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Yet Another Turn of the Screw: The FTC Again Targets Pharmaceutical Industry, This Time Through the HSR Act

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Fresh from its victory in the Third Circuit on “pay-for-delay” deals involving brand name and generic pharmaceutical companies, the Federal Trade Commission (“FTC”) has announced yet another initiative aimed at the pharmaceutical industry. The FTC seeks to add to its arsenal against the industry, already central to the FTC’s enforcement agenda, by requiring that certain patent licenses be notified under its Hart-Scott-Rodino (“HSR”) premerger review procedures.

Four weeks ago, the Third Circuit announced it was adopting the FTC’s approach to pay-for-delay settlements, setting up an unambiguous conflict with three other circuits very likely to be taken up by the Supreme Court.¹ Less than two weeks later, on July 31, 2012, the agency announced a new policy concerning disgorgement, giving itself freer rein to seek monetary relief from companies engaging in anticompetitive conduct.² Now the agency proposes to target patent licenses in the pharmaceutical industry—the first instance of an industry-specific filing obligation in the nearly 40-year history of the HSR Act. Under the proposed FTC rule, patent licenses conferring “commercially significant” rights on a licensee in the pharmaceutical industry would be required to be filed under the HSR procedures that give the federal antitrust agencies advance notice of significant mergers and acquisitions. Adding to the sense of an industry under antitrust siege, the HSR proposal came on the same day that the FTC announced it had filed an *amicus* brief arguing that licenses of authorized generics should be treated the same as other pay-for-delay deals.³

Background

Much of the FTC’s work involves the health care industry, including, if not especially, pharmaceuticals. In addition to its regular review of pharmaceutical mergers, the agency has focused a tremendous amount of attention on so-called “pay-for-delay” deals—arrangements in which the manufacturer of a brand name pharmaceutical product pays a generic company as part of the settlement of a patent infringement suit, allegedly to delay the introduction of a bioequivalent drug. The FTC contends that such deals are anticompetitive because they constitute in essence an agreement by the two companies to divide the monopoly profits during the period of delay. After a string of FTC losses in which courts upheld such agreements as legitimate exercises of the branded company’s patent rights, two weeks ago the Third Circuit became the first to side with the FTC’s approach in nearly a decade, breathing new life into its enforcement efforts.⁴

The HSR Act is designed to give the antitrust agencies an opportunity to investigate, and possibly challenge, mergers and acquisitions before they close, avoiding the problem of having to unwind transactions once the merged companies’ assets and operations have been scrambled. The Act covers only the acquisition of assets (which includes intellectual property) or voting securities. Under long-standing FTC practice, a patent license is not considered an acquisition of the patent unless the license is exclusive as to all others (including the grantor), and includes the right to make, use, and sell the

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products using the patent. If the licensor retains the right to make the patented product, the license is not considered an asset acquisition. As the agency put it, “without the right to manufacture, [these licenses] are viewed as distribution agreements rather than asset acquisitions,” and are therefore not reportable.⁵

Under the proposed rule, a license agreement pertaining to a pharmaceutical product (including biologicals) would be considered “exclusive” even if the licensor retains the right to manufacture the product at issue. In explaining its proposal, the FTC stated that it considers such licensing arrangements to be unique in the pharmaceutical industry because, unlike in other industries, pharmaceutical patent owners often commit in license agreements to manufacture the licensed products exclusively for the licensee. “As the licensor is manufacturing solely for the use of the licensee, this is substantively the same as giving the licensee the exclusive right to manufacture, use and sell the product(s) covered by the license.”⁶ Provided the licensee receives all “commercially significant” rights, its license would thus be considered an asset acquisition.

The proposed rule would also codify an existing FTC policy that treats exclusive patent licenses as asset transfers even when the licensor retains “co-rights” in the patent, defined as “shared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent.”⁷ Co-rights include co-development, co-promotion, co-marketing and co-commercialization. Because the FTC believes that such rights are aimed at maximizing the sales of the licensed product and do not permit the licensor to use the patent in the same therapeutic area, the retention of co-rights does not render the license non-exclusive.

Analysis

The proposed change marks the third time in four weeks that the FTC has announced an initiative to assist it in challenging pharmaceutical deals that it considers to be anticompetitive. While the agency has sometimes addressed specific industries under the HSR rules, it has always done so in the context of *exemptions* from HSR.⁸ We are not aware of another instance in which the agency has singled out a specific industry in this way, requiring members of that industry to file in circumstances in which firms in other industries would be under no such obligation.

