The Forward-Looking Nature of Merger Analysis Advanced Antitrust U.S. – San Francisco 2014 Deborah L. Feinstein, Director, Bureau of Competition, Federal Trade Commission^{*}

This year marks the 100th anniversary of both the Federal Trade Commission Act and the Clayton Act. Together with the Sherman Act, enacted in 1890, these laws remain a central feature of our national economic policy, setting standards for vigorous competition and preventing the undue accumulation of market power that threatens consumer welfare and stymies economic growth. Indeed, the basic antitrust statutes have changed little since 1890. With great purpose and foresight, Congress drafted the antitrust laws in general terms specifically to accommodate changing markets and new products. Despite profound changes in the American economy, the common law approach has allowed the antitrust laws to stand the test of time while taking account of changing market environments and economic analysis.

Congress designed Section 7 of the Clayton Act to deal directly with the evolving nature of competition, and in particular, the likely course of future competition in the aftermath of a single event: the elimination of one independent firm. As the Supreme Court noted in *Brown Shoe*, "Congress used the words '*may* be substantially to lessen competition' to indicate that its concern was with probabilities, not certainties."¹ Congress settled on "may be" to mean "reasonable probability" of anticompetitive effects, finding that "[a] requirement of certainty and actuality of injury to competition is incompatible with any effort to supplement the Sherman Act

^{*} The views expressed in this speech are my own and not necessarily those of the Commission or any Commissioner.

¹ Brown Shoe v. United States, 370 U.S. 294, 321-22 (1962). In fact, Congress considered a range of standards of proof, from the merely possible to the absolutely certain, all of which were arguably defensible under prevailing precedent. *Id.* n. 39. The Horizontal Merger Guidelines also note that "Most merger analysis is necessarily predictive, requiring an assessment of what will likely happen if a merger proceeds as compared to what will likely happen if it does not. Given this inherent need for prediction, these Guidelines reflect the congressional intent that merger enforcement should interdict competitive problems in their incipiency and that certainty about anticompetitive effect is seldom possible and not required for a merger to be illegal." Dep't. of Justice & Fed. Trade Comm'n, 2010 HORIZONTAL MERGER GUIDELINES (HMG) § 1.

by reaching incipient restraints."² The task of merger review is to predict with some level of confidence – but not absolute certainty – whether the merger's likely competitive effects based on facts, economic learning, and reasoned analysis require intervention to prevent substantial harm to competition and consumers.

The notion of incipiency imbedded in Section 7 is one of many flexible language choices in antitrust law that can confound business people and provide ample fodder for scholarly debate. These ambiguities have led courts to adopt simplifying rules and burden-shifting to give both sides of a merger case the opportunity to present and rebut evidence bearing on the likely competitive effects.³ But the Commission's analysis does not rest on presumptions. Rather, in this world of probabilities, modern merger analysis at the FTC uses a variety of tools, both qualitative and quantitative, to assess the likely competitive outcome of a proposed transaction.⁴

To prevent this forward-looking analysis from veering into mere speculation, the agencies and courts focus on facts. As any antitrust practitioner knows, a change in one or two key facts can alter the outcome of a merger investigation. Markets – and competitors – can and do change. Predicting competitive conditions after a merger requires an understanding of market

² S. Rep. No. 1775, 81st Cong., 2d Sess. 6. See also 51 Cong. Rec. 14464 (remarks of Senator Reed).

³ United States v. Baker Hughes Inc., 908 F.2d 981, 35-36 (D.D.C. 1990) ("By focusing on the future, section 7 gives a court the uncertain task of assessing probabilities. In this setting, allocation of the burdens of proof assumes particular importance. By shifting the burden of producing evidence, present law allows both sides to make competing predictions about a transaction's effects."). See also Chicago Bridge & Iron Co. v. FTC, 534 F.3d 410, 423 (5th Cir. 2008) ("Typically, the Government establishes a prima facie case by showing that the transaction in question will significantly increase market concentration, thereby creating a presumption that the transaction is likely to substantially lessen competition."); and HMG § 2.1.3 ("Mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power, but this presumption can be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power.") For over six decades, all merger enforcement under Section 7 was post-consummation. There was no premerger review until 1978, after Congress passed the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and the FTC promulgated the HSR Rules to implement premerger notification for most mergers meeting certain fiscal thresholds. The HSR Act enables the antitrust agencies to identify mergers prior to closing that present potential competitive problems, at a point when the agencies can craft an effective prophylactic remedy. See generally Fed. Trade Comm'n, A Study of the Commission's Divestiture Process (1999), available at http://www.ftc.gov/sites/default/files/attachments/merger-review/divestiture.pdf.

dynamics developing in real-time that will likely bear on future competition. In markets, the past is not always prologue. For example, the Commission recently closed its investigation of the Office Depot/OfficeMax transaction without action, 17 years after obtaining an injunction to block the Staples/Office Depot combination. The Commission found significant changes in the competitive environment, including a greater reliance by customers on mass merchants rather than office supply superstores and continued growth of on-line competitors. ⁵

