Advisory

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Federal Trade Commission Expands Requirements for Reporting Pharmaceutical Patent License Transactions

Upcoming revisions to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act") will result in numerous additional pharmaceutical licensing transactions becoming subject to filing requirements under the HSR Act. On November 6, the U.S. Federal Trade Commission (the "FTC") released the final version of amendments to be made to the HSR Act. The amendments will impact the analysis of whether parties to a transaction involving the exclusive license of pharmaceutical patents will have to file a pre-merger notification form ("HSR Form") and observe the mandatory waiting period before consummating the transaction, and some experts are predicting at least a fifty percent increase in required filings in this sector.

Under the HSR Act, if an asset is going to be transferred from one party to another and certain thresholds are met in terms of the value of the transaction and the size of the parties to the transaction, the parties will likely be required to file an HSR Form and observe the corresponding waiting period. While exclusive licenses are considered "assets" for purposes of the HSR Act, historically if the licensor retained manufacturing rights, the license was deemed non-exclusive, which in turn meant that there was no transfer of assets and the transaction was, in effect, exempt from filing requirements. Under the revised rules, retaining manufacturing rights generally does not result in an exemption from filing requirements. Instead, if all "commercially significant rights" are to be transferred from the licensor to the licensee, the FTC considers the license to be exclusive and, therefore, an asset will be transferred. Consequently, when a licensor grants to a licensee the exclusive rights to use a patent for all purposes, in a particular therapeutic area or for a specific indication within a therapeutic area, all may be subject to filing requirements if the transaction meets the aforementioned thresholds.

Furthermore, while the retaining of "co-rights" (e.g. the rights to co-develop or co-commercialize products) by the licensee has generally not been viewed by the FTC as rendering an exclusive license non-exclusive and therefore exempting such transaction from filing requirements, the revised rules confirm that such retention does not result in an exemption. Additionally, co-exclusive licenses, in which the licensor and licensee share equally in the intellectual property rights of the patent, are not reportable.

The amended rules were published in the Federal Register on November 15, 2013 and will take effect on December 16, 2013. While the FTC intended that the amendments apply specifically to pharmaceutical patent licensing, they have instructed that all other exclusive licenses should be analyzed and considered on a case-by-case basis.

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Finally, it is worth noting that in spite of these revisions to the rules, many early-stage development deals will continue to be exempted from filing requirements due to the size of the transaction or size of the parties thereto. Because speculative "future payments" (e.g. potential future development milestone payments) can be discounted based on their likelihood of occurrence, often times early-stage development deals do not reach the $70.9 million (adjusted annually) size-of-transaction threshold. Furthermore, it is also common that at least one party to such transaction will not meet the $14.2 million (adjusted annually) size-of-person test. Still, because each transaction carries its own set of nuances, all exclusive licenses approaching the size-of-transaction threshold should be analyzed to determine whether a filing will be required.

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