are particularly well-suited for limited divestitures, we are unlikely to see the parties (who would rather get the remainder of the deal approved) push back on whether the FTC's exacting requirements are unnecessary at best, and counterproductive at worst. For now, those of us observing from the outside eager await the results of the FTC's retrospective on merger remedies.

Hospitals, the National Health Service and Competition Law in the UK

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Introduction

Lauded by the British public as a "national treasure," the UK's National Health Service (**NHS**) was the first of its kind in the world to provide free and comprehensive healthcare. It is Britain's largest employer and the world's fifth largest. It serves the entire population of the UK, from the urban centers of London to the rural communities in the Outer Hebrides. NHS England's 2014 budget was £97 billion, which is bigger than the GDP of Hungary.

As with many healthcare systems, the NHS faces immense financial pressures. An aging population, escalating drugs bill, lifestyle changes and high profile hospital failures - such as the Mid Staffordshire NHS Foundation Trust - have all added to this pressure.

Into this mix, in 2013, came competition law. The Health and Social Care Act 2012 (**HSCA**) sets out the framework for the application of competition law to NHS bodies for the first time in England. The HSCA provides that UK competition legislation, the Enterprise Act 2002 (**EA02**) and Competition Act 1998 (**CA98**), applies to providers of NHS services. It empowers a healthcare specific regulator, "**Monitor,**" with investigatory and enforcement powers in relation to the sector alongside the generalist competition regulator - the Competition and Markets Authority (**CMA**).

Antitrust oversight has been a shock to the system. Sir David Bennett, the previous head of NHS England, lamented that "we are bogged down in a morass of competition law. We have competition lawyers all over the place telling us what to do, causing enormous difficulty."[1] It is also highly politicized. The then Health Minister, Simon Burns, was forced to deny that antitrust did not mean stealth privatization. "Just in case there's any doubt, we are not privatizing the NHS. This Bill [HSCA] is not about privatizing the NHS."[2]

It has also created huge expectations. NHS England's CEO Simon Steven's "Five Year Forward View" report sets out how competition

[1] Polly Toynbee, *Competition is killing the NHS, for no good reason but ideology*, THE GUARDIAN, Nov. 15, 2013, http://www.theguardian.com/commentisfree/2013/nov/15/competition-killing-nhs-bournemouth-poole.

[2] Simon Burns, *The truth about "privatization" and why government is a risky business*, GOV.UK (Feb. 22, 2012, 6:34 PM), https://www.gov.uk/government/news/the-truth-about-privatisation-and-why-government-is-a-risky-business.

law should drive NHS efficiencies.[3] The New Care Models program is intended to combine best of breed high performing NHS providers to collaborate in the design and establishment of new patient care models.

This article examines how competition law applies to the NHS and Monitor's first enforcement actions in the sector.

How the NHS Works

The Department of Health (**DH**) oversees the NHS. NHS England is responsible for strategic planning and direction of NHS services and also acts as commissioners for specialized or tertiary services and public health services. At a local level, Clinical Commissioning Groups (**CCGs**) are responsible for commissioning Primary Care and Secondary Care for a given local area. They are also responsible for community services, mental health services and rehabilitation Services. They have a statutory duty to act in the best interest of the patients but do not provide any healthcare services. Hospitals are organized into corporate structures of "NHS Trust" and "Foundation Trusts (**FTs**)" though some NHS funded services (e.g. community services) are also provided by private companies. NHS Trusts and FTs are further discussed below.

NHS England and CCGs are together referred to as Commissioners. FTs, NHS Trusts and other providers of NHS funded care are collectively referred to as providers. In addition, there are a number of regulators of NHS services, such as the Care Quality Commission, which is responsible for assessing providers on the quality of care, and the National Institute for Health and Care Excellence (**NICE**), which provides national guidance and advice to improve health and social care.

NHS Market Mechanisms

Treatment is free at the point of delivery, so normal measures of price competition are not easily applied.