Today I will describe the methods of factual development and the analytical process that we use to predict the likely course of competition going forward and the impact of an acquisition on that competition. As Yogi Berra reputedly said, "It's tough to make predictions, especially about the future." But for nearly 100 years, merger enforcement has grappled with the inherent limitations of predicting the future. It can be tempting when considering an industry that has been around for decades to think that "it has been this way for years, so it will continue this way." Alternatively, for some industries it may be tempting to think that "this industry is evolving so rapidly that no merger can stifle competition, because another game-changing competitor or innovation will come along." A commitment to sound antitrust enforcement should lead us to resist either of these extremes. As the court noted in *Bazaarvoice*, "[i]t is not the Court's role to weigh in on the debate [about how well antitrust is suited to analyzing competition in dynamic markets but rather] to assess the alleged antitrust violations presented, irrespective of the dynamism of the market at issue."⁶ The court noted that "while Bazaarvoice

⁵ See, e.g., Fed. Trade Comm'n, Statement of the Commission Concerning the Proposed Merger of Office Depot, Inc. and OfficeMax, Inc., FTC File No. 131-0104 (Nov. 1, 2013), available at http://www.ftc.gov/sites/default/files/documents/closing_letters/office-depot-inc./officemaxinc./131101officedepotofficemaxstatement.pdf.

⁶ United States v. Bazaarvoice, Inc., 2014 WL 203966, 260 (N.D. Cal.).

evolving nature of the market itself precludes the merger's likely anticompetitive effects."⁷ Hopefully, with requisite humility and open-mindedness, antitrust enforcers will instead continue to employ rigorous fact-finding and analysis to sift out likely outcomes from mere wishes or unfounded speculation when predicting what lies ahead.

Assessing What Current Competitors Will Look Like Going Forward

A typical transaction the FTC investigates is the combination of two direct competitors. Both firms currently sell products into the marketplace and affect the competitive dynamic that determines price and output to customers. The central question of merger review in this situation is whether the elimination of that direct competition is likely substantially to lessen competition. As part of that analysis, we look at whether the transaction will affect not only competition on price, but also other dimensions of competition such as quality, service or innovation. ⁸

To analyze a merger between two long-standing competitors, we typically start by examining historical facts. We look at what market shares have been in past years, whether the companies have marketed or bid against each other before and what factors influenced the prices they set. In a market where competitive conditions are stable, those historical facts may provide all the information we need to feel comfortable in our predictions of the future. But where the

 $^{^{7}}$ *Id.* at 261.

⁸ For instance, in the Commission's action against Precision Castparts' acquisition of Wyman Gordon, the Commission alleged that the combination would result in both higher prices and reduced innovation. *See* Analysis to Aid Public Comment, In the Matter of Precision Castparts Corp. and Wyman Gordon Co., Dkt. C-3904 (November 10, 1999), *available at* <u>http://www.ftc.gov/sites/default/files/documents/cases/1999/11/pccana.htm</u>. HMG section 6.4 outlines circumstances in which a merger may raise concerns about the ability of the merged firm to unilaterally diminish innovation efforts or reduce product variety. For example, a merger that eliminates a likely future entrant is likely to substantially lessen competition if it puts an end to the output expansion or price competition that would otherwise occur. The acquirer of a would-be innovator to the market may have reduced incentives to develop and commercialize a new competing product as quickly as would have occurred but for the merger, or it may reposition the product once it is brought to market in a way that would minimize cannibalization of its existing product.

fortunes of a competitor are likely to change – for better or for worse – we need to take a closer look.

The classic case in which the past was not an adequate predictor of the future is *U.S. v. General Dynamics.*⁹ Both General Dynamics and the company it acquired, United Electric Coal Companies, had high shares of current coal sales. The Supreme Court found, however, that because United Electric had limited uncommitted coal reserves, its past sales were not an accurate predictor of its future competitive significance. Based on that forward-looking analysis, the Court allowed General Dynamics' acquisition to proceed.

Even where a competitor's long-term prospects look dim, the Commission still must assess whether there is short-to-intermediate term competition worth protecting. Imo's 1989 acquisition of Optic-Electronic Corporation is a good example. Both companies produced second-generation image intensifier tubes used in night vision devices used by the Department of Defense. The facts showed that the second-generation product was nearly obsolete and was soon to be replaced by third-generation intensifier tubes and thermal imaging in which the transaction was not likely to cause competitive concerns because Optic-Electronic was not expected to be a significant competitor. Nonetheless, DoD was requesting one final round of bids for products employing second-generation technology. To protect competition in that DoD bid, the Commission challenged the transaction. The district court found that products based on emerging technologies would replace second-generation products, but not for another three to five years. The court pointed to the on-going DoD bid as important competition worth preserving, and granted the FTC's request for a preliminary injunction.¹⁰ When the DoD bid

⁹ 415 U.S. 486 (1974).

