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Expanded HSR Antitrust Reporting for Pharma Licensing Deals Is Here to Stay

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On June 9, 2015, the U.S. Court of Appeals for the D.C. Circuit, in its ruling in *Pharm. Research & Mfrs. of Am. v. FTC*, upheld the FTC's expansion of HSR reporting requirements for pharmaceutical companies, and solidified the need for companies entering into licensing agreements in the industry to consider their HSR filing obligations and the implications for antitrust review.

In the court's decision, Senior Circuit Judge Edwards rejected the pharmaceutical industry's arguments that the new rule would bring delay, increased cost, and uncertainty to transactions, as well as the argument that the promulgation of such a rule was outside the scope of the FTC's rulemaking authority. Instead, the court sided with the FTC's arguments that in the pharmaceutical industry, the right to commercialize is so superior to the right to manufacture that the transfer of commercialization rights alone essentially is equivalent to the sale of all patent rights. Given this, the licensing of commercialization rights, rather than of manufacturing rights, should be used to define whether a transaction in the pharmaceutical industry requires disclosure under the HSR Act. The agency also was successful in arguing that the legislative intent of the HSR Act did not preclude the agency from implementing an industry-specific rule.

We first addressed the implications of this Rule in August 2012, when it was proposed and introduced for public comment by the FTC. Now that the Rule is here to stay, awareness of its expanded impact on potential HSR reporting obligations as they relate to licensing transactions is a must. Before the new rule, only those licenses that involved the transfer of all patent rights had to be reported under the HSR Act. Now, those transactions which involve (1) the transfer of exclusive rights under a patent to use and sell, with retention by the licensor of the right to manufacture, or (2) the transfer of exclusive rights under a patent to make, use, and sell, with retention by the licensor of co-rights, in whole or part, must be reported under the HSR Act.

The FTC has estimated that the Rule would only effect about 30 transactions annually; however, in its complaint to the FTC, PhRMA said that it is "overwhelmingly likely that the Rule will cover many more than 30…licenses, at a substantially higher cost to [pharmaceutical companies]." PhRMA also estimated that even taking the agency's estimated 30 filings at face value, the industry could face additional filing and legal fees of almost $20 million annually as a result of the additional reporting requirements.

Our antitrust and life sciences groups are available to address any issues on the operation and implications of the Rule.

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