

PFIZER-WYETH: LESSONS FROM THE FIRST MAJOR MERGER REVIEW OF THE OBAMA ADMINISTRATION

Scott A. Stempel and Dan Schiffer ¹

On October 14, 2009, the Federal Trade Commission (“FTC”) announced that it accepted a Consent Order concluding its investigation of Pfizer Inc.’s proposed \$68 billion acquisition of Wyeth. Later that day, the U.S. District Court for the Northern District of California dismissed a private lawsuit seeking to enjoin the acquisition based on claims under Sections 7 and 16 of the Clayton Act and Section 1 of the Sherman Act. Pfizer completed the acquisition on October 15, 2009, making Wyeth a wholly-owned subsidiary of Pfizer.

This article focuses on the events leading up to the acquisition, the theories of anticompetitive harm considered by the FTC Staff, the theories – or lack thereof – of anticompetitive harm alleged in a private lawsuit brought by a group of pharmacists, and the successful strategies and defenses pursued by Pfizer and Wyeth to address the Staff’s concerns and the private litigants’ allegations. In particular, it analyzes the Staff’s consideration of non-traditional theories of potential competitive harm, exploring whether the acquisition would: 1) substantially lessen innovation competition generally in the pharmaceutical industry; 2) generate the ability and incentive for Pfizer to engage in anticompetitive bundling; 3) create a company that was “too large to fail;” and 4) leave Pfizer so highly leveraged that its future competitiveness would be undermined.

To experienced practitioners, these questions must seem like inquiries from some country far away that recently established a new merger control regime. But for Pfizer and Wyeth, they were very real questions that had to be

¹ Mr. Stempel is a partner and Mr. Schiffer is an associate in the Washington, DC office of Morgan, Lewis & Bockius. Morgan, Lewis & Bockius represented Pfizer in connection with the FTC investigation and subsequent private litigation. The views expressed in this article are those of the authors and do not necessarily represent the views of any of the Parties or their counsel.

addressed in order to persuade the FTC to approve the transaction. Ultimately, the FTC gave closer scrutiny to the transaction's competitive effects in more traditional markets and concluded that the transaction "does not raise anticompetitive concerns in any human health product markets."² With divestitures required to remedy competitive concerns in certain animal health markets, the FTC voted 2-0 to approve the transaction.

The Parties and Rationale behind the Transaction

Pfizer was founded by Charles Pfizer and Charles Erhart in 1849 as a fine chemicals business in Brooklyn, NY. By January 2009, it was the largest prescription pharmaceutical company in the world, with annual worldwide revenue of \$48.4 billion. In addition to a broad array of marketed pharmaceuticals and animal health products, Pfizer had a significant research and development pipeline for pharmaceuticals. At the end of 2008, Pfizer had 114 products in various stages of clinical development.

In January 2009, Wyeth was the twelfth-largest prescription pharmaceutical company in the United States, with annual revenue totaling \$22.2 billion in 2008, \$16.8 billion of which was from pharmaceutical and biological sales. Wyeth researched, developed, manufactured, and sold a wide variety of pharmaceutical, consumer health, and animal health products, with a strong portfolio of biological and vaccine products for humans. Wyeth was the fourth largest biotechnology company by revenue in the world and had 18 biologic products in clinical development.

Pfizer viewed the acquisition as an opportunity to diversify its pharmaceuticals portfolio and expand its pipeline, with a particular focus on biopharmaceuticals and vaccines. From the beginning, Pfizer understood that a limited number of animal health overlaps would likely require a divestiture, but it anticipated that the combination of complementary human health businesses

² Statement of the Federal Trade Commission Concerning Pfizer/Wyeth, FTC File No. 091-0053.

would not require an antitrust remedy. The company nonetheless recognized that a robust investigation would be necessary to make the Staff comfortable that competition would not be reduced in any human health market and that the animal health divestitures that likely would be required would be somewhat challenging and time consuming.

The FTC in Transition

Pfizer announced its proposed acquisition of Wyeth on January 26, 2009 – six days following the inauguration – making it the first major deal of the new Obama administration. During his campaign, President Obama criticized the Bush administration for “what may be the weakest record of antitrust enforcement of any administration in the last half century.”³ He singled out the health care industry – and prescription drug manufacturers in particular – as an area in which “lax enforcement” under the Bush administration had harmed consumers,⁴ and promised that his administration would be more willing to challenge mergers and more strictly enforce the antitrust laws.⁵

Although it typically takes some time for a new president to put his imprint on the FTC given the reality of staggered terms for the five Commissioners, there were unique circumstances that created unusual – and unexpected – challenges for the parties in this transaction at least partly due to the transition to a new administration. Following the March 2008 resignation of former Chairman Majoras, the FTC was down to four sitting Commissioners in January 2009. Further, as the parties later discovered, Commissioners Harbor and Kovacic recused themselves, meaning that the fate of the transaction would be decided by votes from Commissioner Rosch and newly-designated Chairman

³ Barack Obama, Senator, Statement of Senator Barack Obama for the American Antitrust Institute (Sept. 26, 2007), *available at* http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf.