Rather, competition should, in theory, improve quality for patients and value for money for tax-payers. Academic studies have shown that increasing competition between providers by adding a rival hospital leads to increased efficiency and improvement in services; this is measured by markers as crude as an increase in survival rates of 9.6% following a heart attack.[4]

Competition in the NHS was introduced by the creation of an internal market in the 1990's where the funding and provision of healthcare were split.

Competition between hospitals for commissioning contracts

Competition in the NHS was also reinforced by the introduction of a "payment by results" system. In 2003, the hospital funding system shifted from block contracts, where they are paid a fixed fee based on historic funding arrangements and locally negotiated adjustments, to a system where hospitals were paid for each patient it treats, taking into account the complexity of the patient's healthcare needs. Therefore, "payment by results" gave hospitals an incentive to operate more efficiently and to innovate.

With the ability to "earn" money, further organizational changes to NHS providers also

[3] NATIONAL HEALTH SERVICE, FIVE YEAR FORWARD VIEW (Oct. 2014), http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf. Simon Stevens is the Chief Executive of NHS England since April 1, 2014.

[4] *See e.g.*, Nicholas Bloom et al., *The Impact of Competition on Management Quality: Evidence from Public Hospitals*, REVIEW OF ECONOMIC STUDIES 1-33 (2015).

allowed them to compete with one another. In 2004, New Labour introduced the first "foundation trusts," which benefitted from increased budgetary autonomy. This encouraged the hospital boards to invest any surpluses in improving quality. At that time, Gordon Brown, the Labour Chancellor of the Exchequer, prevented foundation trusts from becoming fully financially autonomous. They remain under certain constraints. The Coalition Government[5] proposed in 2011 that all NHS trusts become foundation trusts or part of existing NHS foundation trusts by April 2014, a deadline which has long passed.

Competition between hospitals for patients

Since 2006, patients have the right to choose the provider from which they can receive healthcare services. Patients are entitled to choose where they would like to be treated with respect to most elective services, i.e. medical or surgical services for patients who do not need to be treated right away.

This created competition between providers to have high quality of care to attract patients, via physician referrals, directly for elective services.

These policies were intended to create incentives for hospitals to improve quality and innovation to compete for contracts offered by commissioners of healthcare.

The NHS was Historically Antitrust Exempt

In 2002, the BetterCare Group (a private company selling nursing and residential care in Northern Ireland) alleged to the then Office of Fair Trading (**OFT**, since replaced by the **CMA**) that an NHS commissioner (North & West Belfast Health & Social Services Trust, which both commissioned and provided care home services) abused its dominant position by settling a low contract price for private nursing home beds. The OFT in *Bettercare*[6] concluded that competition law was not applicable to NHS bodies in relation to activities funded from general taxation. The rationale given was that the care home was not carrying out an "economic activity" and therefore did not constitute an "undertaking" within the meaning of the CA98. Thus, CA 98 did not apply to the care home *per se*. BetterCare Group appealed against this ruling on the grounds, among others, that the European Court of Justice, which interprets European competition law, defines purchasing care as an economic activity, not one of the welfare state. The appeal was successful,[7] but in 2004 the OFT restated its view that competition law does not apply to NHS services.

Competition Regulation in the NHS

Prior to the HSCA, competition issues in the NHS were addressed with by the Cooperation and Competition Panel (**CCP**) within Monitor. NHS commissioners and providers have been required to comply with the Department of Health's Principles and Rules for Cooperation and Competition (**PRCC**) in relation to NHS funded services. The third and final iteration of the PRCC came into force in October 2010 and they cover four areas: (1) procurement of NHS services; (2) anticompetitive conduct by

[5] Referred to as the Coalition Government, as it was composed of a coalition between the Conservatives and the Liberal Democrats.

[6] OFFICE OF FAIR TRADING, BETTERCARE GROUP LTD / NORTH & WEST BELFAST HEALTH & SOCIAL SERVICES TRUST, No. CA98/09/2003, http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www. oft.gov.uk/ OFTwork/competitionact-and-cartels/ca98/decisions/bettercare.

