Dissenting Statement of Commissioner Rohit Chopra

In the Matter of AbbVie, Inc. / Allergan plc
Commission File No. 1910169
May 5, 2020
Executive Summary

- The Federal Trade Commission is settling charges regarding AbbVie’s unlawful takeover of Allergan. For the first time, the FTC is ordering drug divestitures to a company that does not offer any prescription drugs: Nestlé. This is risky and concerning.

- I have been unable to identify any time in the agency’s history where the FTC has filed a lawsuit to block an unconsummated drug company merger. The agency’s default strategy of requiring merging parties to divest overlapping drugs is narrow, flawed, and ineffective. It misses the big picture, allowing pharmaceutical companies to further exploit their dominance, block new entrants, and harm patients in need of life-saving drugs.

- Divesting assets is only an appropriate remedy if the buyer will fully replace the competition lost by a merger. But, merging parties have little incentive to sell to a strong competitor and, in fact, succeed more when the buyer fails. New entrants face high hurdles even with well-capitalized buyers. The agency must always closely vet divestiture buyers and conduct careful financial due diligence to determine whether they can or will aggressively compete. If no suitable buyers exist, the FTC should sue to block the merger outright, rather than settling.

- The Commission is too confident that Nestlé can cure this merger. Nestlé is not a pharmaceutical company. Its core focus is on food, beverages, and other grocery store items. While it has a nutrition subsidiary, this line of business does not match the capability and capacity of Allergan, which currently owns the rights to drugs that treat patients with serious pancreatic conditions. In addition, Nestlé has a checkered record in its past experiments with pharmaceuticals. If this new venture into pharmaceuticals does not succeed, it will not have a meaningful impact on Nestlé’s financial results.

- To address other harmful effects of this proposed merger, the FTC is not ordering a traditional sale of assets. Instead, the agency is ordering AbbVie and Allergan to give back the rights to a major drug development project to AstraZeneca. This is a windfall for AstraZeneca, who will pay nothing for a valuable drug development project and is free to re-license the business to another company. It is unclear where this project falls in AstraZeneca’s development priorities and whether the company is committed to the project over the long-term.

- The FTC should take concrete steps to move forward from this unfortunate decision and its troubling outcome. The Commission should improve its approach to analyzing mergers where new market entrants drive innovation, enhance our divestiture buyer evaluation process by including staff with financial and technical expertise, strengthen our coordination and cooperation with state attorneys general in merger investigations, and provide greater transparency to the public about the scope of merger reviews and remedies.
I. Introduction

The current coronavirus outbreak and resulting public health and economic emergency are rightfully leading many government officials to question status quo approaches to policy, regulation, and enforcement. At the Federal Trade Commission, we should be doing the same.

I have been unable to identify any time in the agency’s history where the FTC has filed a lawsuit to block an unconsummated drug company merger.¹ Instead, the FTC examines whether or not the two merging drug companies offer any competing products. If not, the agency clears the deal unconditionally, like in Takeda’s recent $62 billion takeover of Shire. If companies do have competing products, the agency requires them to divest overlapping drug product offerings to another company, like in Bristol Myers-Squibb’s recent $74 billion takeover of Celgene.

Over the years, individual Commissioners and FTC officials have questioned whether this fully remedies competitive harms.² However, the agency continues to defend its work, and, in my view, largely believes the status quo is working just fine. But, it isn’t. The FTC’s strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective. This strategy fails to account for how executives make decisions about their drug product portfolios, how larger portfolios can suppress new entry, and how companies use portfolios to increase bargaining leverage across the supply chain. The approach has contributed to a shrinking number of Big Pharma giants that increasingly prioritize maintaining patent monopolies over discovering new medicine.

Drug prices are exorbitant and continue to climb, price-gouging patients in life or death situations. And too many new innovators can’t get off the ground to break through the barriers to entry that incumbents have created to defend their drug turf.

Today’s proposed resolution to the latest pharma megamerger, AbbVie’s (NYSE: ABBV) $63 billion takeover of Allergan (NYSE:AGN), is a stark display of the agency’s myopic approach. The FTC has given the green light to a merger that offers no meaningful benefits, but raises many alarm bells.

For the first time, the FTC is proposing a pharmaceutical merger settlement that divests a prescription drug business to a buyer that isn’t a drug company. The settlement requires Allergan to divest drugs used to treat patients with pancreatic cancer, cystic fibrosis, and other serious pancreatic disorders. The Commission is putting its full faith in Nestlé (SIX: NESN), the maker of KitKats and Tidy Cats, to take Allergan’s place in the market. The Commission is confident it can restore competition by divesting essential medicine to a company whose core business is selling packaged consumer products like candy and cat litter.

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¹ The FTC has filed lawsuits in other non-drug pharmaceutical markets, such as medical instruments and technology. However, those markets are distinctly different from small molecule drugs and biologics. They do not share any of the dynamics at issue in drug mergers such as the one here. As I discuss in this statement, these dynamics make the industry fraught with competitive problems not easily resolved by one-off divestitures.