⁴ *Id.*

⁵ *Id.*

Leibowitz.⁶ Moreover, the leadership of the Bureaus was in transition, leaving a management vacuum during the early stages of the investigation.⁷

At around the same time, Commissioner Rosch foreshadowed his interest in exploring “non-traditional” questions in the context of merger investigations in two speeches he delivered that winter. First, in a January 29, 2009 speech to the New York Bar Association on Implications of the Financial Meltdown for the FTC, Commissioner Rosch mused that “mergers should arguably be examined with an eye toward whether they are creating a merged entity that is ‘too big to fail.’ If so, the transaction may violate Section 7 (or Section 1).”⁸ In addressing whether such a consideration is appropriate under Section 7, he observed that “if a merger creates a firm whose failure is likely to have a catastrophic effect on the market as a whole, because it is so integral to the market, the end result may be a substantial lessening of competition.”⁹ In the same speech, Commissioner Rosch noted approvingly a related theory of harm to competition earlier offered by former Commissioner Leary:

[A] merger involving two firms who do not compete in the same relevant market may violate Section 7 or Section 5 if, because of the resulting financial weakness of the merged entity, the merged entity may not constrain the exercise of monopoly or near-monopoly power by a powerful competitor as much as that power is likely to be constrained prior to the merger.¹⁰

⁶ Jon Leibowitz was designated to serve as Chairman of the FTC on March 2, 2009.

⁷ Chairman Leibowitz announced his senior staff appointments on April 14, 2009.

⁸ J. Thomas Rosch, Commissioner, Fed. Trade Comm’n, Implications of the Financial Meltdown for the FTC, Remarks at New York Bar Association Annual Dinner (Jan. 29, 2009) at 8, *available at* <http://www.ftc.gov/speeches/rosch/090129financialcrisisnybarspeech.pdf>.

⁹ *Id.* at 9.

¹⁰ *Id.*

The following week, Commissioner Rosch delivered a speech addressing “antitrust regulation of innovation markets.”¹¹ In reviewing the application of the antitrust laws to innovation competition, he observed that “the most fundamental practical consideration [involving innovation markets] is whether, from a policy standpoint, the application of antitrust laws to innovation markets provides consumers with better products or products that are developed more quickly.”¹² He then discussed the history of the agencies’ views and enforcement actions directed toward so-called “innovation markets” and concluded rather cryptically with rhetorical questions directed at whether changes in enforcement direction due to the new administration would lead to a more aggressive posture or, instead, policies closer to those of the prior eight years. His own conclusions were wrapped in mystery: “Your guess is as good as mine. All I know is that there exist a host of policy and legal questions that have yet to be answered, and it will be fascinating to see how the agencies – and the courts – answer them.”¹³ At the time, Pfizer and Wyeth could not appreciate the extent to which Commissioner Rosch would want to explore these “fascinating” issues in the context of the Commission’s review of their transaction.

Added to this stew just a few days later was a memorandum addressing the Wyeth acquisition by Professors William Comanor and F.M. Scherer, submitted on behalf of the American Antitrust Institute (“AAI”) to Attorney General Eric Holder and the Commissioners of the FTC.¹⁴ Comanor and Scherer argued against the acquisition and stated that a combination of Pfizer and Wyeth

¹¹ J. Thomas Rosch, Commissioner, Fed. Trade Comm’n, Antitrust Regulation of Innovation Markets, Address at ABA Intellectual Property Conference (Feb. 5, 2009), *available at* <http://www.ftc.gov/speeches/rosch/090205innovationspeech.pdf>.

¹² *Id.*

¹³ *Id.*

¹⁴ William S. Comanor and F.M. Scherer, Memorandum on the Proposed Acquisition by Pfizer of Wyeth, The American Antitrust Institute (Feb. 9, 2009), *available at* http://www.antitrustinstitute.org/Archives/PfizerWyeth_ashx.

was unlikely to benefit the public.¹⁵ They argued that “an innovation market analysis should be undertaken, and if the overlaps are large, that would provide a further basis for opposing the merger.”¹⁶ They also contended that the government’s investigation should focus on macroeconomic issues that are not typically the focus of antitrust investigations, particularly an argument that Pfizer’s financing depended substantially on TARP funds that were provided to its lenders and were intended to stimulate the economy.¹⁷

