



United States of America
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

September 3, 2020

The Honorable Xavier Becerra
Attorney General
California Department of Justice
Office of the Attorney General

Re: *AbbVie, Inc. and Allergan, plc*, FTC File No. 191 0169, C-4713

Dear Attorney General Becerra:

Thank you for your letter submitted in connection with the Consent Order issued by the Commission to address antitrust concerns arising from AbbVie Inc.'s ("AbbVie") proposed acquisition of Allergan plc ("Allergan"). The Commission values its longstanding and productive relationship with your office and appreciates the dialogue with you and your staff regarding this transaction. As you are aware, the Commission reviewed the proposed acquisition of AbbVie and Allergan to determine if it was likely substantially to lessen competition in violation of Section 7 of the Clayton Act and determined that, if consummated without a remedy, it would. After a careful and thorough investigation, the Commission also determined that the Consent Order remedies all competitive concerns raised by the acquisition by requiring the merging parties to divest Allergan's EPI drugs Zenpep and Viokace to Nestlé, S.A. ("Nestlé") and to transfer Allergan's assets related to its IL-23 inhibitor brazikumab in development back to AstraZeneca plc ("AstraZeneca"), the drug's original developer.

Your letter raises several issues that the Commission addresses in this response. First, your letter raises issues about the scope of the Commission's investigation in this case and indicates that you believe the Commission's standard process in evaluating pharmaceutical mergers is limited to identifying overlaps between party products that are current or potential substitutes for each other, and requiring divestitures of such overlapping products in concentrated markets. As we have stated publicly, however, the Commission looks well beyond product overlaps in every pharmaceutical merger review, and this investigation was no different. During our extensive review of this transaction, the Commission investigated a wide range of theories of competitive harm. For example, consistent with the Horizontal Merger Guidelines, the Commission investigated whether the "merger will diminish innovation competition by combining two of a very small number of firms with the strongest capabilities to successfully innovate in a specific direction." Other than the harm the merger would create related to the parties' ongoing development of IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis and Crohn's disease, the investigation yielded no evidence that other ongoing product development efforts would likely be altered due to diminished competition.

The Commission also evaluated whether the transaction would lead to competitive harm in any therapeutic areas, as well as narrower disease areas and specific conditions, in which the parties were currently investing in research and development. The evidence, including party

forecasts and market analyses created in the ordinary course of business, interviews with third parties, and publicly available information, indicates that there is no therapeutic area, disease, or condition where the parties are two of a limited number of competitors. To the contrary, the evidence indicates the parties face considerable competition in each area.

The Commission also investigated whether the merger eliminated competitive restraints on either AbbVie or Allergan that would allow for anticompetitive rebating or pricing practices that otherwise would fail due to the independence of the two companies, and did not find evidence to support such a theory. As to other non-merger-specific conduct that some have argued should be remedied through the merger review and order process, Section 7 of the Clayton Act does not afford the Commission the authority to extract remedies unrelated to remedying the substantial lessening of competition caused by the merger. The evidence in this case did not support a reason to believe that the merger would lead to competitive harms beyond those that will be remedied by the divestitures.

Your letter also suggests that the Commission deviated from its established practices for evaluating and ensuring effective divestitures. First, your letter expresses concern that the Commission disregarded its preference for divesting on-market products over pipeline products when it approved the divestiture of Allergan's IL-23 product (Brazikumab) rather than AbbVie's IL-23 (Skyrizi). However, this is not the case; Skyrizi, like Brazikumab, remains a product in development for the indications that raise antitrust concerns. In analyzing whether the divestiture of brazikumab would restore competition, the Commission considered several factors related to the risk created by divesting one of the parties' pipeline products or the other and found that several factors indicated that a divestiture of the Allergan's brazikumab created less risk than a divestiture of AbbVie's Skyrizi. For example, one factor the Commission considered important in its analysis was what would be required to ensure the divestiture buyer could continue ongoing clinical trial work without disruption and manufacture the divested product going forward without entanglements with the merging parties. With respect to this factor, Allergan currently uses third parties to manage its clinical trials and to manufacture brazikumab, whereas AbbVie does this work in-house. This is important because the Commission knows from past experience that transferring pre-existing third-party relationships typically poses significantly less risk than implementing complex technology transfers or hiring third parties to do work previously performed by a party. In addition, AstraZeneca's history with brazikumab, including the fact that several AstraZeneca employees who played important roles in the early stages of developing the product will once again work on its development, makes it well suited to bring brazikumab to market with minimal complications.

Your letter also suggests that by divesting Zenpep and Viokace to Nestlé, the Commission deviated from its best practices, but this is not the case. The Commission determined that Nestlé would be an effective buyer of these products by following the Commission's established practice of analyzing the business plans, supply chain, transition plans, strategic fit, financial projections, financing, incentives, experience, and management expertise of Nestlé. Nestlé is a sophisticated company with tremendous financial resources, a large sales infrastructure in the United States, and deep experience in the U.S. healthcare space. It operates Nestlé Health Science ("NHSc"), an integrated multi-billion dollar health company that focuses on nutrition products, including medical nutrition products that physicians order or

recommend for patients who have digestive health conditions—the same types of patients that use Zenpep and Viokace. Nestlé has prior experience in the pharmaceutical industry, and several of its senior executives, including Nestlé’s CEO, have deep experience leading and managing pharmaceutical companies, and NHSc’s leadership has substantial experience successfully developing and marketing branded pharmaceutical products. The evidence in this case indicated that Nestlé has both the ability and incentive to compete successfully with the divested products, and the Commission’s decision to approve Nestlé is supported by its 2017 Merger Remedies Study, which found that buyers that “had a complementary product line into which the divested business could easily fit” tended to succeed. In this matter, Nestlé’s line of medical nutrition products is a natural fit with Zenpep and Viokace because all of these products target the same patients and are purchased by the same healthcare providers, and Nestlé has the plans, resources, and experience necessary to quickly and successfully compete for sales of Zenpep and Viokace to these customers.

Next, you suggest that the Commission should undertake an empirical study regarding the effectiveness of divestitures in pharmaceutical mergers. As you know, the Commission is constantly evaluating its enforcement efforts, including conducting studies under Section 6(b) of the FTC Act, which authorizes the Commission to conduct wide-ranging studies that do not have a specific law enforcement purpose. Further, the Commission recently completed a Remedy Study in 2017 that evaluated previous Consent Orders and recommended best practices to continue to refine our approach to remedies and the remedy process. The Commission will take your suggestion of an empirical study regarding divestitures in pharmaceutical matters under consideration for future potential assessment.

The Commission is satisfied that the Consent Order in this matter protects against the potential for competitive harm created by AbbVie’s acquisition of Allergan. In its view, based on a thorough and extensive investigation that considered a wide array of theories of competitive harm, the relief contained in the Order appropriately addresses the competition concerns arising from the acquisition.

In its work on antitrust and consumer protection issues, the Commission finds it helpful to hear from a variety of sources, including other law enforcers that we regularly work closely with such as your office, and we appreciate your interest in this matter.

By direction of the Commission, Commissioner Chopra dissenting and Commissioner Slaughter not participating.

April Tabor
Acting Secretary