Without a doubt, Nestlé is a large company with many capabilities – in food and beverages. Currently, the company does not offer a single prescription drug product. It strains the bounds of credulity that the Commission feels so certain that this company will be a formidable, committed competitor for a drug that patients with pancreatic cancer, cystic fibrosis, and other serious conditions depend on.

In a separate provision, AbbVie and Allergan will pull out of a licensing and development deal for a pipeline immunology drug with AstraZeneca (NYSE:AZN). AstraZeneca will pay nothing for this “divestiture” and is free to re-license the product. The FTC has put its faith in a proposal that AstraZeneca, who publicly reported a few years ago that it was retreating from immunology, will follow Allergan’s path to bring this drug to market.

Commissioners should always rely on evidence and examination, rather than ideology or intuition. We are accountable for agency decisions and for giving appropriate direction to staff. This is particularly true when it comes to merger enforcement. FTC merger settlements are supposed to restore the competition killed off from a transaction. Looking for product overlaps and then accepting risky or questionable buyers to eliminate them is not sound competition policy.

There are a number of problematic aspects with the FTC’s investigative approach to pharmaceutical industry mergers and to proposed remedies. In this statement, I will focus primarily on the issue of divestiture buyers. Accepting risky buyers that are unlikely to fully restore competition does a disservice to patients and worsens the out-of-control drug costs in our country. If no buyers are capable of restoring competition, the FTC should take steps to block the merger outright.

Below, I discuss some background information on divestiture remedies. I then describe why Nestlé and AstraZeneca are no cure for this proposed merger. I conclude with a set of concrete steps that the Commission should include in its work going forward.

II. Divestiture Remedies and Supporting Conduct Provisions

Before discussing the specific divestiture buyers approved by Chairman Simons, Commissioner Phillips, and Commissioner Wilson, we must bear in mind the challenges and distorted incentives that are inherent in the divestiture process.

Divestiture remedies to address a harmful merger can only succeed if the buyer fully restores the competition that existed prior to the merger. FTC merger settlements typically require the merging parties to divest a line of business, usually tied to specific products or geographies, to one or more approved buyers. But, given the incentives of merging parties and buyers of divested assets, the entire process can be fraught. The FTC must be especially careful. These practices are likely even more prevalent in industries rife with anticompetitive abuses, such as the pharmaceutical industry.³

³ The pharmaceutical industry has long been the focus of anticompetitive conduct enforcement by the FTC, state attorneys general, and private litigants. Challenged conduct includes pay-for-delay settlements, anticompetitive product hopping, fraudulent orange book listings, and sham litigation. Both AbbVie and Allergan have been the
A. Merging companies want to sell assets to weak buyers, because these buyers will be their competitors.

When merging companies need to divest an asset, a set of assets, or a line of business to address a reduction in competition stemming from the transaction, the combined entity is actually selling to its future competitor. The merging companies may not want to sell to the highest bidder. They have an incentive to also consider who is likely to be the weakest buyer and the easiest to dominate once the buyer takes full ownership of the divested product.

A 1999 analysis confirmed this concern, noting that merging companies “recommended marginally acceptable buyers and, on some occasions, engaged in post-divestiture strategic behavior aimed at minimizing the competitive impact of the buyer’s entry into the market.”

B. Buyers might find a bargain, but they may not have the same incentives or ability to fully restore competition.

When merging parties are eager to consummate their transaction in as little time as possible, they often look to satisfy concerns of antitrust enforcers by quickly finding buyers for specific assets in markets where a merger would cause competitive harm. This allows prospective buyers to purchase divested assets more cheaply than they otherwise might be able to. If the asset is already generating significant cash flow, the investment may still be worthwhile even if sales decline significantly post-transfer.

Sometimes, companies may simply want to purchase an “option.” In other words, buyers might find it worthwhile to purchase an asset because it could become useful sometime in the future, even if they don’t have concrete plans to focus on it immediately.

There are many other problems that make for a bad divestiture buyer. For example, as I noted in *Praxair/Linde*, the buyer might be loading up the asset with debt, making it less likely they will have the flexibility to grow the divested business and effectively compete. In addition, a buyer might have already been planning to enter the market anyway, which means that they are bolstering their own competitiveness rather than replacing competition.

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C. Divestiture remedies can fail even with well-capitalized buyers and experienced management, especially when the business is not a core focus of the owner.

Rather than block a merger outright or weed out questionable buyers, the FTC sometimes rolls the dice. When rental car giant Hertz sought to get even bigger with its illegal takeover of Dollar Thrifty, the FTC entered into a settlement to address the illegal merger by ordering a divestiture of its Advantage Rent a Car business to Franchise Services of North America (FSNA) and Macquarie Capital. FSNA didn’t operate a traditional airport rental car operation; it ran a U-Haul and Rent-a-Wreck business that served a different customer need. The CEO of FSNA had previous experience in traditional rental cars, and the FTC approved the buyer. But, soon after the FTC settlement, the new enterprise filed for bankruptcy.