¹⁰ FTC v. Imo Industries Inc., 1992-2 Trade Cas. (CCH) § 69,943 at 68,555 (D.D.C. Nov. 22, 1989) (redacted memorandum opinion).

took place, the winning bid came in much lower than the parties predicted, saving DoD an estimated \$23 million.¹¹ Shortly after the bid concluded, the parties again sought to merge. Because there was unlikely to be second-generation competition and no overlap in third-generation technology, the Commission granted prior approval for the combination.¹²

Similarly, the prospects for a new or improved technology can differ by end-use. The Commission took action against the combination of Panasonic and Sanyo with respect to portable NiMH batteries used in two-way radios by police and fire departments, finding that such customers were locked into the use of that type of battery. In contrast, the Commission took no action in the hybrid electric vehicle (HEV) battery market. Although Panasonic and Sanyo were the most significant suppliers of the NiMH batteries used in most current-generation HEVs, improvements in Li-ion technology made Li-ion HEV batteries a superior alternative to NiMH batteries for HEVs.¹³

Assessing Whether a Competitor is "In the Market"

Because Section 7 requires forward-looking analysis, the agencies must assess whether firms not currently selling products or services should be included as "market participants" for purposes of the competitive analysis. This applies both to the merging parties and other competitors that may enter the market. For instance, as the Guidelines note, firms that are committed to entering the market in the near future can be considered market participants even if

http://www.ftc.gov/sites/default/files/documents/reports annual/annual-report-1990/ar1990_0.pdf

¹¹ Janet Steiger, Remarks at Am. Bar Ass'n Section of Antitrust Law Spring Meeting (April 12, 1991), reprinted in 7 Trade Reg. Rep. (CCH), ¶ 50,055, at 4,697.

¹² Fed. Trade Comm'n, 1990 Annual Report, available at

¹³ Press Release, In the Matter of Panasonic Corporation and Sanyo Electric Co., Ltd., Dkt. C-4274 (Nov. 24, 2009), *available at* <u>http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2010/01/panasonic-corporation-</u> corporation-and-sanyo-electric.

not currently deriving revenues from the market.¹⁴ Once we determine that a firm is in the market, we must assess the competitive impact it is having or is likely to have on competition.

In contrast to committed entrants, some firms must expend more effort, either in terms of time or sunk costs, to begin making sales in the relevant market. The competitive significance of such firms will depend on how far along they are in the variety of concrete steps needed to begin actual sales and the likelihood such entry will occur.¹⁵

It is relatively easy to predict the nature of competition going forward when an existing competitor in one geographic market is months away from entering a new geographic market. Pinnacle Entertainment Inc.'s proposed acquisition of Ameristar Casinos presented such a fact pattern.¹⁶ The Commission filed suit in 2013 to block the transaction. In part, the complaint alleged that the acquisition would reduce competition and lead to higher prices and lower quality for casino customers in the Lake Charles, Louisiana market. While Pinnacle already had a casino operating in Lake Charles, Ameristar did not. However, Ameristar had begun building a new casino, Mojito Pointe, that was scheduled to open by the third quarter of 2014.¹⁷ It was not difficult to predict that significant head-to-head competition would exist in the near future absent the acquisition. To settle the allegation concerning Lake Charles, Pinnacle agreed to sell all of

¹⁴ HMG § 5.1.

¹⁵ Section 9 of the HMG identifies various elements of an entry effort: "planning, design, and management; permitting, licensing, or other approvals; construction, debugging, and operation of production facilities; and promotion (including necessary introductory discounts), marketing, distribution, and satisfaction of customer testing and qualification requirements."

¹⁶ In the Matter of Pinnacle Entertainment, Inc. and Ameristar Casinos, Inc., Dkt. 9355 (May 29, 2013).

¹⁷ The Commission's complaint relied on projected 2015 revenues to determine the nature of likely future competition. Complaint, In the Matter of Pinnacle Entertainment, Inc., and Ameristar Casinos, Inc., Dkt. 9355 at 14 (May 29, 2013), *available at*

http://www.ftc.gov/sites/default/files/documents/cases/2013/05/130529pinnaclepart3cmpt.pdf.

the assets associated with the development and construction of the Mojito Pointe casino to an FTC-approved buyer within six months.¹⁸

In other cases, a more detailed inquiry into whether a company is likely to be a competitor going forward is required. The Commission's recent decision in *In the Matter of Polypore* discusses the evidence needed to determine whether a firm not currently making sales should nevertheless be considered a market participant. In its Complaint, the Commission charged that Polypore International Inc.'s completed acquisition of Microporous violated Section 7 because it substantially reduced competition in four North American end-use markets for battery separators. In each of the four markets, the Administrative Law Judge found that the elimination of competition would have adverse effects. On appeal, the Commission upheld the decision in three of the markets and reversed in the fourth.