[7] *BetterCare Group Ltd. v. Director General of Fair Trading*, [2002] CAT 7 (Judgment, Aug. 1, 2002), http://www.catribunal.org.uk/237-570/1006-2-1-01-BetterCare-Group-Limited.html.

providers and commissioners; (3) mergers between NHS organizations; and (4) false and misleading advertising of NHS services. There was no enforcement of the rules, however and PRCC therefore had little or no effect on competition. In addition, as it only applies to NHS Trusts which are being phased out, the PRCC further diminishing in importance.

The CCP only had an advisory role and no enforcement powers to address a breach of competition law by an NHS body.

Passage of the HSCA in 2013 officially introduced competition law to NHS bodies for the first time in England. As a result, NHS providers are subject to EA02 and CA98. The HSCA granted Monitor and the CMA various investigatory and enforcement powers in relation to the NHS.

NHS and the CMA

The HSCA gives the CMA exclusive jurisdiction to review mergers involving NHS organizations. The UK merger review regime has two phases, Phase 1 and Phase 2. A UK merger that qualifies for review is considered at Phase 1 initially and if there are no competition concerns, the merger is allowed to proceed or to proceed with certain conditions. If there is a "realistic prospect for a substantial lessening of competition", the merger is referred to Phase 2 for further review and analysis. The merger control process was recently revised by the Enterprise and Regulatory Reform Act 2013 which amended the EA02.

Since taking responsibility for reviewing NHS mergers, the CMA has investigated three mergers involving only NHS healthcare providers (i.e. where no private healthcare provider is involved) under the new 2014 merger control regime, and one merger under the previous regime (under the EA02). Two of these four cases have been subject to in depth investigation. Bournemouth/Poole[8] was blocked by the CMA following a Phase 2 investigation in 2014[9] and Ashford/St Peters was subject to a Phase 2 investigation but ultimately cleared.[10]

In response to New Care Models introduced in the Five Year Forward View[11] and in anticipation of a potential influx of merger notifications, the CMA published guidance for NHS providers on August 26, 2015 in relation to transactions involving New Care Models. Monitor does not have merger control powers. But it is responsible for advising the CMA's Merger Unit on patient benefits arising from a merger. To date, it has only advised the Mergers Unit on two cases. Most merging parties appear to prefer to spend resources persuading the CMA that *prima facie*, there are no competition concerns, instead of preparing a benefits case to obtain clearance of the transaction. While this strategy may be appropriate for a merger between two hospitals operating in competitive market conditions that are not close competitors, failing to consider patient benefits has led to two Phase 2 referrals and one prohibition out of four NHS mergers.

[8] CMA's investigation of the anticipated merger of Poole Hospital NHS Foundation Trust and The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (2012).

[9] Press Release, Office of Fair Trading, OFT refers healthcare product merger to the Competition Commission (Mar. 24, 2014), http://webarchive.nationalarchives.gov.uk /20140402142426/http://www. oft.gov.uk/news-and-updates/press/2014/20-14.

[10] COMPETITION & MARKETS AUTHORITY, ASHFORD AND ST PETER'S AND ROYAL SURREY COUNTY, A REPORT ON THE ANTICIPATED MERGER OF ASHFORD AND ST PETER'S HOSPITALS NHS FOUNDATION TRUST AND ROYAL SURRY COUNTY HOSPITAL NHS FOUNDATION TRUST (Sept. 16, 2015), https://assets.digital.cabinet-office.gov.uk/media/55f92d86ed915d14f1000016/ Final_report.pdf.

[11] *See supra* note 3.

NHS and Monitor

Monitor is the health sector regulator and is responsible for regulating the NHS, including enforcement of the new NHS Provider Licence[12] which set out conditions on healthcare providers relating to the safeguarding of patient choice and the prevention of anticompetitive behavior.

As a result of the HSCA, Monitor now has new enforcement and investigatory powers as a concurrent regulator with the CMA. However, Monitor and CMA would normally agree between themselves which entity is the best placed to exercise these powers. A Memorandum of Understanding between Monitor and the CMA has been in negotiation since 2014 and yet to be published.