When the FTC reviewed the illegal merger of Dollar Tree and Family Dollar, it settled for divestitures to Sycamore Partners, the private equity outfit. Sycamore Partners proposed a management team with experience in the business. Nevertheless, the arrangement quickly failed and stores were ultimately resold to Dollar General. Instead of creating a new competitor, the big national players simply grew more powerful.

In the illegal takeover of Safeway by private equity-owned Albertson’s, the FTC didn’t sue to block the merger outright. Instead, the agency approved Haggen as the buyer of 146 stores. Haggen was an experienced grocer and was backed by a financial partner, but only operated 18 stores. Within nine months, Haggen filed for bankruptcy. Haggen would later accuse Albertson’s of sabotaging the divestitures in order to steal customers from its new rival. Albertson’s then bought back many of the divested stores in bankruptcy.

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8 Id.
11 In the Matter of Cerberus Institutional Partners V, LP et al., FTC File No. 141-0108 (July 2, 2015).
Despite these outcomes, the FTC published a study in 2017 and declared that its merger remedies were effective.\textsuperscript{14} It is important that we learn from these and other divestitures that did not fully restore competition.

\textit{D. Divestitures are more likely to fail when the FTC relies on speculation, rather than real-world data and robust due diligence.}

During my two years as a Commissioner, I have expressed concerns that the FTC makes many of its decisions based on superficial evidence, rather than a close examination of the underlying dynamics in an industry. As a result, the agency can inadvertently miss marketplace realities.

To combat these concerns, I have strongly advocated that we increase the level of analytical rigor in our decision-making across the agency’s mission, particularly when it comes to remedies. In the context of a divestiture remedy, this includes a careful assessment of divestiture buyers. Our process should more closely resemble how a lender, insurer, or equity investor might assess a corporate entity’s likelihood of success.

A divestiture buyer cannot simply have management or a sales force with expertise or access to capital. Instead, a well-developed long-term strategy that fits within the overall goals of the corporation is necessary. Therefore, we must conduct due diligence that specifically explores how divested assets will fit into a buyer’s broader business and long-term financial strategy. For example, we should gather specific evidence that speaks to the likelihood of a divestiture buyer quickly reselling or repurposing an asset. We should examine whether an asset may simply be a part of a branding strategy to increase sales of its other products. Of course, we must always discount the assertions of their executives and lawyers, and we must always seek to substantiate their assertions. Without this level of due diligence, we roll the dice and risk failure.

Assessing the suitability of a divestiture buyer is difficult, and we must keep these challenges in mind as we evaluate the likelihood that Nestlé and AstraZeneca will fully replace Allergan’s role in key product markets.

\textbf{III. Nestlé Cannot Cure This Harmful Merger}

Pancreatic cancer is expected to be the second leading cause of cancer-related death in America this year. It has the highest mortality rate of all major cancers.\textsuperscript{15} Cystic fibrosis is a hereditary condition that clogs a person’s lungs and obstructs the function of their pancreas. Patients are typically diagnosed as babies. Chronic pancreatitis is a condition where individuals experience persistent inflammation of the pancreas that leads to permanent damage. Patients with pancreatic cancer, cystic fibrosis, chronic pancreatitis, as well as those with other conditions that affect the pancreas, may require pancreatic enzyme replacement therapy.


According to the agency’s investigation, the two major prescription drugs used for pancreatic enzyme replacement therapy were AbbVie’s Creon and Allergan’s Zenpep, with Creon as the clear leader. While there are three other drugs that are also approved for this therapy, two of the three products are made by small pharmaceutical companies that have struggled to make inroads in capturing market share. Allergan owns the third, Viokase. There are no generic competitors.

The merger of AbbVie and Allergan would allow the merged companies to dominate the market, reducing competition in violation of the law. To cure this harm, the majority proposes that the merged AbbVie-Allergan sell the rights to Zenpep and Viokase to Nestlé. This is a risky gamble.

A. Nestlé’s core business is focused on food and beverages, not prescription drugs.

Nestlé may be one of the world’s largest corporations, but it is not a pharmaceutical company. As the company’s mission – “Good Food, Good Life” – indicates, Nestlé is a food and beverage company. The lion’s share of its revenue and profits comes from its candy products like CRUNCH and KitKat chocolate bars; coffee products like Nespresso, Nescafé, Blue Bottle, and packaged Starbucks offerings; and other items typically purchased while grocery shopping. In the United States, Nestlé is particularly successful in pet care through its subsidiary Purina, which markets Friskies, Beggin’, Tidy Cats, and other brands.

Nestle seeks to outperform its industry peers in the STOXX Global 1800 Food and Beverage Index,16 whose major components include Coca-Cola, PepsiCo, and Diageo. The company’s public financial statements note that the company ties certain executive compensation components to this metric. Neither the Board nor management have recently stated that they intend to transform Nestlé into a major player in the pharmaceutical business.