Microporous' participation varied by market. For deep-cycle and motive batteries, Microporous operated one plant in Piney Flatts, Tennessee and was scheduled to open a second plant in Feistritz, Austria the month after the transaction. From its Tennessee plant, Microporous competed head-to-head with Polypore and the evidence showed Microporous became a stronger competitor once it began constructing its plant in Austria because of its ability to commit to making additional sales.¹⁹ Both the ALJ and the Commission found that the elimination of that current competition, which would only intensify, would harm competition.

¹⁸ Other local markets in which the Commission has relied on planned construction as the basis for concerns about potential competition include supermarkets. *See., e.g.,* In the Matter of Albertson's Inc., Dkt. C-3986 (June 22, 1999) (divestiture of 144 supermarkets and five supermarket sites in 57 local markets); In the Matter of Koninklijke Ahold NV, Dkt. C-3861 (Oct. 20, 1998) (in addition to seven markets in which both companies were direct competitors, Ahold was an actual potential competitor against Giant in Hilltown, Pennsylvania; divestitures included Giant's store in Hilltown).

¹⁹ Opinion of the Commission, In the Matter of Polypore International, Inc., Dkt. 9327, at 38 (Dec. 13, 2010), *available at* http://www.ftc.gov/sites/default/files/documents/cases/2010/12/101213polyporeopinion.pdf.

Microporous had also begun to develop a third type of separator for use in starter, lighting, and ignition (SLI) batteries. The Commission rejected Polypore's argument that Microporous did not compete in the SLI market at the time of the merger. Although Microporous was not yet generating revenues from the sale of SLI separators, it had bid on several supply contracts. It had also made "meaningful progress" to supply two of the largest automotive battery manufacturers in the world. The Commission also pointed to evidence that Daramic (the relevant Polypore business) had reduced its SLI prices in response to Microporous' efforts. Indeed, business executives at Daramic perceived that Microporous was "a true legitimate big competitor entering the market and for sure they will capture volume whatever it takes."²⁰ In the Commission's view, although Microporous lost a bid contest for a major contract, it was exerting sufficient competitive influence to be considered a market participant. Thus, the elimination of an independent Microporous in the SLI market increased the likelihood of anticompetitive coordinated conduct between the two remaining firms.²¹

Finally, Microporous had certain R&D projects underway that could have led to direct competition with Daramic's uninterruptible power source (UPS) products. On review, the Commission found the evidence insufficient to determine that Microporous was a market participant in UPS separators in North America. The Commission cited Microporous' lack of a commercially viable separator to offer UPS customers, and the absence of any customer that had qualified a Microporous UPS separator for future purchases. Moreover, there was no evidence that Daramic perceived Microporous to be a competitive threat, or that it had reacted competitively to any perceived threat. Finally, the Commission pointed to mixed evidence as to the likelihood that Microporous' R&D efforts would bear commercial fruit. On this record and

²⁰ *Id*. at 22. ²¹ *Id*. at 31.

in light of substantial barriers to entry that Microporous had not yet surmounted, the Commission determined that Microporous could not be counted as a market participant in the North American UPS separator market. The Commission dismissed that portion of the complaint.

Polypore also provides insight into the Commission's approach to assessing which fringe firms might be considered in the market based on excess capacity or previous sales. Respondent Polypore argued that Entek, a firm that had sold battery separators for industrial uses a decade earlier, could rapidly respond and counter any price increases by re-entering the market. After considering additional post-trial evidence offered by respondent, the Commission found there was no evidence that Entek was in a position to provide a rapid and effective supply response: "More than two years after the acquisition, and despite evidence of Daramic's post-acquisition price increases in the deep-cycle market, there is nothing to suggest Entek has entered the deepcycle market or even qualified a product. At best, the record shows that Entek is testing product with [two potential customers], which is not enough to show that Entek is a market participant."²²

Competitive Concerns in Mergers that Eliminate a Future Entrant

Polypore makes clear that employing a forward-looking approach involves a fact-specific inquiry. A firm not currently making sales can nonetheless be in the market as an actual competitor based on evidence that it is already having an effect on the behavior of firms currently making sales. A question of competitive harm also arises in mergers in which one of the firms is in the process of entering the market but has not yet had a meaningful effect on the competitive environment. In this scenario, the acquisition may substantially lessen competition

²² *Id.* at 25.

by eliminating a future competitor whose entry, once complete, would have a beneficial impact on competition. Considering the future significance of such a firm involves more than just an assessment that market conditions are conducive to entry, such that one of the merging firms could enter. In *Polypore*, the firm in question had already identified the market opportunity, and was expending resources to begin to supply customers in the market.

A word here on terminology. There is often no clear line – and often more semantics than analytical difference – between a committed entrant, a likely entrant, a potential entrant and a future entrant. Where companies are taking steps to enter, there can always be some question as to whether they will in fact enter the market. But a fact-based analysis allows us to predict whether a firm is sufficiently likely to enter that its acquisition will harm competition. As noted above, the Commission found both that Microporous was a market participant in the SLI market, although it had not made sales, and that the firm was not likely to enter the UPS market, despite making efforts to do so.