Application of Competition Law to Commissioners

Prior to the HSCA, it was not clear whether commissioners of healthcare are "undertakings" within the meaning of EU competition law and therefore were subject to competition rules.

Section 75 of the HSCA prohibits commissioners from engaging in "anti-competitive behaviour" and they are obliged to "protect and promote the right of patients to make choices." The framework is set out in "The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013," commonly referred to as the "**section 75 Regulations**."

Commissioners must also abide by EU public procurement legislation for the procurement of healthcare. The Public Contracts Regulations 2015 and the section 75 Regulations are both intended to provide a transparent and fair procurement process. Commissioners must not discriminate against providers based on whether they are private or public. Their duty is to ensure that the best provider is selected to meet the needs of the population.

Monitor is responsible for the investigation and enforcement under the section 75 Regulations of commissioner procurement practices and behavior. To date, Monitor has opened five investigations under the section 75 Regulations for alleged unfair procurement practices and for failing to ensure patient choice. Monitor made three decisions and two investigations are ongoing. These investigations were met with outcry,[13] but it is interesting to note that the investigations all began as a result of complaints, from both public and private sector players.

So far, Monitor has taken a pragmatic approach. In one case, a private provider complained to Monitor of the conduct and procurement practices of NHS England in relation to the commissioning of radiosurgery services. Monitor decided to close the case when the issue was no longer relevant because NHS England decided to enter into a contract with the provider who alleged the improper procurement practices.[14] In this case, Monitor acknowledges that issuing guidance is the best way to use available resources and to achieve its objectives. In other cases, however, Monitor accepted undertakings (or conditions), in examples such

[12] The NHS Provider Licence sets out conditions that healthcare providers must meet to help ensure that the health sector works for the benefit of patients.

[13] *See e.g.*, Sarah Neville, *NHS chief says service is 'bogged down in competition law,'* FINANCIAL TIMES (Nov. 5, 2013), http://www.ft.com/cms/s/0/8f1526ec-463b-11e3-b495-00144feabdc0.html#axzz3oRKadYJB.

[14] MONITOR, CASE CLOSURE DECISION ON THE COMMISSIONING OF RADIOLOGY SERVICES (Feb. 26, 2014), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/298501/RadiosurgeryServicesClosure.pdf.

as the *Blackpool* case,[15] and to close the Greater Manchester case,[16] after it revised its commissioning practices to Monitor's satisfaction.

Given the lack of case volume, the regulators and the NHS organizations are still defining their respective roles and responsibilities in the new regulatory landscape.

Current Trends

Mergers

Hospital mergers between 2010 and mid-2015 were essentially driven by the need to combine failing, or substandard, NHS trusts and foundation trusts. This was usually a last resort often to rescue providers from financial difficulties.

There is skepticism as to the effectiveness of mergers to alleviate providers from financial failure and to improve performance. And in some cases, such as *Bournemouth/Poole*[17] and *Frimley Park*,[18] the merger offers little demonstrable benefit to patients.

The *Bournemouth/Poole* merger sought savings to prevent both hospitals sinking further into debt and to harness economies of scale. It involved the merger of two competing hospitals in the same geographic area. The parties proposed to reconfigure five major clinical services (maternity, hematology, emergency department, acute general surgery and cardiology). The merger raised *prima facie* competition concerns. The parties, therefore, were required to demonstrate to the OFT that the merger will give rise to significant relevant customer benefits (RCBs) in the form of improved quality of those services, and that the RCBs could not be achieved without the merger. The parties submitted to the OFT (as it was before the October 2013 of the CMA) that the merger will lead to (1) improved quality and safety of services, (2) delivery of financial savings through economies of scale, (3) improved scope of services and (4) enhanced ability to raise capital.