B. Nestlé’s efforts on nutrition do not come close to Allergan’s capabilities and capacity to compete in pharmaceuticals.

Like many other food and beverage companies, Nestlé has sought to increase its offerings that appeal to health and wellness across its businesses. For example, in its pet care business, Nestlé has launched brands like Purina ONE and Beneful, which cater to consumers looking for healthy food for their dogs. Nestlé recently launched a new Starbucks packaged coffee product with “essential vitamins.”

Nestlé also has a subsidiary called Nestlé Health Science that develops and markets “nutritional therapies,” such as vitamins, supplements, nutritional shakes, and soups. One of its top-selling products is the Boost nutritional drink.17 Like Nestlé’s other lines of businesses, Nestle Health Science is heavily engaged in traditional food marketing. For example, the company markets the Boost business by developing new varieties of the product and catering to special diets, such as

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lactose-free and gluten-free. Boost now offers multiple flavors, a pudding format, and special varieties for men and women.18

The Nestlé Health Science subsidiary has also invested in other vitamin and supplement businesses. Recently, it made a major investment to acquire Persona, a personalized vitamin startup.19 It also purchased Atrium Innovations for $2.3 billion, which makes probiotics, vitamins, and meal supplements.20

Nestle and its nutrition subsidiary cannot match Allergan’s experience and know-how. While this subsidiary is offering over-the-counter products to those suffering from pancreatic conditions,21 is marketing some of its products through doctors,22 and is run by executives with related pharmaceutical expertise,23 the subsidiary’s capabilities pale in comparison to what Allergan is today.

Over the years, Allergan and its predecessor companies have developed and acquired a large portfolio of top-selling drugs.24 Today, Allergan has “built one of the broadest pharmaceutical and device research and development pipelines in the industry.”25 It takes many years for a pharmaceutical company to develop into what Allergan is today. Companies like Allergan don’t build themselves into the behemoths they are by accident: they do so for the very specific purpose of achieving the scale and breadth of products across a portfolio that they can then use as leverage in negotiations with health insurers and pharmacy benefit managers. Pharmaceutical businesses have increasingly evolved this way over the last twenty years. This does not happen overnight.

There is simply no comparison between Allergan, with its strategic focus and experience in pharmaceuticals, and Nestlé’s nutrition business.

C. Nestlé has a checkered record when it comes to its past experiments with pharmaceuticals.

25 We Are Allergan, ALLERGAN (last visited May 1, 2020), https://www.allergan.com/about/about-allergan.
In 2014, Nestlé became the sole owner of Galderma, a dermatology company. Galderma was originally a joint venture between Nestlé and L’Oréal until Nestlé bought back all the shares in 2014. The venture was not particularly fruitful. Documents produced to the FTC confirm that Nestlé was unsuccessful in XXX XXXX XX XX XX XX XXXXXXXXXXXX XX. Under pressure from activist investor Third Point, Nestlé sold the business in 2019.

In 2011, Nestlé Health Science purchased Prometheus Laboratories. Prometheus held the U.S. rights to an oncology drug that Nestlé sold off in 2019. Nestlé then exited its investment in Prometheus later that year. In 2010, Nestlé also exited its eye care business. Typically, Nestlé has justified these and other exits on the basis of a periodic strategic review of whether or not the acquired business fit into the company’s core strategy. This raises the risk of whether Zenpep might find itself facing similar considerations of whether it fits into the company’s core strategy in the future.

D. Other competitors with a small prescription drug footprint have failed to gain traction in this market, which suggests that Nestlé faces an uphill battle relative to Allergan.

Today, only four companies sell prescription pancreatic enzyme replacements: AbbVie’s Creon, Allergan’s Zenpep and Viokace, Vivus’ Pancreaze, and Digestive Care’s Pertzye. Because all of the products have similar clinical effectiveness, sales are heavily dependent on whether the drug is listed as “preferred” by a patient’s insurance company, since patients typically pay lower co-pays for drugs with preferred status.

The market leader, Creon, is the only medication approved for treatment of five exocrine pancreatic insufficiency medical diagnoses (also known as “indications”) in adults. Allergan’s Zenpep and Digestive Care’s Pertzye have approval for only three of Creon’s five indications. This may give Creon a competitive advantage, since the eligible patient population that can be treated with Creon is larger than the population that can be treated with Zenpep. This also may

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give AbbVie more leverage to bargain for preferred positions on an insurance company’s list of covered drugs.

Currently, Allergan aggressively markets its portfolio of drugs to make sure its drugs are preferred by insurance companies. The evidence in the investigation shows

Chairman Simons, Commissioner Phillips, and Commissioner Wilson argue that Nestlé can simply copy Allergan’s strategy, even though it will only have one drug to market compared to the many that Allergan offers today.