This fact-based approach is also used to determine whether meaningful entry by third parties will be timely, likely and sufficient. We look at such evidence as the circumstances that led to past entry, whether conditions are conducive to entry, and what the most likely entrants say they would do in the face of a changed market environment. In the recent *Bazaarvoice* decision, the parties argued that a number of formidable firms – Amazon, Facebook, Twitter and Google – had the resources and market position from which to launch a product to compete with Bazaarvoice. Yet, the court dismissed the likelihood of each of these companies' entry into the market, mainly because they had not taken any steps toward entry. As the court summarized, "The companies just discussed have the size and strength to enter virtually any technology

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market and become strong competitors. But there is no credible evidence that any of them are considering entry into the R&R platform market in the U.S."²³

The Quintessential Likely Entry Story: FDA Pipeline Cases

The Commission has required relief in numerous pharmaceutical markets. The Commission devotes significant resources to promoting competition in these markets as one way to contain health care costs. Section 7 is an important tool for preventing mergers that would likely stave off emerging competition for life-enhancing products under development.

In many of the cases, the concern was that the transaction involved a firm without a commercially available product but which would likely provide important competition in the near future. Pharmaceutical products must be approved for use by the Food and Drug Administration. As a result, the path to introducing a new product is clear, well-defined and often long. There are identifiable stages and timeframes that provide a degree of transparency and predictability as to on-going efforts for those firms developing a product.²⁴ Information from the FDA as to which firms have filed applications for product approval is a useful starting point to assess the likely status of and timing of a firm's entry into the market.²⁵ Yet the inquiry does not begin and end there. We look at all the available evidence to assess the likely future

²³ United States v. Bazaarvoice, Inc., 2014 WL 203966, 49 (N.D. Cal.).

²⁴ See, e.g., Analysis to Aid Public Comment, In the Matter of Amgen Inc. and Immunex Corp., Dkt. C-4053 (July 12, 2002), available at http://www.ftc.gov/sites/default/files/documents/cases/2002/07/amgenanalysis.htm ("Entry into the neutrophil regeneration factor market requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration ("FDA"). Clinical development and FDA approval can extend from 6 to 10 years and cost over \$200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development in the relevant market without: (1) clinical trial expertise; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity; and (4) regulatory approvals.").

²⁵ Fed. Trade Comm'n, Office of Policy Planning, Anticipating the 21st Century: Competition Policy in the New High-Tech Global Marketplace at 174 (1996), *available at* <u>http://www.ftc.gov/reports/anticipating-21st-century-competition-policy-new-high-tech-global-marketplace</u>.

competitive landscape of a market. Moreover, the Commission's experience in studying competition in pharmaceuticals markets provides a sound basis for projecting the likely price effect that the introduction of the next competing product would bring.²⁶

Many of our matters occur at a stage in which one of the merging firms has the only branded drug approved by the FDA to treat a particular condition, and the other firm is at some stage in the process of obtaining FDA approval, whether in clinical trials²⁷ or, for a generic product, at an earlier stage. Typically, the expiration of patent protection stimulates investment in developing generic formulations of branded drugs, which must be approved by the FDA. As a result, the Commission has required divestitures to preserve future competition from the likely first generic supplier.²⁸

In other cases, transactions may combine existing generics, an existing generic with a company developing a generic product, or two companies both developing generic products.

²⁶ Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), *available at* <u>http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commets/reports/pay-offs Cost</u> 20% discount to the brand product; Fed. Trade Comm., *Pay-For-Delay: How Drug Company Pay-offs Cost* Consumers Billions 8 (2010), available at http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (subsequent generic entry creates greater price competition, with discounts of 85% or more off the price of the brand name drug).

²⁷ See, e.g., In the Matter of Amgen Inc. and Immunex Corp. Dkt Ct-4053(IL-1 inhibitors); In the Matter of Allergan, Inc., Dkt. 4156 (Apr. 21, 2006) (phase III clinical trials) and In the Matter of Thoratec, Inc. and HeartWare Int'l., Inc., Dkt. 9339 (July 30, 2009).

²⁸ See, e.g., Analysis to Aid Public Comment, In the Matter of Actavis and Warner Chilcott, Dkt. C-4414 (Sept. 27, 2013), *available at*

http://www.ftc.gov/sites/default/files/documents/federal_register_notices/2013/10/131031activisfrn.pdf ("Evidence, including information regarding the status of the FDA approval process for potential suppliers of generic Loestrin 24 FE, suggests that Actavis will be the first generic supplier to compete against Warner Chilcott's branded product. Moreover, no other generic supplier is likely to enter the market for a significant period of time. Thus, the combined firm would likely delay the entry of Actavis's generic version of Loestrin 24 FE or, at a minimum, cause Actavis's generic drug to compete less vigorously against Warner Chilcott's branded product, resulting in higher prices for consumers. Similarly, in the markets for Lo Loestrin FE and Atelvia, Actavis may be the first and only generic competitor to Warner Chilcott's branded products for a significant period absent the Proposed Acquisition. By eliminating this potential competition between Warner Chilcott and Actavis in each of these markets, the Proposed Acquisition would harm U.S. consumers by substantially increasing the likelihood of higher post-acquisition prices for Lo Loestrin FE and Atelvia.").