The FTC Investigation

The investigation began in fairly typical fashion for a large, complex, multi-product merger review that potentially spans dozens of relevant markets. The parties communicated with the Staff early and often to help identify areas of overlap in their respective human and animal health product and pipeline portfolios. The parties’ pre-filing engagement, as one would expect, included responding to requests for detailed information about specific products and therapeutic categories. But it also included an unexpected line of questions unrelated to any product or therapeutic category. The Staff posed a number of questions relating to what they themselves characterized as “non-traditional” theories of potential competitive harm, specifically: 1) would innovation in the pharmaceutical industry as a whole be harmed by the transaction; 2) would the transaction create the incentive and ability for Pfizer to engage in anticompetitive bundling; 3) would the transaction create an entity that was “too big to fail;” and 4) would the post-acquisition entity be so highly leveraged that its ability to compete aggressively would be compromised?

The Staff issued a Second Request on April 3, 2009. Much of the pre-filing engagement paid dividends as the Second Request focused on a fairly narrow set of human health therapeutic areas. But in addition to the specific

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ No bank loans were ultimately used to fund the acquisition.

overlaps of animal and human health products, the Second Request also sought information relating to the broader “non-traditional” issues about which the staff had inquired, including an open ended question seeking a broad array of information about every instance, since 1994, in which either company introduced a new human pharmaceutical product. Although the parties had prepared for requests related to specific therapeutic areas, these broader and more amorphous areas of inquiry posed an unforeseen challenge.

A. Innovation Markets

Innovation market analysis evaluates competition taking place between two companies each involved in research and development efforts that could lead to the development of competing products in the future. True innovation market analysis differs from potential competition analysis, in which the agency evaluates the future competitive significance of products that have already been developed but that may not be launched until some date in the future. Although the FTC has frequently examined potential competition between different pipeline products or pipeline and marketed products in the context of pharmaceutical mergers, it has rarely, if ever, examined the effects of a transaction on the overall level of innovation in the broader industry in which the parties compete.

The Staff posed separate questions relating to effects on innovation as follows:

1. Would the combination harm innovation in the pharmaceutical industry as whole?
2. Would the combined company’s patent portfolio enable it to block new drug development with a patent thicket?
3. Would the combination of Pfizer and Wyeth harm innovation in specific therapeutic areas – namely Alzheimer’s disease?

1. Would the combination harm innovation in the pharmaceutical industry as whole?

Although the FTC had expressed some concern in a handful of prior investigations about innovation effects in discrete areas in which only a handful of firms possessed specialized assets, to our knowledge it had never focused on broad industry-wide innovation effects before this investigation. Attempting to evaluate the effects on innovation across the entire pharmaceutical industry was particularly challenging both because there was no precedent for such an inquiry and because the required frame of reference was the total output of all innovation in the entire pharmaceutical industry.

Lacking any template for analysis and being given none by the FTC, the parties had to create one. They first posited that in order to pose a threat to industry-wide innovation, Pfizer and Wyeth collectively had to represent a very substantial share of all innovation relating to the discovery and development of new drugs (just how substantial was, and is, unclear). Even with significant consolidation over the last decade, the pharmaceutical industry as a whole remains highly fragmented. The parties were able to demonstrate the relative lack of concentration in pharmaceutical R&D by using various industry databases to show that they collectively accounted for a small percentage of large pharmaceutical company activity in 1) ongoing clinical trials for new molecular entities, 2) in-licensing opportunities with smaller startup entities, and 3) R&D spending. In particular, the parties presented data showing the very high aggregate spending for R&D by a multitude of companies across the industry. Pfizer and Wyeth were only two of twelve companies with R&D budgets exceeding \$3 billion in 2008. Eight companies had R&D budgets in excess of \$4 billion, and Wyeth was not one of them. In addition, the parties presented evidence that the share of spending on R&D at each of the top five largest pharmaceutical companies at every stage of the clinical development process represented a tiny share of the aggregate spending of the next 27 largest firms.

Although any single metric might be subject to criticism as an inadequate proxy to measure concentration in innovation, collectively they told the same story. Moreover, a substantial amount of pharmaceutical innovation takes place outside of large pharmaceutical companies, such as smaller companies, universities, and non-profit organizations. So if anything, the data that the parties presented overstated the combined entities' level of concentration using these metrics.

Finally, the parties pointed out that there is no empirical support for the proposition that a reduction in R&D spending would necessarily lead to a reduction in innovative output. Indeed, there were strong reasons to believe that there could be substantial efficiencies arising from a combined R&D pipeline so that even if the combined entity were to spend less than Pfizer and Wyeth separately, innovative output could still increase as a result of cross-pollination of the companies' respective R&D teams.