Unsurprisingly, smaller pharmaceutical companies that don’t offer an expansive list of drugs have less bargaining leverage. Pancreaze and Pertzye have less than 2% market share, even though they work just as well for most patients that use Creon and Zenpep. This reality relegates companies like them to market their products on a more limited basis, with the hopes that another drug company may one day take them over. Nestlé, which will not have much bargaining leverage, may find itself losing more share to Creon and suffering the same fate as Pancreaze and Pertzye.

Chairman Simons, Commissioner Phillips, and Commissioner Wilson claim that Nestlé has “budgeted” funds for marketing and future development. This is not a promise but is instead a sales pitch. I prefer to approach these assertions with skepticism and evaluate them against how they fit into the buyer’s overall financial incentives.

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33 Data for Digestive Enzymes (2018 – 2019), IQVIA (on file with IQVIA); see also Analysis of Agreement Containing Consent Orders to Aid Public Comment, In the Matter of AbbVie Inc. and Allergan plc, FTC File No. 191-0169, 2 (May 5, 2020).
E. Nestle manages its business to maximize its overall profits. Even if the Zenpep business shrinks, it will have little impact on Nestlé’s overall financial results.

When taking a risk of divesting a drug to food and beverage company, it is particularly important to determine whether success or failure will make a meaningful difference in Nestlé’s overall financial performance – especially for a company that is seeking to enter a market outside of its core capabilities and strategic focus. In my view, the Commission primarily focused on whether Nestlé would have the personnel and manufacturing capabilities to offer Zenpep. However, I am concerned that we did not conduct sufficient financial due diligence.

After conducting my own analysis of financial information from Nestlé, it is clear that the purchase of these divested businesses is fairly minor. In fact, the purchase was not even significant enough to disclose the financial details to Nestlé’s investors. While other transactions and business developments have been carefully examined in management calls with analysts, the company has been mostly silent on this transaction, potentially due to the fact that the acquisition is much smaller than its other transactions. Based on my review, evidence suggests that even if Zenpep lost significant share to a combined AbbVie and Allergan, it would not materially impact Nestlé’s overall earnings per share.

I can also conclude that Nestlé’s top management and board directors will not have an incentive to devote significant energy to ensure that this divestiture is successful. Based on my assessment, it is more likely to prioritize revitalizing its Perrier and San Pellegrino sparkling water brands, investing further in pet care, and increasing sales of its Starbucks packaged coffee business. All of these would make more financial sense than allocating significant time and effort to make Zenpep a true success. In addition, based on Nestlé’s approach to mergers and acquisitions, I also believe that there is a significant risk that the Zenpep business will be resold.

F. Supplemental order provisions could have reduced the risk of Nestlé as the divestiture buyer.

While I believe there would be many buyers that may have been superior to Nestlé, the Commission could have taken steps to increase the chance that Nestlé would succeed in taking Allergan’s place over the long term. These provisions could be designed after thorough due diligence on Nestlé’s corporate governance, executive compensation, mergers and acquisition strategy, and capital allocation strategy.

For example, the Commission could have sought amendments to the company’s senior management compensation agreements that incentivize investment and attention to Zenpep. The Commission could have sought binding assurances that Nestlé senior management would not resell assets without prior Commission approval. The Commission could have sought terms that give the nutrition subsidiary more independence when seeking outside financing to grow the business. Other supplemental provisions could also bolster senior management’s commitment to long-term success of the divestiture.

34 Merging parties typically propose a buyer to the Commission rather than the Commission selecting a buyer from a list of bidders that parties are willing to sell to.
Given Nestlé’s core focus, track record, and the financial aspects of this deal, I have serious doubts that Nestlé will be able to replace the competition killed off by AbbVie and Allergan’s merging. The combined company has essentially selected a new competitor that it will clearly be able to crush in the market, and the FTC has given the go-ahead. This is too risky and is a mistake.

IV. AstraZeneca Has an Option to Compete, Not a Commitment to Compete

Injectable biologic drugs that affect the body’s immune system can be used to treat a host of conditions and disorders. Unsurprisingly, such drugs can be very expensive for companies to develop and for affected patient populations to afford. Under the FTC’s status quo approach of analyzing pharmaceutical mergers, the agency determined that Allergan had an immunologic pipeline drug in development that could one day rival those currently marketed by AbbVie. Since AbbVie also has a pipeline drug very similar to Allergan’s in development, the FTC is proposing that the merging companies renegotiate a development deal with AstraZeneca.

Both AbbVie and Allergan are developing “IL-23” inhibitors to treat moderate-to-severe Crohn’s disease and ulcerative colitis. These two diseases are caused by chronic inflammation in the digestive track and have similar symptoms: severe diarrhea, abdominal pain, fatigue, and weight loss. Both can be debilitating and lead to life-threatening complications.

The parties are two of only four companies developing IL-23 inhibitors for Crohn’s disease and ulcerative colitis. AbbVie’s IL-23 inhibitor Skyrizi is expected to be approved in to treat Crohn’s disease and in to treat ulcerative colitis. Allergan is expected to launch its IL-23 inhibitor in 2025 for Crohn’s disease and in 2026 for ulcerative colitis.

