

**ANALYSIS OF THE AGREEMENT CONTAINING CONSENT ORDER
TO AID PUBLIC COMMENT**

In the Matter of Valeant Pharmaceuticals International, Inc.

File No. 111-0215

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Valeant Pharmaceuticals International, Inc. (“Valeant”), which is designed to remedy the anticompetitive effects of Valeant’s acquisition of certain assets of Sanofi’s dermatology unit, Dermik (“Dermik”)

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Valeant proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”). Both parties sell topical pharmaceutical products in the United States. 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 FTC Act, as amended, 15 U.S.C. § 45, in the markets for 1) BenzaClin and 2) topical fluorouracil cream (“topical 5FU”). The proposed Consent Agreement remedies the loss of competition in these markets that would result from the Acquisition. Specifically, under the terms of the Consent Agreement, Valeant would be required to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex (“AG Efudex”). Valeant has proposed Mylan Inc. (“Mylan”) as the buyer of generic BenzaClin and AG Efudex assets.

II. The Products and the Structure of the Market

Valeant’s proposed acquisition of Dermik from Sanofi would create a monopoly in the BenzaClin market. Dermik manufactures and markets BenzaClin, which is a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. BenzaClin is a combination of clindamycin, an antibiotic, and benzoyl peroxide, an antimicrobial. Valeant owns the only Abbreviated New Drug Application (“ANDA”) for the generic version of BenzaClin, which it licenses to Mylan. Pursuant to that license, Mylan sells the only generic equivalent of BenzaClin in the United States and Valeant receives the vast majority of royalties from those sales. Currently Dermik’s BenzaClin sales account for approximately 50 per cent of sales, while sales of Mylan’s generic version account for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

In addition, Valeant's proposed acquisition of Dermik is likely to result in anticompetitive effects in the market for topical 5FU products. Topical 5FU products are used to treat actinic keratosis ("AK"), which is a pre-cancerous lesion that can result from years of repeated sun exposure. Three branded topical 5FUs are currently on the market, including Valeant's Efudex and Dermik's Carac. There are also two generic versions of Efudex, as well as an "authorized" generic, also sold by Valeant. The price of the generic drugs in this market determines the pricing of branded Carac. Post-acquisition, Valeant's market share in the topical 5FU market would be over 50 per cent. Other treatments for AKs are not viable substitutes for topical 5FUs because they are more costly, less efficacious or impracticable.

III. Entry

Entry into the manufacture and sale of both BenzaClin and topical 5FU products is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration approval for the manufacture and sale of topical pharmaceuticals takes over two years due to substantial regulatory, technological and intellectual property barriers. Furthermore, entry would not be likely by other barriers. F

Mylan is a particularly well-suited acquirer of generic BenzaClin because it has been manufacturing and marketing the product, pursuant to an agreement with Valeant, since it was introduced in August 2009. Mylan is the second-largest generic pharmaceutical manufacturer in the United States, and is well-positioned to replicate the competition that would be lost with the proposed Valeant/Dermik acquisition. Headquartered in Pittsburgh, Pennsylvania, Mylan employs more than 18,000 employees and generated approximately \$5.45 billion in revenue in 2010. Mylan sells approximately 270 products and has a manufacturing facility where BenzaClin is manufactured. It is in the process of upgrading that facility to handle compounds such as 5FU.

Mylan expects to begin manufacturing generic Efudex at that facility in 2013. Until that time, the proposed Consent Agreement contemplates Mylan's purchase of topical 5FU from Valeant pursuant to a supply agreement. In order to ensure that there is no supply interruption, the proposed Consent Agreement would require that Valeant build up a two-year inventory and establish its own manufacturing as a back-up supply until Mylan is able to manufacture 9.24-up supply until Mylan