Where the combination involves two of only a few companies developing a generic product, that combination is highly likely to lessen competition. I should note that we define the market differently once at least two generics enter the market. When the first generic version of a branded pharmaceutical is launched, the generic supplier typically prices its drug at a significant discount to the brand. The branded drug, however, provides some constraint on the price of the generic. Once multiple generic suppliers enter a market, the branded drug usually ceases to provide any competitive constraint on the prices for generic versions. Rather, the generic suppliers typically compete only against each other. Again, the facts matter. Where a branded drug manufacturer chooses to lower its price and compete against generic versions of the drug, it is properly considered a participant in the generic drug market.

Recently, the Commission required divestitures in a number of pharmaceutical markets threatened by Watson Pharmaceutical's acquisition of Actavis, Inc. In addition to alleging that the acquisition threatened current competition between Watson and Actavis, the Commission charged that the transaction would have reduced future competition in generic markets that did not yet exist. These were markets in which generic development was underway and generic entry was imminent. The Commission found six generic markets in which the transaction would have eliminated likely entry, by either a Watson or an Actavis product, into what would have been a concentrated generic market.²⁹

Of course, the very information that enables us with some precision to determine whether the merging firms are among the few future entrants also allows us to determine whether

²⁹ In the Matter of Watson Pharmaceuticals Inc. and Actavis Inc., Dkt. C-4373 (Oct. 15, 2012). Similarly, in Endo's acquisition of Boca, the Commission recently found reduced future competition in two generic markets that do not yet exist, but will be highly concentrated at the time Endo and Boca enter: the generic Bromfed-DM market and the generic Zamicet market. *See*, In the Matter of Endo Health Solutions, Inc. and Boca Life Sciences Holdings, LLC, Dkt. C-4430 (Jan. 30, 2014); see also In the Matter of Mylan Inc. and Agila Specialties Global Pte. Ltd., Dkt. C-4413 (Sept. 26, 2013).

sufficient entry by third parties is likely. In many pharmaceutical combinations, there are markets in which we decline to take action because the evidence shows that there will be sufficient other entrants to make competitive concerns unlikely. We will often be able to eliminate a number of possible markets of concern before a Second Request is issued and many others early on in our investigation.

There is an important time element in assessing competitive consequences of a merger and the sufficiency of entry. It is of course easier to obtain evidence on what is likely to occur in the near-term. Nevertheless, where the facts show two firms likely to compete in the future – even if their products will not be on the market for some number of years – we may have concerns that such a combination could adversely affect competition, as we did with Merck & Co.'s acquisition of Schering-Plough Corporation. Merck introduced the first NK1 receptor antagonist for CINV and PONV (side-effects associated with chemotherapy). At the time of the transaction, Merck was the only firm in the United States with an approved drug in the class. A very limited number of other firms, including Schering-Plough, had NK1 receptor antagonists in development. At the time of the proposed acquisition, Schering-Plough was in the process of out-licensing its NK1 receptor antagonist, rolapitant, to a third party. The acquisition would likely have diminished the combined firm's incentive to license the product; in the hands of a competitor, rolapitant's launch - even if years away - would have significantly reduced the revenues for Merck's NK1 receptor antagonist. The Commission charged that the proposed acquisition could therefore delay or eliminate a future entrant into the U.S. market for NK1 receptor antagonists for CINV and PONV, and required a divestiture of all assets relating to rolapitant.30

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³⁰ In the Matter of Schering-Plough Corporation and Merck & Co. Inc., Dkt. C-4268 (Oct. 29, 2009).

There is an important time element in evaluating third party entry as well. For instance, we may conclude with great certainty that entry (either already committed entry or new entry as a result of the transaction) is almost certain to occur. The evidence may also show that such entry would have a meaningful impact on competition once the entering firm began selling product. Yet if there is an intervening time period when harm is likely to occur from a transaction, the Commission will take action. For instance, consider the following set of facts. There are three generic firms on the market, one of which is the acquiring firm. The acquired firm will enter within 6 months. Other firms will enter, but not until 18-24 months later. In such a case, we will take action against the combination of the acquiring firm and the near-term entrant. Although there likely will be entry – and even within a two-year horizon – the empirical evidence we have seen shows that entry by a generic firm has a price effect only when it has actually begun making sales. Thus, under Guidelines parlance, entry might be likely, but it would not be sufficient to counteract or deter the likely anticompetitive effect of reducing the number of future competitors from three to two - at least for the period until the additional firms entered.

