

May 11, 2018

FTC Applies its Merger Remedy Best Practices and Announces a New Divestiture Principle in Recent Pharmaceutical Enforcement Action

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On April 27, 2018, the Federal Trade Commission (“FTC”) announced a proposed consent agreement with Amneal Pharmaceuticals LLC (“Amneal”) and Impax Laboratories, Inc. (“Impax”) to settle charges that Amneal’s acquisition of Impax would likely harm competition in a number of generic pharmaceutical markets.¹ Under the proposed settlement, Amneal must divest Impax’s rights or assets for ten generic pharmaceutical products to three divestiture buyers: ANI Pharmaceuticals, Inc. (“ANI”), Perrigo Company plc (“Perrigo”), and G&W Laboratories (“G&W”).

The FTC’s proposed consent agreement in this matter reinforces principles it announced in a recent Merger Remedies report and also appears to announce a new principle that the FTC may use to determine which of the merging parties’ products should be divested in pharmaceutical mergers going forward. The FTC’s analysis to aid public comment highlights the “easier-to-divest” principle for pharmaceutical divestitures and appears to expand its guidance for divestitures of complex pharmaceutical products that are difficult to manufacture when one party has an overlapping product in development.

Background: FTC Merger Remedies Report

In January 2017, the FTC Bureaus of Competition and Economics published *The FTC’s Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics*,² which expanded on the FTC’s similar report in 1999.³ The report is an evaluation of the success or failure of past remedies and the remedy process generally. Based on a review of 89 past orders covering over 400 product markets, including 24 orders related to the pharmaceutical industry, the report identifies several goals and best practices. In *Amneal/Impax*, the FTC followed several principles outlined in the pharmaceutical divestiture section of its Merger Remedies report to determine which of the parties’ products would go on the auction block, including:

- “To ensure the success of divestitures in the pharmaceutical industry, **the respondent should divest the easier-to-divest product wherever possible**, such as products already made at a third-party manufacturing site”⁴
- “The goal of **divestiture [of a product in development]** is to put the product development effort (including any pending regulatory filings) in the hands of a new firm with the same ability and incentive to bring the pipeline product to market.”⁵

Best Practices Applied in *Amneal/Impax* Consent Agreement

In October 2017, Amneal agreed to acquire Impax. After a six-month investigation, the FTC concluded that, absent a remedy, the proposed acquisition likely would have reduced competition in three markets where both Amneal and Impax currently compete: (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin immediate release (“IR”) tablets; and (3) generic felbamate tablets. The FTC also found that the proposed acquisition would reduce future competition in seven markets where Amneal or Impax is a current competitor and the other would have been likely to enter the market absent the acquisition: (1) generic aspirin and dipyridamole extended release (“ER”) capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol delayed release (“DR”) tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray.

“Easier-to-Divest” Products

With respect to “easier-to-divest” products, the FTC reiterated in its analysis to aid public comment that “products made at third-party manufacturing sites are easier to divest and involve less risk than the technology transfer from in-house manufacturing to a new facility” and “in most cases, if one of the products is developed or manufactured by a third party, the Commission will require divestiture of that product.”⁶ In this case, the FTC applied the “easier-to-divest” principle even in one instance where the contract manufacturer had to resolve “manufacturing issues” before it could resume manufacturing the product to be divested. In the market for generic methylphenidate hydrochloride ER tablets, both Amneal and Impax had approved Abbreviated New Drug Applications (“ANDAs”). Impax, however, had not launched its product because its contract manufacturer had to address manufacturing issues. Nonetheless, the FTC required divestiture of Impax’s product on the grounds that methylphenidate hydrochloride ER tablets are complex products, and it would be less risky for Impax to assign its manufacturing contract to ANI than to transfer technology from Amneal for such a complex product.

In addition, the FTC appeared to apply the “easier-to-divest” principle where Impax sold products in partnership with a third party. Impax partnered with Perrigo to sell generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray products and partnered with G&W to sell generic fluocinonide -E cream. Perrigo and G&W also were the ANDA-owners for these products. Unlike the other seven divestiture products which are being sold to ANI, the FTC required Impax to return any rights and assets relating to Impax’s third-party partnership products to the relevant partner, Perrigo and G&W.

