



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

Office of the Secretary

[Commenter's Name]  
[Commenter's City, State]

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

Dear Commenter:

Thank you for the comment that you submitted electronically in connection with the Consent Order issued by the Commission to settle antitrust concerns arising from AbbVie Inc.'s proposed acquisition of Allergan plc. The Commission reviewed the proposed acquisition to determine if the combination of AbbVie and Allergan was likely to substantially lessen competition in violation of Section 7 of the Clayton Act.

The Commission placed your comment on the public record and has given it careful consideration.

*I. Concerns about the scope of the investigation*

To challenge a merger successfully under the Clayton Act, the Commission must have proof that the likely effect of the merger may be to substantially to lessen competition in a relevant market. The Commission cannot meet that burden of proof by surmising that the merger will cause harm, but must be able to present evidence demonstrating that this harm is likely. Commission staff sought information from the merging parties and from third parties on a wide range of theories of competitive harm. The evidence gathered from both the parties and multiple industry participants, competitors, and other third parties did not provide a basis to believe that the merger, itself, would lead to competitive harms in any market beyond the ones that are remedied by the divestitures.

Consistent with the Horizontal Merger Guidelines, staff 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.”<sup>1</sup> A wide array of evidence indicates that, besides the divestiture areas, there is no therapeutic area, disease, condition, or product where the parties are two of a limited number of competitors in a therapeutic area, or are the competitors with the strongest ability to innovate in a specific direction. The staff also investigated whether the merger eliminated competitive restraints on either AbbVie or Allergan that would allow for anticompetitive rebating practices that otherwise had failed due to the independence of the two companies, and did not find evidence to support such a theory.

Finally, the agency does not have the authority under Section 7 of the Clayton Act to extract remedies, including remedies related to pharmaceutical product pricing, patent practices

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<sup>1</sup> Horizontal Merger Guidelines § 6.4.

by either company, or any past actions by the companies, which are unrelated to remedying the substantial lessening of competition due to the proposed merger.

## *II. Concerns about the divestiture to Nestlé*

The Order remedies the competitive concerns in the market for drugs to treat exocrine pancreatic insufficiency (“EPI”) by requiring the merging parties to divest Allergan’s EPI products Zenpep and Viokace to Nestlé, S.A. (“Nestlé”). EPI is a digestive disorder in which the pancreas does not make or deliver enough enzymes. With inadequate enzymes, patients with EPI are unable to digest fats, proteins, and carbohydrates and may suffer from malnutrition.

Nestlé is the world’s largest food and beverage company, but it also operates a multi-billion dollar health company, Nestlé Health Sciences, which sells medical nutrition products that are ordered or recommended by physicians to patients with digestive disorders. While not pharmaceutical products, these nutrition products are prescribed by doctors, used in hospitals and clinics, and covered by health insurance. As a result, Nestlé has substantial experience marketing to and interacting with the healthcare providers and payors that have responsibility for EPI products, and it already has developed important relationships with these key decision-makers. The Order transfers Allergan’s EPI sales force for Zenpep and Viokace, which augments Nestlé’s capabilities and positioning it for success.

Beyond its current nutrition products, Nestlé also has research and development partnerships with companies developing new pharmaceutical products in the nutrition space.

## *III. Concerns about the divestiture to AstraZeneca*

As described in the Commission’s complaint, both AbbVie and Allergan are developing IL-23 inhibitors to treat Crohn’s disease and ulcerative colitis. Neither company currently sells a product in these two markets; both IL-23 inhibitors are pipeline products. No drug development is without risk, and there is no guarantee today that either AbbVie or Allergan would have been successful in developing and commercializing their respective products. The proposed merger, however, would eliminate any future competition between AbbVie and Allergan in the development and sale of IL-23 inhibitors to treat Crohn’s disease and ulcerative colitis.

As a result, the Order remedies the competitive concerns in the market for IL-23 inhibitors to treat ulcerative colitis and Crohn’s disease by requiring the merging parties to divest Allergan’s assets related to its IL-23 inhibitor, brazikumab, to AstraZeneca plc (“AstraZeneca”). AstraZeneca is the original developer of brazikumab, Allergan’s IL-23 inhibitor, and licensed the product to Allergan. The divestiture terminates that license and returns the product to AstraZeneca.

The purpose of the divestiture is to position AstraZeneca to develop and launch the drug in the same fashion as would have occurred without the merger. While there is no guarantee that AstraZeneca will be successful in developing and commercializing brazikumab (just as there is no guarantee that either AbbVie or Allergan would have been successful), the Commission has ensured that AstraZeneca has the required assets and appropriate incentives to push forward with

development and bring the drug to market in the same manner that Allergan would have done absent the merger.

*IV. Concerns about the divestiture process*

Pursuant to longstanding Commission practice, under any Order requiring a divestiture, the respondent's obligation is to propose one or more divestiture buyers that the Commission approves. The Commission's 2017 Merger Remedies study confirmed that this practice, together with others related to designing, drafting, and implementing the agency's merger remedies, generally yields effective outcomes. The staff may, and often does, reject a proposed buyer of the divested assets. This may be because the buyer raises competitive concerns, lacks commitment to the market, lacks the expertise or funding to compete with the divested products, or because the buyer has business operations or strategies that could limit its incentives to compete in the future.

In this case, the Commission staff followed its established practices by analyzing the business plans, supply chain and transition plans, strategic fit, financial projections, financing and incentives, experience, and management expertise of Nestlé and AstraZeneca. Further, the 2017 Merger Remedies Study found that buyers that "had a complementary product line into which the divested business could easily fit" tended to succeed. The evidence here indicates that Nestlé's line of medical nutrition products is a natural fit with Zenpep and Viokace as these products target the same patients and providers as Nestlé's existing product line and that brazikumab will fit nicely into AstraZeneca's Respiration and Immunology product line.

The Commission is satisfied that the Order in this matter protects against the potential for anticompetitive harm as a result of AbbVie's acquisition of Allergan. In our view, based on a thorough and extensive investigation that considered all of the theories raised in comments submitted by the public, 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, 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