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FTC Proposes Broadening HSR Reporting Requirements for Licensing Pharmaceutical Patents

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The Federal Trade Commission ("FTC") recently issued a Notice of Proposed Rulemaking to broaden the circumstances under which the transfer of rights to a pharmaceutical patent can be reportable under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act").[1] The FTC estimates that approximately 30 more transactions each year will be reportable as a result. This is of great interest to the biopharmaceutical sector because many deals take the form of collaborations and other forms of joint venture and partnering, including the license of patents. Under current agency guidance, transactions involving the licensing of pharmaceutical patents can be reportable under the HSR Act only if they involve the transfer of exclusive rights to a patent. An exclusive license is viewed as akin to the sale of a patent, which is treated as an asset sale that is reportable under the HSR Act. To determine whether a license qualifies as exclusive, the FTC focuses on whether the license grants exclusive rights to "make, use and sell" the product; in particular, the FTC considers whether it confers the right "to exclusively manufacture a product, develop the product for all potential uses, and sell that product without restriction." If the patent holder retains the right to manufacture the product but grants an exclusive license to develop, market and sell the product, the deal currently is not reportable: the FTC views the transaction in relevant part as analogous to a distribution agreement.

The FTC now proposes to broaden the types of licenses that are considered "exclusive." Under the proposed rule, transactions can be reportable if they involve the transfer of "all commercially significant rights" to a patent within a therapeutic area, even if the patent holder retains manufacturing rights.

The decision to de-emphasize manufacturing rights in determining whether a license involves the transfer of exclusive rights reflects the FTC's view that "the right to manufacture is far less important than the right to commercialize" because "the right to manufacture is often retained by the licensor who has the relevant manufacturing expertise and facilities." Moreover, when the patent holder is manufacturing the product solely for the use of the licensee, the FTC views it as "substantively the same as giving the licensee the exclusive right to manufacture, use, and sell" the product at issue.

The full text of the Federal Register Notice is available **here**. Comments may be submitted until October 25, 2012.

[1] Whether transactions ultimately are reportable depends on the value of the transaction and the size of the parties involved.

This memorandum is a summary for general information and discussion only and may be considered an advertisement for certain purposes. It is not a full analysis of the matters presented, may not be relied upon as legal advice, and does not purport to represent the views of our clients or the Firm. Dave Beddow, an O'Melveny partner licensed to practice law in the District of Columbia, Stan Lovenworth, an O'Melveny counsel licensed to practice law in New York, and Julia Schiller, an O'Melveny associate licensed to practice law in the District of Columbia and New Jersey, contributed to the content of this newsletter. The views expressed in this newsletter are the views of the authors except as otherwise noted.