Of course, this is a fact-specific inquiry. There are certainly instances in which an entrant not yet making sales can have an effect on the marketplace. And if the period of theorized competitive harm in this scenario were very short, we might decide that our ability to predict the timing of entry was insufficiently precise. In such cases, we might decline to take action.

Taking Account of the Impact of Market Innovators

The pharmaceutical cases described above involve the introduction of a generic product that offers significant price savings, but does not result in marketplace innovation in the classic sense of developing something beyond what exists today. A transaction between an existing competitor and a future entrant working on a product that customers would likely view as superior to existing products can be particularly problematic. In 2009, the Commission authorized litigation to block Thoratec Corporation's proposed \$282 million acquisition of rival medical device maker HeartWare International, Inc. The Commission charged that the transaction would substantially reduce competition in the U.S. market for left ventricular assist devices (LVADs), a life-sustaining treatment for patients with advanced heart failure. Thoratec was the only firm with a commercial LVAD in the United States, the HeartMate II. HeartWare was engaged in clinical trials for what many considered to be a superior device, with FDA approval expected by 2012. Although the path to regulatory approval of these devices is challenging, there was ample evidence that HeartWare's device, the HVAD, was the most likely future competitor to Thoratec's HeartMate II. The HVAD was undergoing clinical trials in the United States and was approved and commercially available in Europe. Analysts viewed the product as having "billion-dollar potential" even before it gained approval. The few other companies developing LVADs were significantly behind HeartWare in their clinical trials. None of those LVADs was likely to reach the market as soon as or be as competitive as HeartWare's device.³¹ The Commission alleged that no other firm had the ability to replace the current and

³¹ In the Matter of Thoratec Corp. and HeartWare Int'l., Inc., Dkt. 9339 (July 30, 2009). Similarly, the Commission alleged that, through a series of acquisitions, Inverness engaged in a course of conduct to maintain its monopoly power in the market for research, development, manufacture and sale of consumer pregnancy tests by threatening to hamper or stifle future competition from two emerging alternative consumer pregnancy test technologies. *See* In the Matter of Inverness Medical Innovations, Inc., Dkt. C-4244 (Dec. 23, 2008).

future competition eliminated by the merger and filed a complaint to block the transaction.³² The parties abandoned the transaction in the face of the Commission challenge.³³

Similarly, in 2007, the Commission filed a complaint charging that Kyphon Inc.'s acquisition of Disc-O-Tech Medical Technologies, Ltd. would reduce competition in the market for minimally invasive vertebral compression fracture (MIVCF) treatment products. These products treat vertebral compression fractures (VCFs), which can cause debilitating pain for some patients. In 1999, Kyphon introduced kyphoplasty as a treatment for VCFs. While similar to other vertebroplasty products, kyphoplasty used a technology that reduced the chance of bone cement leakage. Because of its safety advantages and other factors, kyphoplasty became the most widely used MIVCF treatment product in the United States, with an almost 90 percent market share. At the time of the transaction, Disc-O-Tech had just introduced the Confidence system to the U.S. market. Similar to kyphoplasty, the Confidence system method of treating VCFs had a reduced chance of leakage compared to traditional VCF treatments. The evidence showed that the Confidence system would be a closer substitute for Kyphon's product than other vertebroplasty products. The Commission charged that the acquisition eliminated the threat that the Confidence system posed to Kyphon's near-monopoly position and required a divestiture of all assets related to the Confidence system.³⁴

 ³² Press Release, Fed. Trade Comm'n, FTC Challenges Thoratec's Proposed Acquisition of HeartWare Int'l., (July 30, 2009), *available at* <u>http://www.ftc.gov/news-events/press-releases/2009/07/ftc-challenges-thoratecs-proposed-acquisition-heartware</u>.
³³ Press Release, Fed. Trade Comm'n, Bureau of Competition Statement Regarding the Announcement that Thoratec

³⁵ Press Release, Fed. Trade Comm'n, Bureau of Competition Statement Regarding the Announcement that Thoratec Corp. Will Not Proceed with its Proposed Acquisition of HeartWare Int'l (July 31, 2009), *available at* <u>http://www.ftc.gov/news-events/press-releases/2009/07/bureau-competition-statement-regarding-announcement-thoratec</u>.

³⁴ See In the Matter of Kyphon, Inc. and Disc-O-Tech Medical Technologies Ltd. et al., Dkt. C-4201 (October 9, 2007).