2. Would the combined company's patent portfolio enable it to block new drug development with a patent thicket?

The parties also addressed the slightly less novel question of whether the acquisition would create a patent thicket by virtue of the breadth of the combined company's patent portfolio. The Staff wanted to determine whether the acquisition would enable the combined firm to reduce or eliminate competition in human pharmaceutical products through the enforcement of intellectual property rights. This concern was reflected in the FTC's decision approving Ciba's merger with Sandoz in 1996, but requiring the licensing of certain gene therapy patent rights and technology to resolve the concern that the two companies were among the few in the industry with sufficient IP rights and technology to develop new gene therapy products.

The parties submitted evidence relating to their respective patent portfolios that showed that the combination of the companies' intellectual property would not pose any greater barrier to entry by third-parties than the

intellectual property held by the companies individually. Although, as Ciba/Sandoz arguably demonstrated, broad patent positions covering fundamental, enabling technologies are possible in the pharmaceutical industry, they are rare. More typical are the patent positions of the parties to this transaction, which were largely limited to narrow compound and method patents that were sufficient to prevent competitors from developing specific products, but not species of products. Indeed, given the relatively narrow focus of many of the companies' respective patents, even a collectively large number of total patents proved to be irrelevant in assessing the competitive effects of the combined portfolio. Absent proof that the parties' owned complementary patent positions that collectively could foreclose significant specific innovation by others, the combined portfolios did not raise any concern.

3. Would the combination of Pfizer and Wyeth harm innovation in specific therapeutic areas – namely Alzheimer's disease?

In addition to analyzing innovation broadly across the pharmaceutical industry, the Staff also focused with some intensity on whether innovation in the development of new drugs for Alzheimer's disease would be reduced. Alzheimer's disease is a brain disorder that destroys brain cells, causing memory loss and severe behavioral problems. Alzheimer's is not yet curable and ultimately leads to death. It is the seventh-leading cause of death in the United States. As many as 5.3 million Americans live with Alzheimer's disease, including one in eight people aged 65 and older.¹⁸ The number of Alzheimer's patients is expected to grow exponentially over the next ten years. The money spent on Alzheimer's treatments is predicted to more than triple from \$4.3 billion in 2009 to \$13.3 billion in 2019.¹⁹

¹⁸ Alzheimer's Association, 2010 Alzheimer's Disease Facts and Figures, *available at* http://www.alz.org/documents_custom/report_alzfactsfigures2010.pdf.

¹⁹ Lynne Taylor, *Alzheimer's Drug Market "Set to More than Triple"*, PHARMA TIMES, Sept. 13, 2010, *available at* http://www.pharmatimes.com/Article/10-09-13/Alzheimer_s_drug_market_%E2%80%9Cset_to_more_than_triple%E2%80%9D.aspx.

At the time of the investigation treatments for Alzheimer's disease were limited to drugs that managed symptoms of the disease. The only four Alzheimer's drugs sold in the United States were Aricept, Razadyne, Exelon, and Namenda. All four improved neurological functions by boosting the performance of the remaining neurons, but failed to modify the underlying disease pathology. Pfizer marketed Aricept, the leading drug on the market at the time of the investigation, and had a number of compounds in its pipeline that were in various stages of clinical trials. Wyeth had no marketed product in its portfolio, but like Pfizer had a number of products in its development pipeline. And both companies had made a high priority of discovering new mechanisms and molecules in the hunt for an effective disease modifying treatment for Alzheimer's.

Accordingly, the Staff focused both on the potential competition for drugs to treat Alzheimer's disease, by looking at products in clinical trials, and earlier stage innovation that might lead to the discovery of new drugs to treat Alzheimer's. The parties were able to address the potential competition arguments by demonstrating that a multitude of companies were working to develop more effective symptomatic and pathology-modifying products. They provided evidence that approximately 50 companies, including 14 of the largest pharmaceutical companies in the world, had at least 66 products in various phases of development. Further, the parties demonstrated that although there were several different therapeutic approaches being pursued to treat Alzheimer's disease, the R&D programs of Pfizer and Wyeth overlapped in only a small number of those approaches.

In this part of the FTC's inquiry, as is the case in many pharmaceutical transactions, it is often the scientific case that is persuasive and the parties relied more heavily on science to address the pure innovation arguments. The parties produced substantial literature, and their key scientists, to demonstrate that there was no clear scientific consensus on the causes of Alzheimer's. Indeed, the clinical trials for dozens of drugs being studied for Alzheimer's covered a wide variety of different mechanisms of action, none of which could be regarded as

more likely to succeed than any others. Indeed, it was this lack of understanding of the underlying causes of the disease combined with the staggering societal cost of dealing with the disease and the lack of any disease modifying agent currently on the market that ensured a tremendous flow of future investment by a multitude of entities directed at attempting to find an effective treatment. Against this backdrop, the parties demonstrated that the combined company would continue to have the same incentive to pursue innovation aggressively in seeking new drugs to treat Alzheimer's and it would have no ability to foreclose Alzheimer's treatment innovation by other companies. In the limited number of areas where the two companies did overlap, there were several other companies developing products.