In Monitor's first merger advice to the OFT, it assessed that RCBs only arise from the merger in relation to the provision of maternity services and (to a lesser and temporary extent) in cardiology services. In addition, Monitor not persuaded by the other benefits claimed by the merger parties as RCBs. In line with the OFT's merger guidance, Monitor weighed the impact on competition against the RCBs. In January 2013, the OFT referred the merger to the Competition Commission (**CC**) for a Phase 2 assessment. On October 17, 2013, the CC issued a decision to block the merger. In that decision, the CC strongly emphasized the need for early engagement and timely provision of accurate and consistent information by merging parties. The CC's main substantive reasons for blocking the merger were as follows:

[15] MONITOR, INVESTIGATION INTO THE COMMISSIONING OF ELECTIVE SERVICES IN BLACKPOOL AND FYLDE & WYRE: MONITOR'S DECISION TO ACCEPT UNDERTAKINGS FROM NHS BLACKPOOL CLINICAL COMMISSIONING GROUP, https://www.gov.uk/government/publications/case-investigation-into-the-commissioning-of-elective-services-in-blackpool.

[16] MONITOR, CASE CLOSURE DECISION ON GREATER MANCHESTER AND CHESHIRE CANCER SURGERY SERVICES (Jan. 31, 2014), https://www.gov.uk/government/publications/case-investigation-into-the-commissioning-of-cancer-services-in-manchester.

[17] Please see above.

[18] COMPETITION & MARKETS AUTHORITY, ANTICIPATED ACQUISITION OF HEATHERWOOD AND WEXHAM PARK HOSPITALS NHS FOUNDATION TRUST BY FRIMLEY PARK HOSPITAL NHS FOUNDATION TRUST, ME/6432-14, https://assets.digital.cabinet-office.gov.uk/media/538dcd34ed915d192f000007/Heatherwood_and_Wexham_full_text_decision.pdf.

1. The parties' proposals on patient benefits were lacking in detail and did not demonstrate that these benefits could be achieved in the near future.

2. There was no evidence that other benefits such as cost savings to commissioners were likely to arise as a result of the proposals.

3. The parties' proposed use of the "friends and family test,"[19] a method of measuring quality by asking patients whether they would recommend the service to family and friends, to offset the substantial lessening of competition was not considered an effective remedy.

In contrast with *Bournemouth/Poole,* competition authorities saw *Frimley Park* as a blue print for the future of NHS mergers reviews[20] and this was echoed by the wider NHS community.[21] In particular, the CMA emphasized that "constructive discussions with the hospitals prior to their formal notification of the proposal, along with the close cooperation between the CMA and Monitor, has enabled us to complete this investigation swiftly." In this case, Monitor did not actually assess whether RCB arose as a result of the merger because it did not receive sufficient information from the parties to do so. Instead, in its role as an interested party to the merger, Monitor wholeheartedly supported the transaction and advised the CMA that the "proposed acquisition appears to us to be the best available solution to the problems faced at Heatherwood and Wexham FT and the most likely way of achieving the necessary improvements to services for patients."[22] CMA noted in its decision that

> [B]ased on the information available to it [Monitor], it is not able to determine that any relevant customer benefits for the purposes of the Act will arise. With respect to Monitor's advice on 'matters relating to the matter under investigation', Monitor stated that in light of HWPH's sustainability, quality and management issues, the merger appears as the best available solution to the problems at HWPH [Heatherwood and Wexham FT] and the most likely way of achieving the necessary improvements to services for patients.[23]

In its decision, the CMA also did not believe that the merger will lead to a material reduction in the quality of services for patients (including clinical factors such as outcomes, infection rates and mortality rates and non-clinical factors such as waiting times and patient experience) and will not materially reduce the hospitals' incentives to innovate and improve their services. As such, given that the CMA had no competition concerns, the CMA did not have to

[19] National Health Service, *The NHS Friends and Family Test (FFT), available at* http://www.nhs.uk/NHSEngland/AboutNHSservices/Pages/nhs-friends-and-family-test.aspx

[20] Press Release, Competition and Markets Authority, CMA clears Foundation Trust hospitals merger (May 14, 2014), https://www.gov.uk/government/news/cma-clears-foundation-trust-hospitals-merger.