On-Market Vs. In-Development Products Involving Complex or Difficult to Manufacture Pharmaceuticals

With respect to divesting on-market products versus in-development products, the FTC’s analysis appears to have adopted a new principle for divestitures in markets for complex or difficult to manufacture drugs where one of the merging parties has an on-market product and the other has a product in development. The Merger Remedies report notes that for 32 pharmaceutical products in the study, one or both of the merging parties had products in development. According to the report, all 32 divestitures were successful where the goal was “to put the product development effort . . . in the hands of a new firm with the same ability and incentive to bring the pipeline product to market.” The FTC’s analysis in *Amneal/Impax* goes a step further by announcing a preference for on-market divestitures in situations involving divestitures of complex drugs: “[I]n mergers involving complex pharmaceutical products that are difficult to manufacture, the Commission generally will require the divestiture of an on-market product over a pipeline product to place the greater risk on the merging parties rather than the public, with exceptions for compelling and fact-specific reasons.”⁷ Despite this new guidance from the FTC, *Amneal/Impax* appears to have raised such compelling exceptions in four product markets because the FTC required divestitures of the product in development notwithstanding the complexities of the drugs.

- Three products – generic aspirin and dipyridamole ER capsules, generic methylphenidate hydrochloride ER tables, and generic diclofenac sodium and misoprostol DR tablets – have extended or delayed release characteristics that the FTC viewed as complicated to manufacture.
 - For generic aspirin and dipyridamole ER capsules, Amneal is the only manufacturer with an on-market product. Impax received FDA approval for its ANDA in 2017, but has not yet launched a product. The FTC observed that divestiture of Amneal’s product could jeopardize the only generic product on the market.
 - As discussed above, for methylphenidate hydrochloride ER tablets, the FTC required divestiture of Impax’s in-development product notwithstanding that methylphenidate hydrochloride ER tablets are complex products, on the grounds that it would be less risky for Impax to assign its manufacturing contract to ANI than to transfer technology from Amneal for such a complex product.
 - For generic diclofenac sodium and misoprostol DR tablets, Amneal has an on-market, in-house manufactured product, and Impax holds only marketing rights to a product that Micro Labs develops and manufactures. The FTC required Impax to transfer to ANI its marketing agreement with Micro Labs.
- For erythromycin tablets, Amneal recently launched a product, and only one other competitor, Arbor Pharmaceuticals, is currently selling a product. Impax is one of few companies developing erythromycin tablets, and it planned to outsource the manufacturing. The FTC preferred to leave the on-market Amneal product with the merged firm to ensure an “ongoing and viable competitor to Arbor.”

Key Takeaway

This enforcement action serves as further indication that the FTC is focused on ensuring the success of divestitures. When the FTC requires divestitures in pharmaceutical markets, merger parties should anticipate the need to divest the product that is (1) easier to divest and (2) on-market (in situations involving complex pharmaceuticals that are difficult to manufacture). These two issues overlap and may have exceptions depending on factors such as the competitive landscape, the complexity of the product, and capabilities of third-party manufacturers or other third-party partners. In both cases, the FTC seeks to ensure that the divested product will be as competitive in the hands of the buyer as it would have been absent the merger.

- ¹ Press Release, Federal Trade Commission, FTC Requires Generic Drug Marketers Amneal Pharmaceuticals LLC and Impax Laboratories Inc. to Divest Rights to 10 Generic Medications as Condition of Merger (Apr. 27, 2010), *available at* <https://www.ftc.gov/news-events/press-releases/2018/04/ftc-requires-generic-drug-marketers-amneal-pharmaceuticals-llc>.
- ² Federal Trade Commission, *The FTC's Merger Remedies 2006-2012: A Report of the Bureau of Competition and Economics* (Jan. 2017), *available at* https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf [hereinafter FTC Merger Remedies report].
- ³ A Study of the Commission's Divestiture Process," Bureau of Competition (Aug. 1999), *available at* <https://www.ftc.gov/sites/default/files/attachments/merger-review/divestiture.pdf>.
- ⁴ FTC Merger Remedies report, at 36.
- ⁵ FTC Merger Remedies report, at 31.
- ⁶ Federal Trade Commission, Analysis of Agreement Containing Consent Orders to Aid Public Comment In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC, Apr. 27, 2017, at 4, *available at* https://www.ftc.gov/system/files/documents/cases/1810017_amneal_impax_analysis_4-27-18.pdf.
- ⁷ *Id.*

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