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Costly Deals

New FTC rules on patent licences in M&As have caused a storm. Two experts discuss why they could be bad for the pharma business.

FRANKI WEBB REPORTS

In the US, the FTC has broadened the type of patent licences that have to be reported following mergers and acquisitions. In your opinion, how onerous are the 6 November Premerger Notification Rules, and why?

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Peter Barbur: The Hart-Scott-Rodino (HSR) Act requires parties to certain large asset acquisitions to notify the Federal Trade Commission and Department of Justice and wait a period of time before consummating the transactions.

Patents are considered assets under the act and the sale of a patent is potentially reportable under the act. An exclusive patent licence that is functionally equivalent to a sale is thus potentially reportable under the act.

The FTC Premerger Notification Office (PNO) historically analysed all exclusive patent licences under a 'make, use and sell' approach, whereby a patent licence triggered the act's reporting requirements only if it transferred "the exclusive right to use a patent or part of a patent to develop a product, manufacture the product, and sell that product without restriction".

However, the recent trend among pharmaceutical companies to transfer some, but not all, of that bundle of rights under an exclusive patent licence has called into question the adequacy of the 'make, use, and sell' approach in the pharmaceutical context. Today, pharmaceutical patent licences frequently transfer to the licensee the exclusive right to use and sell, but allow the licensor to retain the right to manufacture the patented product exclusively for the licensee.

Under the PNO's view, the retention of such 'limited manufacturing rights' renders the transaction non-reportable under the 'make, use, and sell' approach, even though the licensor still cannot manufacture for its own commercial use.

In response to the 'limited manufacturing rights' loophole, the FTC amended the Premerger Notification Rules in November of 2013 to provide that an exclusive patent licence in the pharmaceutical industry that transfers "all commercially significant rights" is a reportable asset acquisition. The new rule is limited specifically to "[t]ransfers of patent rights within NAICS Industry Group 3254", which includes medicinal and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing and biological product manufacturing.

The term 'all commercially significant rights' is defined as "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)".

The 'all commercially significant rights' test focuses on "whether the licence has transferred the exclusive right to commercially use a patent or part of a patent" and states that "[a]ll commercially significant rights are transferred even if the patent holder retains limited manufacturing rights ... or co-rights".

Because the rule has only been in effect since 16 December 2013, there is considerable uncertainty regarding how onerous the new compliance burden will be. The FTC estimates that the rule will require HSR filings for 30 additional transactions per year, a substantial increase for the pharmaceutical industry given that the PNO received HSR filings for only 66 transactions involving exclusive licences for pharmaceutical patents during the entire five-year period ending on 31 December 2012.

Whether or not that estimate proves accurate, the attendant filing fees and other costs of HSR filing, including document collection and review, for each newly-reportable transaction will be significant, even if small relative to the size of the newly-reportable transactions.

One key uncertainty is the extent to which the new rule leads the agencies to issue additional Second Requests. In amending the rules, the FTC focused solely on the costs of preparing and filing HSR forms, seeming to assume that the level of scrutiny the agencies apply to these kinds of transactions will remain the same. However, as a practical matter, it is hard to imagine that additional HSR filings will not also lead to additional Second Requests, and the costs of compliance with a Second Request are substantial ($5 to $20 million, according to American Bar Association estimates).

And then there's the elephant in the room: although the new rule on its face is limited to the pharmaceutical industry, the FTC has foreshadowed a potentially broader implementation. It remains to be seen whether, and to what extent, the potential consequences of the new rule will spread to other industries that engage in exclusive patent licensing. **IPPro**