FTC Proposes Changes to HSR Reportability of Patent Licenses

The Federal Trade Commission has announced proposed rule changes that will impact the reportability of pharmaceutical patent licenses under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act"). If the rules are enacted, a transfer of "all commercially significant rights" with respect to a patent will potentially subject parties to the premerger reporting and waiting periods under the HSR Act; this will be the case regardless of whether manufacturing rights (a guiding factor in currently determining whether a license is "exclusive" and therefore a potentially reportable asset transfer) are retained by the licensor.

In explaining its rationale for the rulemaking, the FTC indicated that, although the transfer of a patent involves a fairly straightforward analysis under the HSR Act, the transfer of only certain patent rights has caused much confusion. Currently, only the transfer of a bundled right to "make, use and sell" a product covered by a patent is reportable; as a result, manufacturing rights retained by the licensor typically render a license non-reportable even when valuable commercial rights are conveyed to the licensee.

The FTC has focused its rulemaking on the pharmaceutical industry (including biologics and medicine manufacturing) due to what it describes as the "unique incentives" of pharmaceutical companies to enter into exclusive licenses. For example, it is common for an innovator without significant financial resources to team with a larger pharmaceutical company that has the fiscal ability to shepherd a product through the FDA approval process. If the relationship is successful, the parties share profits. The FTC indicated that licenses in other industries will be considered by the Premerger Notification Office, which administers the premerger reporting program on behalf of both the FTC and DOJ, on a case-by-case basis.

Under the proposed rules, a license will be considered to be exclusive (and therefore potentially reportable under the HSR Act) if the:

- Licensor retains no manufacturing rights or only "limited manufacturing rights" with respect to the licensed product (such as the ability to manufacture product for the licensee's benefit only);
- Licensee alone can use a patent in a particular therapeutic area (or for certain indications within such therapeutic area); and
- Licensor's retained co-development and co-marketing rights, if any, do not constitute a continued right to use the licensed product in the particular therapeutic area covered by the license.

The proposed rulemaking is geared towards the licensing activities of pharmaceutical companies but will capture other transfers of commercially significant rights relating to pharmaceutical patents, including assignments and grants. The public comment period remains open through October 25.

If you have any questions regarding these proposed changes, please contact any attorney in Ropes & Gray's antitrust practice group.