[21] Gerard Hanratty, *Heatherwood-Frimley Park shows the way through merger process*, HEALTH SERVICE JOURNAL (Jun. 26, 2014), http://www.hsj.co.uk/home/commissioning/heatherwood-frimley-park-shows-the-way-through-merger-process/5072365.article#.ViA2hmflss0.

[22] MONITOR, ANTICIPATED ACQUISITION OF HEATHERWOOD AND WEXHAM PARK HOSPITALS NHS FOUNDATION TRUST BY FRIMLEY PARK HOSPITAL NHS FOUNDATION TRUST, ADVICE TO THE COMPETITION AND MARKETS AUTHORITY UNDER SECTION 79(5) OF THE HEALTH AND SOCIAL CARE ACT 2012, 3 (May 2, 2014), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317250/Advice_to_CMA_-_Frimley_merger.pdf.

[23] COMPETITION & MARKETS AUTHORITY, *supra* note 18 at 5.

consider whether there were sufficient RCBs to offset any competition issues.

The lessons of the *Poole/Bournemouth* and *Frimley Park* cases are reinforced in the CMA and Monitor's joint guidance to the NHS. The guidance focuses on the importance of early engagement and collating and providing accurate information to the competition authorities. The recently published guidance for NHS providers on transactions involving New Care Models shows that the CMA and Monitor are harnessing the existing expertise to apply the current framework appropriately. In addition, the recent hire by Monitor of a senior CMA economist demonstrates an appreciation of the CMA's experience and approach.

Anticompetitive Conduct

So far, neither the CMA nor Monitor has investigated any NHS body for anticompetitive behavior under CA98. However, Monitor has been active in the investigation of anticompetitive conduct.

In Monitor's investigation of NHS England's selection of future providers of various specialist cancer surgery services in the Greater Manchester area, Monitor decided not to use its concurrent powers under CA98, despite complaints that the process was not based on quality, patient outcomes or patient preferences. Monitor based its decision on the fact that the investigation involved different organizations (including commissioners who are not subject to competition law)[24] and that

> the other rules that these different organisations are subject to, as set out in the previous section, allow us to take enforcement action to address the types of behaviour that might fall within the scope of competition law and it is therefore not necessary to use our competition law powers separately (in particular, Regulation 10 of the Procurement, Patient Choice and Competition Regulations and competition condition (Condition C2) in the NHS provider licence prohibit similar behaviour to the relevant sections of the Competition Act 1998).[25]

As the NHS community becomes more aware of competition law, there are likely to be more investigations as a result of complaints of anticompetitive conduct by providers and commissioners. Monitor is likely to continue to take a lead on these investigations under its powers under the section 75 Regulations and Licence Conditions.

Conclusion

Bringing competition to what is in effect a £100 billion government-run economy was never going to be easy. Its early days have been erratic. Awareness is low, and administrators remain indignant that market rigors have any place in the NHS. So too antitrust is surely not the panacea for all ills that ideologues hoped. But as a brave experiment in flushing out inefficiency and arming the NHS to address the challenges faced globally by healthcare systems, it is to be applauded.

[24] Certain commissioners are not subject to competition law because they do not carry out "economic activities" and are therefore not "undertakings" under UK competition law.

[25] MONITOR, STATEMENT OF ISSUES, CASE CCD 04/13: INVESTIGATION INTO THE COMMISSIONING OF CANCER SURGERY SERVICES IN GREATER MANCHESTER AND CHESHIRE, 10, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284833/CCD_0413_-_Statement_of_Issues_cancer_surgery_services_Greater_Manchester.pdf.

Antitrust is now in place. The immediate challenge remains NHS mergers. These will continue to be a hot topic given the number of providers in the process of becoming part of the New Care Models. In due course, the chill wind of greater rivalry may tempt some to cut corners, and spark enforcement action if collaboration crosses over into anticompetitive conduct, with no countervailing patient benefits. As providers become more aware of competition law, complaints of anticompetitive conduct, or leniency applications, may trigger investigations.

So the NHS remains "national," and competition may yield further "treasure," to the benefits of greater efficiency, better healthcare outcomes, and greater value to UK taxpayers.