B. Would the combined company be in a position to employ anticompetitive bundling?

The Staff asked whether Pfizer's acquisition of Wyeth could create incentives for Pfizer to use bundling as an anticompetitive tool. The antitrust treatment of bundled rebates has been subject to a fair amount of recent controversy.²⁰ Indeed, Commissioner Rosch recognized as much in a speech on February 18, 2010, where he acknowledged the unsettled standards to be applied to the use of bundled rebates.²¹ Although he did not appear to embrace any specific analytical framework, he noted with apparent approval the "perceptive analysis written by District Court Judge Claudia Wilken in *Meijer, Inc. v. Abbott Laboratories*,"²² in which Judge Wilken observed that it would not be appropriate to employ an average variable cost test to pharmaceutical products for purposes of determining whether the competitive product was sold above cost after allocating

²⁰ Compare *LePage's Inc. v. 3M Co.*, 324 F.3d 141 (3d Cir. 2003) (en banc), with *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007).

²¹ Remarks of J. Thomas Rosch, Commissioner, Fed. Trade Comm'n, *The Role of Static and Dynamic Analysis in Pharmaceutical Antitrust*, Remarks at Fifth Annual In-House Counsel Forum on Pharmaceutical Antitrust (Feb. 18, 2010) at 18-20, available at <http://www.ftc.gov/speeches/rosch/100218pharmaantitrust.pdf>.

²² *Id.* at 20.

to it the full bundled discount as suggested by *PeaceHealth*. This was because marginal costs for patent protected prescription drugs are nearly always *de minimis* when compared to the extremely high fixed costs associated with bringing a product to market. As such, even after attributing bundled discounts to the competitive products, those products would always appear to be sold above cost.

The parties fortunately did not address the question of bundled discounts at that level of granularity. Instead, they demonstrated that there were relatively few opportunities to employ bundled rebates successfully in the pharmaceutical industry given the structure of the markets in which prescription drugs were sold. Specifically, the parties provided evidence demonstrating that pharmacies were required to carry a full line of branded prescription drugs because it was primarily doctors, not insurers or pharmacists, who chose the drugs that were ultimately dispensed to patients. Because pharmacies had to stock a full line of prescription drugs, they could not be induced to favor some drugs over others based on the availability of bundled rebates. Thus, for most drugs the decision-making power wielded by doctors prevented branded-drug manufacturers from employing bundling or bundled discounts to exclude competitors.

In addition, the parties demonstrated that those who principally paid for their drugs, namely insurance companies, set up competitive bid processes for purchasing pharmaceutical products on a product-by-product or category-by-category basis. Those customers had sufficient market power to resist any efforts by large pharmaceutical companies to bundle products across categories, unless the bundle was beneficial to them. Finally, and perhaps most germane to the Staff, the parties made clear that the transaction did not bring together products that were susceptible to bundling. To the extent that each party may have had some degree of market power in the sale of certain products before the acquisition by virtue of their patent positions, they would have no increased incentive to employ that market power by bundling those products with other products that faced greater competition. If the incentive to bundle existed, they would have

employed the strategy prior to the transaction and nothing about the transaction altered the surviving entities incentives.

C. Would the combined company be “too big to fail”?

Following the 2008 collapse of Lehman Brothers and the potential for a collapse of GM, a theory emerged that some firms, especially in the financial sector, were considered “too big to fail” by policy makers because they were large enough and interconnected enough that their failure could cause substantial harm to other financial firms, the financial markets, or even the economy as a whole. The Staff investigated whether a combination of Pfizer and Wyeth would create an entity that policy makers would consider to be “too big to fail.”

In addressing the Staff’s concerns, the parties focused on the underlying rationale behind this concern as applied to the financial firms that were propped up through the TARP program, specifically the unique interconnectedness of those firms. Indeed, “too big to fail” was, in fact, a misnomer. What led to the creation of TARP was that the major financial firms were too interconnected with one another for policy makers to allow any of them to fail. At the heart of the interconnections were the massive counterparty risks for derivatives transactions that each had assumed, so that the liability tsunami resulting from the failure of any one firm could swamp several others and, in the process, the effect would be intensified. And because these same firms were instrumental to providing needed credit to the economy as a whole, there was a compelling public policy rationale for the government to step in and bail out the banks. By contrast, as the parties were able to demonstrate, many extremely large non-financial firms have gone bankrupt without any adverse systemic effects to the economy. There was no reason to believe that the merged entity’s operations would be excessively disrupted in the event of bankruptcy, and even less reason to believe that it would have systemic effects on the pharmaceutical industry or the economy as a whole. The parties pointed to the bankruptcy of A.H. Robins, the only large pharmaceutical bankruptcy in the 25 years prior to the acquisition, to illustrate that the bankruptcy process for a pharmaceutical company would not be

excessively disruptive to the combined company's operations and would have no systemic effects. The concern that any pharmaceutical company could ever be "too big to fail" was simply not well founded.