These unusual deal terms make me question whether AstraZeneca will have the incentive to fully replace competition lost from the merger or to complete the development process. I share the view of some industry analysts who believe this deal is a massive windfall for AstraZeneca. The company will pay nothing and gets to keep the $250 million upfront payment it received a few years ago from Allergan. Now, it can re-license the project again, which could further delay needed competition in the immunology space.

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35 IL-23 is a pro-inflammatory cytokine that is secreted by white blood cells. Allergan’s version of the IL-23 inhibitor is called brazikumab, and AbbVie’s is called Risankizumab. See Immunology Pipeline: Risankizumab, ABBVIE (last visited May 4, 2020), https://www.abbvie.com/our-science/pipeline/risankizumab.html; Gastroenterology Pipeline: Brazikumab, ALLERGAN (last visited May 4, 2020), https://www.allergan.com/research-and-development/pipeline.


37 Id., 2.


A. **AstraZeneca has only recently re-focused on the immunology space, which suggests it may not prioritize the development of brazikumab.**

In 2015, AstraZeneca made a strategic decision to focus on a narrow set of core therapy areas that did not include immunology. At that time it began selling off rights to various drugs in its immunology portfolio. Brazikumab was part of that effort. In 2016, it licensed its research and development of brazikumab to Allergan. Prior to that, in 2015, AstraZeneca divested its non-U.S. global rights to Entocort (a medicine for ulcerative colitis and Crohn’s Disease). AstraZeneca decided to discontinue its work on brazikumab because the project is “outside [of] AstraZeneca’s three main therapy areas.” AstraZeneca licensed brazikumab to Allergan, and Allergan took over the work in exchange for a $250 million upfront payment and royalties paid to AstraZeneca. While AstraZeneca is apparently now re-focusing on immunology, these facts raise questions about its long-term commitment to the field.

The Commission proposes to resolve competitive concerns from the overlap between Allergan’s brazikumab and AbbVie’s Skyrizi by requiring Allergan to terminate the 2016 licensing agreement with AstraZeneca. AstraZeneca will take back all intellectual property it previously licensed to Allergan, as well as all the intellectual property Allergan has developed in relation to brazikumab since acquiring the license to the product. In addition, Allergan will assign the contracts related to manufacturing and clinical development of brazikumab to AstraZeneca and transfer ownership of all clinical study materials and clinical data. AstraZeneca will not make an upfront payment for brazikumab, as would normally be expected in a Commission-approved divestiture. Instead, the money is flowing in the opposite direction: Allergan will reimburse AstraZeneca up to \[X\] of AstraZeneca’s development costs related to brazikumab from \[X\].

B. **Given the deal structure of the “divestiture,” AstraZeneca has weaker incentives than Allergan to bring brazikumab to market and to compete successfully.**

The Commission’s proposed remedy is not a divestiture in a traditional sense, because there is no purchase of assets. Allergan is merely terminating a 2016 licensing agreement that Allergan entered into with AstraZeneca for the rights to take over development work of brazikumab. Thus, the Commission’s remedy merely grants AstraZeneca the right to continue the development of a product that it previously decided to get rid of, with funding from Allergan.

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43 AstraZeneca Press Release, supra, note 40.
44 Id.
One analyst correctly noted that this arrangement is “essentially a ‘free’ new pipeline option.” In other words, if AstraZeneca wants to prioritize brazikumab, it can, but it doesn’t have to. It is not a true capital commitment like Allergan’s. AstraZeneca clearly had good cause to believe that Allergan would be better positioned to commercialize brazikumab than it did when it entered into the 2016 licensing agreement. This is not unlike a situation where someone pays $300 for a ticket to a desirable concert performance, but then gives it away. When we make a substantial purchase like that, we are revealing our preferences that we value that good, service, or investment. This can demonstrate that the purchase is a priority ranking above other items we might purchase. Using this analogy, someone who gets a free ticket is much more likely to be a no-show than someone who paid for it. And if the ticket’s market price is $300, there is also a risk that the person getting it for free will simply resell it for a $300 profit.

I am always concerned when a buyer is selected outside of a typical, competitive bidding process. Theoretically, AstraZeneca may find it worthwhile to prioritize this project over others. In my view, the FTC’s investigation did not include a rigorous analysis of all of AstraZeneca’s development projects and the metrics AstraZeneca uses to prioritize such initiatives. Absent this evidence and analysis, we have little to rest on when claiming that AstraZeneca will fill the shoes of Allergan, except for self-interested assertions by the parties benefiting from this settlement.

Of course, there is a risk that the current owner of a drug development project will not succeed. However, we must take steps to ensure that any prospective buyer has the same or higher chance of success.

Unfortunately, the Commission did not require an alternative deal structure that would have increased the likelihood of AstraZeneca’s entry. The deal structure could have easily been altered in ways that would better reveal AstraZeneca’s preferences over other potential projects.

