The Federal Trade Commission ("Commission") has accepted for public comment an Agreement Containing Consent Order ("Consent Order") with Valeant Pharmaceuticals International, Inc. ("Valeant") to remedy the alleged anticompetitive effects resulting from Valeant’s acquisition of Paragon Holdings I, Inc., including wholly-owned subsidiaries Paragon Vision Sciences, Inc. and CRT Technology, Inc. ("Paragon").

The Complaint alleges that the acquisition violated 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 lessening competition in the markets for polymer discs, or “buttons,” used to make three different types of rigid gas permeable (“GP”) contact lenses: orthokeratology contact lenses, large-diameter scleral contact lenses, and general vision correction contact lenses. The Consent Order would remedy the alleged violations by restoring competition in these GP button markets.

Under the terms of the Consent Order, Valeant is required to divest Paragon in its entirety, including the assets of Pelican Products LLC ("Pelican"), a manufacturer of contact lens packaging.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed Consent Order and any comments received, and decide whether the Consent Order should be withdrawn, modified, or made final.

1. THE PARTIES

Valeant is a Canadian conglomerate that develops and markets prescription and non-prescription pharmaceutical products. Through its subsidiary Bausch + Lomb, Valeant is a leading producer of GP buttons used to make GP contact lenses. Prior to its acquisition by Valeant in May 2015, Paragon was a United States corporation with its principal place of business in Arizona. Paragon produces GP buttons used to make GP contact lenses and also produces finished GP lenses.

After the Paragon acquisition, Valeant also purchased Pelican, a manufacturer of contact lens packaging, and the only producer of FDA-approved vials for wet-shipping finished orthokeratology lenses. Pelican became a subsidiary of Paragon. This acquisition ensured Valeant’s access to the vials, after Pelican’s owner announced plans to exit the market.
2. THE RELEVANT MARKET

Both parties engage in developing, manufacturing, and selling GP buttons in the United States. The relevant product markets in which to analyze the effects of the acquisition are the manufacture and sale of FDA-approved GP buttons for: orthokeratology GP lenses, which are worn to reshape the cornea; large-diameter scleral GP lenses, which cover the white of the eye and are used post-surgery, for transplants, and to treat eye disease; and general vision correction GP lenses. Each type of GP lens requires a GP button with parameters unique to that lens type.

GP lenses are used, and in some cases are medically necessary, to address a variety of vision problems, including dry eyes, abnormal curvatures of the eye, corneal disease, post-eye surgery complications, and eye trauma. Optical labs use GP buttons to make GP contact lenses to fulfill prescriptions from eye care professionals. Prescriptions typically specify a particular product and brand of button, and eye care professionals invest significant capital in fitting equipment for the brands they prescribe.

The FDA requires that GP lenses must be made from FDA-approved GP buttons. Thus, there are no alternatives to FDA-approved GP buttons for making each of the types of GP lenses and the relevant geographic market is the United States.

Prior to the acquisition, Valeant and Paragon independently produced buttons for all three types of GP lenses. In the market for orthokeratology GP buttons, the combination of Valeant and Paragon was a merger to monopoly. In the market for scleral GP buttons, the combined company accounted for 70-80 percent of the market. In the market for general vision correction GP buttons, the combined company’s market share was approximately 65-75 percent.

3. EFFECTS OF ACQUISITIONS

The acquisition likely caused significant competitive harm in the relevant markets. Specifically, the acquisition of Paragon eliminated actual, direct, and substantial competition between Valeant and Paragon in the relevant markets for GP buttons and allowed Valeant to unilaterally exercise market power. For instance, following the acquisition, Valeant increased prices in all three GP button markets.

Prior to the acquisition, Valeant and Paragon also competed on innovation, with the incentive to develop new GP lens buttons and improve button materials by investing in research, development, and adoption. This innovation led to broader product lines, improvements to button materials, and marketing and education funding for optical labs. The acquisition also eliminated this innovation competition between Valeant and Paragon.

4. ENTRY AND EFFICIENCIES

Entry into the relevant market has not been, and would not be, timely, likely, or sufficient to deter or counteract the anticompetitive effects of the acquisition. Optical labs have limited short-term ability to switch from Valeant and Paragon, which supply the majority of their GP scleral buttons and GP general vision correction buttons, and 100 percent of their GP
orthokeratology buttons. Optical labs might try to persuade eye care professionals to switch to a different material and brand, but ultimately the decision is made by the eye care professional, for whom such a change is costly and time-consuming.

Considerable entry barriers also arise from the FDA approval process. For GP orthokeratology buttons, the FDA premarket approval process takes several years because finished orthokeratology lenses worn overnight are Class III medical devices. For GP scleral and general vision buttons, the FDA premarket notification process likely requires at least one year, as the finished lenses incorporating such buttons are Class II medical devices.

We did not find any evidence of efficiencies that would outweigh the competitive concerns arising from the Paragon acquisition.

5. CONSENT ORDER

The proposed Consent Order requires Valeant to divest Paragon in its entirety no later than ten (10) days after the order date, to remedy the concerns raised by the acquisition and restore competition in the relevant markets by instituting Paragon as an independent, viable competitor to Valeant. The proposed Consent Order also requires Valeant to divest Pelican with Paragon to ensure continued access to FDA-approved vials for shipping its finished lenses.

The proposed Consent Order requires that Valeant must divest Paragon and Pelican to Paragon Companies LLC in an upfront transaction. Paragon Companies LLC is a newly created entity owned by Joe Sicari. Mr. Sicari was the president of Paragon prior to its acquisition by Valeant in May 2015.

The Commission may, at any time, appoint a Monitor with the power and authority to ensure that Valeant fulfills all obligations and responsibilities under the Consent Order and Divestiture Agreement.

The Consent Order will remain in effect for ten (10) years, and contains standard compliance and reporting requirements.