D. Would Pfizer's post-acquisition debt prevent it from competing effectively?

As Commissioner Rosch had noted in his January 2009 speech, a concern related to the "too big to fail" concern was whether a given transaction might leave the surviving firm so saddled with debt that its competitive strength would be greatly diminished. Those who represent pharmaceutical manufacturers can be forgiven if they are stifling laughter at this notion. Because a John McEnroe rant was not an option ("you can't be serious!!!???"), the parties dutifully provided evidence to show that there was no reason to believe that financial distress was even a remote risk at a combined Pfizer-Wyeth.

An analysis of the combined firms' anticipated free cash flow showed that it was particularly strong compared to its cost and debt structure so that the company would have a substantial cushion to weather even a severe downturn in sales. Moreover, although the company's leverage would suffer in the short run by comparison to the parties' pre-acquisition levels, the cash flow was sufficient to reduce total indebtedness and leverage to pre-transaction levels as early as 2014. Not surprisingly, then, investors were not concerned with the merged firm's anticipated debt level: 1) analyst reports examining the transaction did not mention post-transaction debt as an important consideration in evaluating the deal; 2) the market capitalization for the combined companies stayed relatively flat after the deal was announced, signaling that equity holders harbored no concerns with debt levels as a constraint on competitive viability; and 3) Pfizer's anticipated credit ratings remained at the high end of the market for corporate issuers. Indeed, as it turned out, Pfizer had no need to call on the bridge financing it had lined up from its banks because the bond offering that it floated to help pay for the acquisition was nearly immediately oversubscribed. Finally, a comparison of various post-acquisition financial metrics of the combined company to other

major pharmaceutical companies showed that even after taking on substantial incremental debt to complete the acquisition, Pfizer remained among the strongest pharmaceutical companies.

E. Human Health Product Markets

Although the “non-traditional” issues received a fair amount of attention, at least in part due to their novelty, the investigation still ultimately turned on a review of typical pharmaceutical industry markets, with the focus on specific therapeutic categories. The Second Request identified four “relevant product” markets consisting of products indicated for use in treating the following specific conditions:

1. Renal cell carcinoma (“RCC”);
2. Methicillin-resistant staphylococcus aureus (“MRSA”) infections;
3. Osteoporosis; and
4. Alzheimer’s disease.

The inquiry with respect to Alzheimer’s disease was limited to innovation, as discussed above. The other three therapeutic areas are addressed below.

1. Renal Cell Carcinoma

Renal cell carcinoma is the most common type of kidney cancer in adults. Although drugs cannot cure the cancer, they extend patients’ lives and focus on clinical endpoints such as overall survival and progression-free survival. Each company sold a marketed product with an RCC indication – Pfizer’s Sutent and Wyeth’s Torisel. There were only two other significant marketed products indicated for RCC.

Sutent and Torisel had different mechanisms of action, different routes of administration, and were prescribed to different types of patients. Sutent was a self-administered oral tyrosine kinase inhibitor, which primarily was prescribed as

a first-line therapy, while Torisel was a physician-administered injectable mTOR inhibitor, which primarily was prescribed as a second or third-line treatment or used as first-line treatment in poor-prognosis patients. Although there were few other marketed products, the evidence showed relatively little competitive interaction between the products. Key opinion leaders and high prescribers of the products confirmed that doctors would not treat the products as interchangeable. There were well understood prescribing protocols that limited the true competitive interaction between the products. And third party payers also confirmed that they could not credibly threaten to favor one product over the other for the purpose of extracting higher formulary rebates. Finally, there were several late stage pipeline products that, when approved, would prove to be closer substitutes to one or the other product than they were to each other.

2. MRSA

MRSA is a prevalent antibiotic-resistant gram-positive pathogen, which causes infections typically in the elderly and people with compromised immune systems. Additionally, community-acquired MRSA is a growing problem in healthy people who often come into skin contact with others. MRSA is known or suspected of causing nosocomial pneumonia, complicated skin and skin structure infections, and other potentially lethal infections.

