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Antitrust Alert

FTC Looks to Accelerate Oncology Drug Growth by Requiring Novartis to Divest Two Protein Inhibitors in Its Clinical Development Pipeline

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The Federal Trade Commission ("FTC") on Monday completed its review of Novartis AG's ("Novartis") proposed $16 billion acquisition of GlaxoSmithKline's ("GSK") oncology drug portfolio with an announced consent decree that requires limited divestitures of BRAF- and MEK-inhibitor drugs used to treat melanoma, ovarian, colorectal, non-small cell lung, and other cancers. To resolve the FTC's competition concerns, Novartis must divest its LGX818 and MEK162 pipeline drug candidates to Array BioPharma Inc. ("Array"), a biopharmaceutical company based in Boulder, Colorado and focused on developing targeted small molecule oncology drugs. Substantively, the matter is another indication of the FTC's willingness to focus upon pipeline drugs and future and potential competition.

The Commission centered its analysis on two types of protein inhibitors demonstrated to limit tumor growth in late-stage, metastatic melanomas and other cancers. BRAF inhibitors act to control the signals sent within cells that often dictate cellular growth, while MEK inhibitors affect certain protein enzymes that are typically uncontrollable in some cancers. The BRAF and MEK inhibitors, used jointly, have shown remarkable progress in slowing tumor growth, particularly in mutated melanomas.

The market for both BRAF and MEK inhibitors, according to the Commission, is highly concentrated, but with the potential for price-reducing competition if the two pipeline drugs launch with non-incumbent support. GSK and Roche market the only two FDA-approved BRAF inhibitors, GSK markets the only FDA-approved MEK inhibitor, and GSK markets the only FDA-approved BRAF/MEK combination therapy. Prior to the acquisition, Novartis actively developed LGX818 and MEK162 for use independently and in combination to compete in each market. The Commission stated that no other pharmaceutical company has BRAF or MEK inhibitors or combination products in late-stage clinical development.

The proposed consent decree, which undergoes a public comment period before finalization, requires Novartis to sell all of its assets related to LGX818 and MEK162 to Array because the acquisition of GSK's oncology portfolio would reduce Novartis's incentives to continue clinical development of its own, competing therapies. The Commission stated that, without the acquisition, "Novartis likely would have obtained FDA approval for and launched its LGX818 and MEK162 products in the near future in direct competition with GSK's combination offering for treating metastatic melanoma patients." Plus, the FTC alleged that entry "would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects" of the acquisition. Divestiture would allow further development and likely future competition.

The two critical takeaways from the Commission's settlement here are two recurring themes in other recent pharmaceutical industry acquisitions: (1) a continuing agency emphasis on future or potential competition in health care markets, and (2) increased international cooperation and coordination on transactions with global implications.

First, the Commission reaches forward, yet again, to demonstrate the significance of the markets for pipeline drug products and their impact on either current pharmaceutical markets or the development of new therapeutic categories. Absent the divestitures, after the transaction closed, Novartis would effectively own the sole MEK inhibitors and BRAF/MEK combination therapies on the market and in late-stage clinical development, with the

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result, as the FTC alleged, of “higher prices for BRAF and MEK inhibitors and reduced choice for U.S. health care consumers.” By requiring a divestiture of the pipeline drugs, the FTC anticipates augmenting future competition, rather than actively affecting or preserving current competition.

This is similar to several FTC merger consent decrees in the past year alone — including Medtronic-Covidien, Endo-Boca, and Akorn-Hi-Tech — that sought to influence and preserve future competition through pipeline divestitures. In each of those settlements the agency required divestitures of products in clinical development to quell anticompetitive concerns. The GSK-Novartis settlement is yet another example of the FTC’s efforts to predict the future of health care competition by looking down the FDA pipeline to assess market entry conditions. The Commission shows no signs of letting up and sees this analysis as key to maintaining competition in markets for new therapies.

Second, the Commission made clear that international cooperation and coordination are increasingly essential to acquisitions involving multinational corporations with worldwide impact. As the FTC has shown several times over the past year, including its decision to green-light Medtronic Inc.’s $42.9 billion acquisition of Covidien PLC with minimal divestitures, international consultation is becoming the norm.

Here, the FTC synchronized its efforts with the European Commission, stating that “[t]his coordination led to compatible approaches on a global scale,” including joint approval of Array BioPharma as the buyer of the divested assets. In addition, the FTC understands that other countries follow its lead — Canada decided not to challenge the acquisition because the FTC settlement was sufficient, while other nations imposed smaller, additional jurisdiction-specific divestitures to satisfy their competitive concerns. The takeaway is clear: international appeasement must be a critical component of any pre-acquisition assessment because the agencies are increasingly looking to their overseas counterparts to coordinate a response.

If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.

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