In an example outside the health care arena, the Commission obtained relief in a merger between two firms with computer-aided design (CAD) engines for Windows-based personal computers.³⁵ Autodesk sold the *de facto* industry standard product and had a 70 percent market share. Softdesk had been working on a competing CAD engine that, unlike other CAD products on the market, would allow users to transfer files generated using Autodesk's CAD engine and applications. At the time of the proposed merger, the product was within months of being introduced. In its Analysis to Aid Public Comment, the Commission explained that the Softdesk product, if brought to market, would have provided direct and significant competition to Autodesk. Indeed, because the Softdesk product offered file compatibility and transferability not available with other products, "some customers ha[d] already altered their buying decisions in anticipation . . . [of Softdesk's product] by delaying or postponing [purchases of]" Autodesk's CAD product.³⁶

Of course, there are instances in which the innovation emerges from firms other than the merging parties. In May 2010, the Commission closed its investigation of Google's acquisition of AdMob. ³⁷ Google and AdMob were leading competitors in the then-nascent market for mobile advertising networks. These networks monetize mobile publishers' content by selling publishers' advertising space. During the investigation, Apple acquired Quattro Wireless, the third-largest mobile advertising network at that time and subsequently announced – and launched – its own mobile advertising network, iAd. The Commission closed its investigation because it

³⁵ In the Matter of Autodesk, Inc. and Softdesk, Inc., Dkt. C-3756 (Mar. 31, 1997). *See also* In the Matter of Sensormatic Electronics Corporation, 119 F.T.C. 520 (Apr. 18, 1995) (merger of actual competitors in the market for research and development for new systems to prevent retail shoplifting).

³⁶ Analysis to Aid Public Comment, In the Matter of Autodesk, Inc. and Softdesk, Inc., Dkt. C-3756 (Mar. 31, 1997), *available at* <u>http://www.ftc.gov/sites/default/files/documents/cases/1997/03/autodesk.pdf</u>.

³⁷ See, e.g., Statement of the Commission Concerning Google/AdMob, FTC File No. 101-0031 (May 21, 2010), *available at* <u>http://www.ftc.gov/sites/default/files/documents/closing_letters/google-inc./admob-inc/100521google-admobstmt.pdf</u>.

lacked reason to believe that the transaction would result in a lessening of competition. It reasoned that as a result of Apple's entry, AdMob's historical success on the iPhone platform was unlikely to be an accurate predictor of AdMob's competitive significance going forward, regardless of its acquisition by Google.

Along the Continuum: Transactions that Eliminate Competition in Future Markets

In markets beyond the pharmaceutical arena, the Commission has applied a similar analysis where neither of the merging firms has a commercially available product yet both are among only a few likely entrants into a future market. Where the merging firms are the only, the most likely, or the furthest along in developing a new product, the Commission will likely take action where:

- Each firm is likely to be a competitor going forward
- The merging companies are two of only a very few firms likely to develop successfully a future product and/or
- Other firms are significantly behind the efforts of either merging party such that the combination is likely to delay the emergence of real competition in the market for the new product.

Those were the facts in the Commission's recent action involving Nielsen and Arbitron. Both companies were developing cross-platform measurement services, which measure viewership across TV, the Internet, and other platforms. The firms had developed plans, invested money and reached out to customers to begin marketing those products, albeit in beta form. Customers believed that Nielsen and Arbitron would compete – and that the two companies were the best positioned to develop a new cross-platform measurement product. Indeed, customers explained that while other companies currently provide estimates of aggregate cross-platform viewership, only Nielsen and Arbitron provide individual demographic data that is valuable to measure effective advertising spends. Each firm was approaching a complete solution from its unique competitive position. Nielsen already offered products that combined television and online viewing. Arbitron was collaborating to combine demographic data from its radio panel with data from set-top boxes and online measurements. Based on these independent efforts, customers believed that Nielsen and Arbitron eventually would compete directly in any national syndicated cross-platform measurement services.³⁸ The Commission based its decision not on crystal-ball gazing about what might happen, but on evidence from the merging firms about what they were doing and from customers about their expectations of those development plans. From this fact-based analysis, the Commission concluded that each company could be considered a likely future entrant, and that the elimination of the future offering of one would likely result in a lessening of competition.

In investigations involving future markets, the Commission will look to the same sources of evidence that inform the contours of competition in existing markets: What are firms doing? Are they developing new products? What do the firms' documents say about those developments? What are third parties doing? Compared to the merging parties, are third parties advantaged or disadvantaged in their efforts to develop a product and then compete in the future? What do customers say about competition in the future based on what they want in next-gen products and what they know about firms' ability to develop them? What is the timeline for these entry developments?

³⁸ A national syndicated cross-platform audience measurement service is one that provides all subscribers with the same universe of data, showing the relative national audiences for various programming and advertising. Complaint, In the Matter of Nielsen Holdings, N.V. and Arbitron Inc., FTC File No. 131-0058, (Sept. 20, 2013), *available at* <u>http://www.ftc.gov/sites/default/files/documents/cases/2013/09/130920nielsenarbitroncmpt.pdf</u>.

We use a fact-based approach to answer these questions. Ultimately, while we are mindful of limitations on the ability to predict too far out into the future – or in markets that are rapidly changing – Section 7 of the Clayton Act requires that we do as much.