D. There are no supplemental conduct provisions to ensure that AstraZeneca will bring brazikumab to market.

The unusual deal structure is enough to disqualify AstraZeneca as a credible replacement for Allergan. Even though the Commission insisted on pushing forward with AstraZeneca, the agency did not take steps to increase AstraZeneca’s chances of success by including supplemental conduct provisions tailored to the features of competition in the market.

As discussed earlier, the FTC often includes supplemental conduct provisions to increase the likelihood that a divestiture buyer can replace the competitive intensity lost by a merger. For example, AstraZeneca is not subject to the Commission’s order, and the Commission is not requiring AstraZeneca to prioritize the brazikumab project over other opportunities.

The Commission could have also taken steps to reduce a key barrier to entry and expansion for AstraZeneca by restricting AbbVie and Allergan’s contracting and rebating practices. This would

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make it more likely that AstraZeneca would exercise its option to develop and bring brazikumab to market.

Importantly, in the immunology space, a key feature of competition is the ability for a market player to engage in “portfolio contracting” and “bundled rebates” across its portfolio of drugs. The evidence in the investigation suggests that AbbVie currently uses its bargaining leverage from its blockbuster drug Humira to preference its other immunology drugs. For example, AbbVie’s rebating practices are suspicious in their own right, and certain aspects of these practices might be unlawful. But, rebating is undoubtedly a fixture of the competitive environment in immunology that might act as a barrier to entry and expansion for other drugmakers with less bargaining leverage.

One potential way to increase the likelihood that AstraZeneca would fully replace lost competition and bring brazikumab to market would be to restrict certain contracting practices by the combined AbbVie and Allergan.

In certain instances, the FTC and Department of Justice (DOJ) have prohibited contracting practices that make entry and expansion difficult for a divestiture buyer. For example, in 2016, the DOJ determined that AnheuserBusch InBev’s (ABI) acquisition of SABMiller would increase ABI’s incentive and ability to disadvantage its remaining brewery rivals by limiting or impeding the distribution of their beers. ABI’s practices typically included incentives for independent wholesale distributors to sell exclusively or near exclusively ABI beers. To remedy that concern, ABI was required to divest SABMiller’s entire U.S. business, including SABMiller’s ownership interest in MillerCoors, the right to brew and sell certain SABMiller beers in the United States, and the worldwide Miller beer brand rights. ABI was also prohibited from engaging in contracting practices designed to limit the ability and incentives of independent beer distributors to sell and promote the beers of ABI’s rivals. It is unclear whether this supplemental conduct provision fully restored competition, though it is certainly better than allowing the divestiture to proceed without meaningful safeguards.

The FTC pursued a similar approach in its 2012 order resolving competitive concerns stemming from the merger of CoStar Group, Inc. and LoopNet, Inc. The FTC imposed supplemental conduct provisions that prohibited the merged firm from restricting customers’ ability to support the divested product or requiring customers to buy any of its products as a condition for receiving other products. Again, we do not know whether this belt-and-suspenders approach

48 Id.
50 Id.
fully restored the competition lost by the merger, but it is certainly less risky than allowing a
divestiture buyer to be squashed by the combined company.

While provisions like these could have ameliorated some of the concerns with AstraZeneca, I
ultimately conclude that simply allowing AstraZeneca to get a windfall without skin-in-the-game
is problematic in its own right.

IV. Conclusion

AbbVie and Allergan are no strangers to the Federal Trade Commission. Both companies are
pioneers in intellectual property abuse and anticompetitive practices. The FTC has battled both
companies for years, including one case that went to the Supreme Court and another that
achieved a record-breaking monetary judgment.51

But in this matter, we took a far different approach. Just days after the President declared a state
development due to the current global pandemic, the FTC’s Bureau of Competition entered into
a settlement with AbbVie and Allergan, eliminating any realistic possibilities of correcting the
deficiencies in the settlement.

The FTC must learn from this experience and let go of the status quo. The Commissioners
should take several steps to move forward.

(1) Dramatically increase rigor and Commission supervision of innovation-merger
investigations, especially in industries where new market entrants drive innovation.

I share Commissioner Rebecca Kelly Slaughter’s concerns about investigations into innovation
effects of mergers. It is difficult to quantify the harms associated with suppressed entry of new
life-saving innovations or breakthrough technologies. When pharmaceutical industries assemble
multiple dominant products or when technology companies combine multiple sources of data,
this affects how those firms can exert bargaining leverage across the supply chain. It also reduces
the ability for new firms to raise capital for entry.

However, in my view we do not have a robust approach to assess how a merger can choke off the
entry of startups and nascent businesses. I have observed that when we do uncover evidence that
a transaction may lead to these effects, we do not give it the appropriate weight.

