ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Bristol-Myers Squibb Company and Celgene Corporation

File No. 191-0061

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Bristol-Myers Squibb Company ("BMS") and Celgene Corporation ("Celgene") designed to remedy the anticompetitive effects resulting from BMS's proposed acquisition of Celgene. The proposed Decision and Order ("Order") contained in the Consent Agreement requires Celgene to divest all rights and assets related to its Otezla business to Amgen, Inc. ("Amgen").

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 an Agreement and Plan of Merger dated as of January 2, 2019, BMS plans to acquire all of the voting securities of Celgene in a cash and stock transaction with an equity value of approximately $74 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. market for oral products to treat moderate-to-severe psoriasis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in this market as a result of the proposed Acquisition.

THE PARTIES

Headquartered in New York City, BMS researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including oncology, cardiology, virology, and inflammatory diseases. Among other products, BMS is developing an oral product to treat moderate-to-severe psoriasis. Like BMS, Celgene researches, develops, manufactures and sells prescription pharmaceutical products in the United States. Celgene markets eight products, including an oral treatment for moderate-to-severe psoriasis.

THE RELEVANT PRODUCT AND STRUCTURE OF THE MARKET

Psoriasis is a chronic skin disease caused by an overactive immune system. The disease causes skin cells to multiply faster than normal and leads to a build-up of cells on the skin surface, forming bumpy red patches that are covered with white scales, known as plaques. The plaques can appear anywhere on the body, although they are most commonly found on the scalp, elbows, knees, and lower back. The severity of psoriasis (mild, moderate, or severe) is determined based upon the percentage of body surface area affected and the parts of the body that are affected. Typically, mild psoriasis covers less than 3 percent of the body, moderate psoriasis covers 3 to 10 percent of the body and severe psoriasis covers more than 10 percent of the body.

When deciding how to treat psoriasis, dermatologists typically evaluate the severity of the disease, any risk factors or contraindications for the patient, and the patient's preferences. Dermatologists consider efficacy data, safety data, and side effect profile of each product, as well as mode of administration to select the appropriate treatment course for their patients. While many injectable and infused products are approved to treat moderate-to-severe psoriasis, a number of patients object to such injections or find them inconvenient. For those patients, dermatologists often select an oral product.

Celgene's apremilast, marketed under the brand name Otezla, is a phosphodiesterase 4 inhibitor. Otezla is the most popular oral product approved to treat moderate-to-severe psoriasis in the United States. Several older oral generic products, including methotrexate and acitretin, are approved by the U.S. Food and Drug Administration ("FDA") to treat psoriasis that does not respond to light, topical agents, and other forms of therapy. These drugs are still occasionally used in the treatment of psoriasis, but most doctors have moved to prescribing newer agents with better efficacy, better safety, or a more favorable side effect profile for patients with moderate-to-severe psoriasis who desire an oral treatment. BMS is developing BMS 986165, an oral, selective tyrosine kinase 2 inhibitor that is the most advanced oral treatment in development for moderate-to-severe psoriasis.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Oral products to treat moderate-to-severe psoriasis 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 market for oral products to treat moderate-to-severe psoriasis. Celgene is

currently the market leader and BMS would likely be the next entrant into the market. Upon entry, BMS 986165 likely will compete directly with, and take sales from, Otezla.

ENTRY CONDITIONS

Entry in the relevant market 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 BMS and Celgene to divest Celgene's worldwide Otezla business, including its regulatory approvals, intellectual property, contracts, and inventory to Amgen. BMS and Celgene also must transfer all confidential business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to employees who possess or are able to identify such information. Additionally, to ensure that the divestiture is successful and to maintain continuity of supply, the proposed Order requires BMS and Celgene to supply Amgen with Otezla for a limited time while Amgen establishes its own manufacturing capability. The provisions of the Consent Agreement ensure that Amgen becomes an independent, viable, and effective competitor in the U.S. market.

Founded in 1980 and headquartered in Thousand Oaks, California, Amgen discovers, develops, manufactures and sells innovative human pharmaceutical and biologic products. Amgen's existing business includes products that are highly complementary to the divestiture assets. Amgen has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

BMS and Celgene must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Amgen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires BMS and Celgene to unwind the sale of rights and assets to Amgen and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that BMS and Celgene 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 Otezla rights and assets to Amgen. The proposed Order further allows the Commission to appoint a trustee in the event that BMS and Celgene 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.