ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of AbbVie Inc. and Allergan plc
File No. 191-0169

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from AbbVie Inc. ("AbbVie") and Allergan plc ("Allergan") designed to remedy the anticompetitive effects resulting from AbbVie's proposed acquisition of Allergan. The proposed Decision and Order ("Order") contained in the Consent Agreement requires Allergan to divest all rights and assets related to its Zenpep and Viokase products to Nestlé S.A. ("Nestlé"). The proposed Order also requires that Allergan return its rights and assets related to brazikumab to AstraZeneca plc ("AstraZeneca").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Pursuant to a Scheme of Arrangement under Irish law, AbbVie will acquire all of the voting securities of Allergan from its shareholders for approximately $63 billion (the "Acquisition"). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for (1) prescription drugs for the treatment of exocrine pancreatic insufficiency ("EPI"); (2) Interleukin-23 ("IL-23") inhibitors for the treatment of moderate-to-severe Crohn's disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

THE PARTIES

Headquartered in North Chicago, Illinois, AbbVie researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including immunology, oncology, virology, neuroscience, and women's health. Among other products, AbbVie sells a product to treat EPI and is developing an IL-23 inhibitor to treat moderate-to-severe Crohn's disease and ulcerative colitis. Like AbbVie, Allergan researches, develops, manufactures, and sells prescription pharmaceutical products in the United States. Among its products, Allergan also sells a product to treat EPI and is developing an IL-23 inhibitor to treat moderate-to-severe Crohn's disease and ulcerative colitis.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

Drugs for the Treatment of Exocrine Pancreatic Insufficiency

EPI is a condition that results from a deficiency of pancreatic enzymes. Patients who have EPI cannot properly digest fats, proteins, and carbohydrates in the foods they eat and, as a result, may suffer from malnutrition and have uncomfortable gastrointestinal symptoms when they eat. EPI is treated using pancreatic enzyme products. Pancreatic enzyme products contain the active ingredient pancrelipase, a mixture of the digestive enzymes amylase, lipase, and protease that is extracted from the pancreas of a pig.

Only four companies sell prescription pancreatic enzyme product in the United States: AbbVie, Allergan, Vivus Inc. ("Vivus"), and Chiesi USA, Inc. ("Chiesi"). AbbVie is the clear market leader with its product, Creon, and Allergan is the second-largest supplier, with its product, Zenpep. Vivus sells Pancreaze and Chiesi sells Pertzye. Allergan also sells a second pancreatic enzyme product, Viokase, although its sales in the United States are much more limited. Together, AbbVie and Allergan have a share of more than 95 percent of the market for drugs to treat EPI.

Interleukin-23 Inhibitors for the Treatment of Moderate-to-Severe Crohn's Disease and for the Treatment of Moderate-to-Severe Ulcerative Colitis

Ulcerative colitis and Crohn's disease are the most common causes of chronic inflammation of the digestive track. Both diseases have similar symptoms—severe diarrhea, abdominal pain, fatigue, and weight loss—and both can be debilitating and lead to life-threatening complications. The location of the inflammation is the primary difference between the two diseases: ulcerative colitis is a continuous inflammation of the colon, affecting only the innermost lining, while Crohn's disease can occur anywhere between the mouth and the anus, has healthy parts of the digestive tract between inflamed parts, and can occur in all layers of the bowel walls. Because the diseases are similar, drugs that are effective in treating ulcerative colitis are also typically effective in treatment Crohn's disease (and vice versa), but the United States Food and Drug Administration ("FDA") requires that companies seeking ulcerative colitis and Crohn's disease indications for drugs conduct separate clinical studies and submit separate applications to market drugs for each indication.

A variety of drugs are approved to treat ulcerative colitis and Crohn's disease, but the effectiveness for most drugs is limited. IL-23 inhibitors are a new class of drugs to treat both diseases. Johnson & Johnson's Stelara is the only IL-23 inhibitor currently approved to treat moderate-to-severe Crohn's disease and ulcerative colitis in the United States. Stelara is both an IL-23 inhibitor and an Interleukin-12 inhibitor. Only three other companies—AbbVie, Allergan, and Eli Lilly and Company—have IL-23 inhibitors in late-stage development for ulcerative colitis and Crohn's disease. Allergan is developing brazikumab and AbbVie is developing Skyrizi.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Drugs to treat EPI and drugs to treat moderate-to-severe ulcerative colitis and Crohn's disease are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would likely result in substantial competitive harm to consumers in the markets for prescription drugs for the treatment of EPI, IL-23 inhibitors for the treatment of moderate-to-severe Crohn's disease, and IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. Together, AbbVie and Allergan account for more than 95 percent of the market for drugs to treat EPI, and they are two of a limited number of companies in late-stage development with IL-23 inhibitors to treat moderate-to-severe ulcerative colitis and Crohn's disease.

ENTRY CONDITIONS

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring the combined company to divest Allergan's Zenpep and Viokase business, including its regulatory approvals, intellectual property, contracts, and inventory to Nestlé, and Allergan's brazikumab business to AstraZeneca. AbbVie and Allergan also must transfer all business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to knowledgeable employees to assist in the transfer. The provisions of the Consent Agreement ensure that Nestlé and AstraZeneca become independent, viable, and effective competitors in the U.S. markets.

Nestlé is the world's largest food and beverage company, operating in more than 190 countries around the world. While the company is most well-known for its chocolate products, it also operates Nestlé Health Science, an integrated health company that focuses on nutrition

products, including enteral feeding products that are used in hospitals and at home by patients who are unable to chew or swallow food. Nestlé's existing business includes products that are highly complementary to the divestiture assets. Nestlé has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

AstraZeneca is a global research-based pharmaceutical company specializing in researching, developing, manufacturing, and marketing prescription products. AstraZeneca was responsible for conducting some of the early phase clinical studies for brazikumab, but out-licensed the product to Allergan in 2016. AstraZeneca is a well-qualified buyer for brazikumab because, as the original innovator of the product, it already has experience developing brazikumab prior to out-licensing it to Allergan, and, further, the key team members who were previously responsible for brazikumab's development are still employed by the company and will take responsibility for the developing the product. With its resources, capabilities, and previous experience with brazikumab, AstraZeneca is well positioned to successfully develop and commercialize the product and thereby replace the competition that otherwise would have been lost through the proposed Acquisition.

AbbVie and Allergan must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Nestlé or AstraZeneca are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires AbbVie and Allergan to unwind the sale of rights and assets and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. The Commission has agreed to appoint a Monitor to ensure that AbbVie and Allergan comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to the buyers. The proposed Order further allows the Commission to appoint a trustee in the event that AbbVie and Allergan fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.