Both companies sold products with similar anti-infective indications. Pfizer sold Zyvox, which is indicated for the treatment of several infections caused by gram-positive bacteria including MRSA, in both oral and IV formulations, while Wyeth sold Tygacil, an IV-only product indicated to treat broad spectrum infections caused both by gram-positive and gram-negative bacteria. The parties highlighted differences in prescription patterns, marketed indications, and routes of administration for the products. They also highlighted a very substantial difference in price – Zyvox cost nearly twice as much as Tygacil for a daily treatment. And the parties once again highlighted other marketed and pipeline products that were closer substitutes for Tygacil than the two products

were for each other. As with their RCC treatments, doctors and payers confirmed the facts that the parties laid out for the FTC.

3. Osteoporosis

Unlike the other specific human health product markets identified in the Second Request, the Staff's investigation of osteoporosis did not involve a product sold by either party. Pfizer had a product in development called lasofoxifene, a selective estrogen receptor modulator (SERM) seeking FDA approval to treat osteoporosis, while Wyeth had bazedoxifene, its own SERM in development. Thus, the Staff was examining whether the transaction would eliminate potential competition between two late stage products that would treat the same condition with the identical mechanism of action. Whereas Pfizer and Wyeth could point to differences in prescription patterns and routes of administration for RCC and MRSA products, the osteoporosis pipeline presented a different challenge.

One challenge that the FTC typically faces in considering potential competition in a pharmaceutical merger is the likelihood that actual competition will materialize in the future from products in the pipeline. Although the likelihood of FDA approval increases significantly as a product passes from stage 1 to stage 2 clinical trials and again as it passes to stage 3, even products in late stage development are not assured of coming to market. As it turned out, lasofoxifene had received a rejection by the FDA for the treatment of osteoporosis on January 16, 2009 – the third such rejection for this compound. After exploring whether lasofoxifene might receive a new lease on life in the hands of another company if the FTC required Pfizer to divest it, the Staff ultimately acknowledged that there was very little likelihood that this compound would ever be competitively relevant in any party's hands.

F. Animal Health Product Markets

Although Pfizer and Wyeth were not direct competitors in any human health product markets, they competed head-to-head in several animal health

markets. The parties approached the animal health investigation knowing that a divestiture would be necessary, but hoped to limit its scope and expedite the review process. Prior to the Second Request, Pfizer and Wyeth provided extensive ordinary course documents and product charts detailing all potential overlaps between the parties, as well as competing products from other competitors. Pfizer also began putting together a divestiture package and identified potential targets to receive an offering memorandum.

Pfizer ultimately agreed to divest products in 21 areas, including products used to treat a wide variety of species and conditions. Unlike the human health markets where the potential overlaps tended to involve only one or two products from each company, the animal health market overlaps involved entire product lines. Although the animal health review did not generate the “non-traditional” questions that the human health review generated, there were myriad challenges associated with what ultimately became a complex divestiture that would require a separate article to address adequately. But in the end, the parties negotiated a Consent Order and successfully divested a range of products sufficient to satisfy the FTC, which allowed the deal to gain approval.

An Eleventh Hour Strike Suit

By late summer, the parties had addressed each of the “non-traditional” questions from the Staff and each of the human health overlaps. They were in the final stages of reaching agreement with the Compliance division on all of the moving parts associated with the animal health divestitures. To date, despite a few twists and turns along the way, everything was on schedule largely as anticipated back in January given the expected complexity of dealing with the divestiture of a broad range of animal health vaccines. Then, on August 21, 2009, the Alioto Law Firm and a group of plaintiffs’ lawyers jointly filed suit against Pfizer and Wyeth on behalf of seven retail pharmacies seeking to enjoin the merger under Sections 7 and 16 of the Clayton Act and Section 1 of the Sherman Act. The complaint, filed in the U.S. District Court for the Northern District of California, was similar to others seeking to enjoin high profile transactions that

were filed by a group of lawyers specializing in antitrust strike suits.²³ The plaintiffs alleged that the transaction would unreasonably restrain trade in an alleged market for all prescription pharmaceutical products. The complaint also alleged that the merger would be financed by banks that received TARP funds to eliminate rather than create jobs, a unique theory of antitrust harm.

The private lawsuit forced Pfizer to make an important decision – accede to a settlement to avoid the potential, albeit minute, threat of disrupting the timing of closing on the acquisition or assume the cost and risk of fighting the complaint. Pfizer chose the latter approach and filed a motion to dismiss the complaint based on the plaintiffs’ failure to sufficiently plead a legally cognizable relevant market or plausible theory of anticompetitive effects. As the publicly announced closing date of October 15, 2009 drew near, the plaintiffs attempted to raise the stakes with a motion seeking a temporary restraining order (“TRO”) to prevent Pfizer from consummating the acquisition. A declaration from Prof. William S. Comanor accompanied the TRO motion, repeating many of the arguments made in the AAI memorandum he coauthored with F.M. Scherer. Like the AAI memorandum, the declaration focused on the acquisition’s threat to innovation and the use of so-called TARP funds. Pfizer and Wyeth argued that it lacked foundation and offered conclusory allegations and theories without the requisite supporting facts. The court agreed. It denied the TRO motion and dismissed the complaint the same day that the FTC announced its approval. The transaction closed the following day.