As Commissioners, we must substantially increase our supervision to ensure we are meeting our
obligations to the public to protect competition. Specifically, the Commission should:

51 In 2018, after years of hard-fought litigation, a federal court awarded the FTC a $448 million monetary judgment
– the highest ever in a litigated antitrust case – after finding that AbbVie broke the law by filing sham patent
infringement lawsuits against potential generic competitors. Fed. Trade Comm’n v. AbbVie et al., 329 F. Supp. 3d
98 (E.D. Pa. 2018). For years, the FTC and Allergan battled in court over so-called pay-for-delay settlements,
where pharmaceutical companies gave payoffs to generic companies to stay off the market. The case was ultimately
purchased Allergan, and the combined company took Allergan’s name. The CEO of Actavis, Brent Saunders,
continues to be the CEO of Allergan).
• Request that the Inspector General conduct a programmatic review of our merger investigations in biomedical, consumer technology, and other innovation markets.
• Hold formal Commission meetings on large merger investigations in these sectors prior to any proposed remedy negotiated between staff and merging parties.
• Analyze “stealth consolidation” in the pharmaceutical sector, in accordance with Commissioner Christine S. Wilson’s statement in February of this year.\(^{52}\)
• Require the Bureau of Competition to obtain a vote of the Commission before closing investigations or granting early termination of the Hart-Scott-Rodino waiting period for large mergers, particularly in sectors where innovation is critical for the public interest.\(^{53}\)

(2) Enhance our analytical capabilities when assessing prospective divestiture buyers and when crafting remedies for anticompetitive mergers and conduct.

During the Senate confirmation process, Chairman Simons outlined his desire to reduce the failure rate of remedies in merger settlements.\(^{54}\) I completely agree with this objective.

The FTC Bureau of Competition’s Compliance Division is one of the most important offices in the entire agency. The office assesses prospective divestiture buyers, creates remedies, and ensures compliance with Commission orders. The Compliance Division largely consists of attorneys. While the division has strong capabilities when it comes to assessing many of the legal dimensions of a transaction, including the transfer of contracts and intellectual property, the Commission has not augmented the division with other needed skill sets related to the financial and technical dimensions.

For example, in the United Kingdom, the Competition and Markets Authority established a highly respected group focused on remedies. The group is interdisciplinary and includes individuals with backgrounds in law, auditing and accounting, financial analysis, investment banking, management consulting, and other analytically minded skill sets.\(^{55}\) It is clear that this group is a tremendous asset to the Competition and Markets Authority’s competition policymaking.

The Commission would also benefit from those with diverse backgrounds and technical expertise. To increase analytical rigor and reduce risk of divestiture remedy failure, the Commission should:

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\(^{52}\) Statement of Commissioner Christine S. Wilson joined by Commissioner Rohit Chopra, Concerning Non-Reportable Hart-Scott Rodino Act Filing 6(b) Orders (Feb. 11, 2020),

\(^{53}\) For example, shortly after the new Commission took office in 2018, the Bureau of Competition was able to grant unconditional clearance to Takeda’s $62 billion takeover of Shire without seeking a Commission vote.


• Support the Compliance Division with additional professionals with experience in transactional due diligence and other technical skill sets.
• Increase the proportion of financial analysts in the Bureau of Economics and elevate their role in investigations.

(3) Increase coordination and cooperation with state attorneys general in merger review.

When law enforcement agencies do not effectively cooperate and coordinate, companies seeking to consummate unlawful mergers can take advantage of the gaps. Given their concurrent jurisdiction, the state attorneys general are key partners in competition enforcement. Coordination and cooperation can include sharing documentary evidence, conducting joint interviews and investigational hearings, and pooling resources on expert analysis. The FTC should do more to strengthen these partnerships. To advance this goal, the Commission should:

• Ensure that Commission staff verify that merging parties have complied with subpoenas and other reasonable information requests from state regulators prior to finalizing any settlement negotiations.
• Update agreements and policies governing joint investigations with state attorneys general on merger review.56
• Assist state policymakers who are seeking to institute state laws on merger control and pre-merger notification.

(4) Provide greater transparency to the public about the scope of FTC merger reviews.

Under agency rules, the Commission must solicit public comments on its administrative settlements regarding unlawful mergers. The agency publishes an Analysis to Aid Public Comment that describes the investigation. However, the FTC provides sparse information in this document. I previously raised this concern in Fresenius/NxStage,57

Greater transparency can increase confidence that the Commission was thorough and independent in its investigation, while still respecting laws and regulations governing confidentiality. It can also offer other merging parties clearer expectations of how it can fully cooperate. The Commission should:

• Publish a more detailed discussion of the analyses conducted regarding potential anticompetitive effects when proposing a settlement.
• Disclose the data sets relied upon to justify a remedy (or lack thereof).

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• Provide the public with more details about the assessment of any proposed divestiture buyers.
• Outline the Commission’s assessment of entry conditions post-transaction.

Today’s uncertain times reveal that the mission of the FTC has never been more relevant. The agency must evolve, and the Commission must take concrete actions to improve agency decision-making to ensure the agency is advancing this mission.