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Antitrust Advisory: FTC Denies Dialysis Clinic a License to Raise Prices to Medicare

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A recent Federal Trade Commission (FTC) order imposing conditions on a licensing agreement between Fresenius Medical Care and Luitpold Pharmaceuticals is an uncommon example of enforcement action in a vertical transaction, and is evidence that the FTC will occasionally challenge a deal term that would otherwise be considered reasonably ancillary to a normal-course transaction. The FTC's focus in this case was not upon the usual issue of market concentration, but rather on the potential for the licensee to inflate its reported costs to Medicare.

Facts of the Agreement

On September 15, 2008, the FTC released a Complaint and Consent Order concerning Fresenius Medical Care Ag & Co. KGaA's (Fresenius's) proposed acquisition of an exclusive sublicense from Luitpold Pharmaceuticals, Inc. (Luitpold). Fresenius is the largest U.S. provider of end-stage renal disease (ESRD) dialysis services. Luitpold is a wholly owned U.S. subsidiary of the Japanese firm Daiichi Sankyo Company, Ltd., and owns the rights to Venofer, a life-saving intravenous iron drug used to treat dialysis patients.

The FTC's Complaint alleges that, if consummated, the proposed license agreement would allow Fresenius to report higher prices to the Center for Medicare & Medicaid Services (CMS) when the drug is used in its own clinics, resulting in a higher average selling price (ASP), and therefore a higher Medicare reimbursement rate for the drug.

The FTC's proposed Consent Order would cap the intra-company transfer price that Fresenius could report to CMS for the drug. Further, if a generic version of Venofer enters the market, Fresenius must report its intra-company transfer price at the lower of the level set forth in the Consent Order or the lowest price at which Fresenius sells Venofer to any customer until December 31, 2011.

The Consent Order also prohibits Luitpold and Fresenius from sharing any confidential business information related to the manufacture, sale, or distribution of Venofer, and requires the parties to provide notice to the FTC before modifying the license agreement.

Why Does This Action Matter?

The FTC's action in this matter is notable for two reasons. First, it is an important reminder that the agencies will occasionally challenge a transaction based on characteristics that would, in most other circumstances, be considered normal-course ancillary deal terms when the deal presents a unique opportunity to raise prices to one or more classes of buyer. Second, it is a reminder that the agencies will occasionally challenge a vertical agreement (which is unusual in itself) even where the deal would create obvious efficiencies.

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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