²³ These lawyers have filed several Section 7 challenges in recent years. *See, e.g.*, *Ginsburg v. InBev NV/SA*, No. 08-cv-01375, 2009 U.S. Dist. LEXIS 66857 (E.D. Mo. Aug. 3, 2009), *aff’d*, No. 09-2990, 2010 U.S. App. LEXIS 22115 (8th Cir. Oct. 27, 2010) (dismissing antitrust challenge to the merger of InBev and Anheuser-Busch); *D’Augusta v. Nw. Airlines Corp.*, No. 08-cv-3007 (N.D. Cal. Jun. 18, 2008) (voluntarily dismissing antitrust challenge to merger of Delta and Northwest Airlines); *Transuero Amertrans Worldwide Moving & Relocations Ltd. v. Conoco, Inc.*, No. 02-cv-00342, 2002 U.S. Dist. LEXIS 27301 (N.D. Okla. Oct. 9, 2002) (dismissing antitrust challenge to merger of Conoco and Phillips). Most recently, on September 27, 2010, the U.S. District Court for the Northern District of California rejected an attempt by many of the same lawyers to temporarily block the \$3 billion merger between United and Continental. Order Denying Motion for Preliminary Injunction, *Malaney v. UAL Corp.*, No. 10-cv-02858 (N.D. Cal. Sept. 27, 2010).

Two days following dismissal of the complaint, on October 16, the plaintiffs filed an amended complaint largely repeating the allegations previously found lacking by the district court, including the facially implausible allegation that there was a relevant market for “all pharmaceutical products.” As with the initial complaint, Pfizer successfully moved to dismiss the amended complaint for its failure to plead a relevant product market or anticompetitive harm. The court also denied two additional motions by the pharmacists seeking a TRO.

Given a final opportunity to amend their complaint, the pharmacists filed a second amended complaint that repeated many of the same conclusory allegations dismissed twice previously, while actually eliminating the most specific allegations found in the previous two complaints. Pfizer once again filed a motion to dismiss the complaint for its failure to plead a cognizable relevant product market or any plausible anticompetitive effects resulting from the acquisition. This time, the court dismissed with prejudice. The case is currently on appeal to the Ninth Circuit.

Conclusion

It may be too soon to tell whether the “non-traditional” issues that the FTC explored in reviewing Pfizer’s acquisition of Wyeth reflect a fundamental shift in the nature of merger review at the FTC – at least for very large transactions – or, rather, were simply the product of an unusual confluence of events. There is some reason to believe that Commissioner Rosch’s acknowledged curiosity about whether, and how, these questions should factor into merger policy conspired with other Commissioners’ recusals and the leadership transition to open the door to this free ranging inquiry. Nonetheless, some of the questions may find their way into future merger reviews. The effect of a transaction on innovation competition, for instance, has long been a subject of interest, albeit waxing and waning depending on the administration. Ultimately, the lack of any empirical consensus on the actual relationship between concentration and innovative output combined with the lack of effective tools to measure innovative output should constrain the agencies from taking extreme enforcement actions. The competitive

effects of bundled discounts, and appropriate treatment under the antitrust laws, also lack a clear consensus but remain of interest to antitrust enforcers. So one might expect that questions directed to innovation effects and bundling might find their way into future reviews in appropriate transactions.

In contrast, the “too big to fail” concern is likely to have been a creature of a unique moment in time. One can envision similar questions arising in the context of mergers of financial institutions, but the government has more direct levers than antitrust law available to address those concerns. And although former Commissioner Leary’s view that the antitrust laws should reach a transaction that leaves the surviving entity so financially crippled that it is no longer a competitive constraint has some theoretical appeal, it is difficult to imagine the concern presenting itself in the real world.

Despite the far ranging inquiry into somewhat esoteric issues, this very large and complex merger review ultimately concluded with a fairly conventional outcome. And the investigation did not present what many counsel to pharmaceutical companies regard as the issue that they would most like to test in litigation – a pure potential competition challenge. Despite the several instances of FTC Consent Orders requiring divestitures of pipeline products (many of which are never approved), the FTC has never litigated a pure potential competition case in a pharmaceutical merger. That may have to await a future deal.