Given the timing and the unprecedented nature of this latest proposal, it is hard not to see an intent by the agency to subject the pharmaceutical industry to even greater scrutiny than the already high level it has been facing. The FTC estimates that the proposed rules would render reportable an additional 30 transactions per year, a relatively small increase in the FTC’s workload, but a potentially significant increase in regulatory burden for the pharmaceutical industry, which will bear the full brunt of the additional regulatory cost.

The FTC justifies the proposal on the basis that “the pharmaceutical industry presents unique incentives for the use of exclusive licenses.”⁹ Specifically, in the pharmaceutical industry there are situations in which “an innovator does not have the financial resources to shepherd the compound through the approval process required by the FDA, nor to effectively market or promote it in drug form after FDA approval.”¹⁰

It is true of course that only pharmaceutical companies are required to endure the lengthy FDA process as a condition of putting a product on the market. But it is unclear why that necessarily presents unique incentives for the licensor/patentee to retain manufacturing rights. It is easy to envision similar types of licenses in other industries involving innovation and lengthy development periods, raising the question why the agency is singling out pharmaceutical companies in this way.

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The FTC evidently believes it might be missing some anticompetitive agreements because they are outside the scope of HSR, though again it has not expressly identified why this would be a greater problem in the pharmaceutical industry than in other industries.

Moreover, the proposed rules might also capture not just anticompetitive agreements in general but branded/generic agreements in particular, and especially ones involving authorized generics—precisely the conduct FTC condemned in its *amicus* brief filed on August 10 as an illegal, non-cash inducement of the generic to delay its entry. In its brief, the agency argued that a “no-AG” commitment “enables the generic company to maximize its revenues during the first-filer exclusivity period.”¹¹ An exclusive license to the AG, it contended, is one form of a no-AG commitment:

A no-AG commitment can take a variety of forms. In some cases, the brand company explicitly agrees not to compete during the generic’s exclusivity period. In other cases, the brand company grants the first-filer generic the exclusive rights to market a generic product, or designates the first-filer generic as the exclusive distributor of the brand’s AG. Regardless of its form, however, the practical effect of the no-AG commitment is always to eliminate competition between the brand’s AG product and the first-filer generic’s product during the marketing exclusivity period and results in higher drug prices for consumers.¹²

Drug companies are already required to file their patent settlements with the agency under the Medicare Modernization Act (“MMA”), another instance of a pharmaceutical industry-specific filing obligation.¹³ Some, if not all, AG license agreements might already be covered by the MMA. But even if all of them are, the MMA, unlike HSR, does not prohibit consummation of the deal pending agency review.

The proposed rule is subject to comment until October 25, 2012, and may be revised prior to its final adoption. Companies interested in voicing their views should begin preparing their submissions now.

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¹ The Third Circuit ruling is discussed in our alert entitled “Third Circuit Sides with FTC Position on So-Called Pay-for-Delay Settlements, Virtually Guaranteeing Supreme Court Review on the Issue,” available at <http://www.klgates.com/third-circuit-sides-with-ftc-position-on-so-called-pay-for-delay-settlements-virtually-guaranteeing-supreme-court-review-on-the-issue-07-25-2012/>.

² This development is discussed in our client alert entitled “The Guns of August: FTC Announces Policy Change Lowering Barrier to Monetary Relief for Anticompetitive Behavior; Action Aimed at the Pharmaceutical ‘Pay-For-Delay’ Cases and Other Top FTC Priorities,” available at <http://www.klgates.com/the-guns-of-august-ftc-announces-policy-change-lowering-barrier-to-monetary-relief-for-anticompetitive-behavior-action-aimed-at-the-pharmaceutical-pay-for-delay-cases-and-other-top-ftc-priorities-08-02-2012/>.

³ See Press Release, FTC Files Amicus Brief Explaining That “No-AG” Agreements Are Used by Drug Companies to Delay Generic Competition (Aug. 13, 2012) available at <http://www.ftc.gov/opa/2012/08/effexor.shtm>.

⁴ Last Friday, August 17, 2012, the Third Circuit refused to grant defendants’ request to stay its *K-Dur* ruling while defendants petition the Supreme Court for certiorari, allowing FTC an opportunity to continue its efforts to expand the reach of the Third Circuit’s *K-Dur* decision. See *In re K-Dur Antitrust Litig.*, Dkt. No. 10-2077, Doc. No. 003110990433 (3d Cir. Aug. 17, 2012).

⁵ See ABA Section of Antitrust Law, *Premerger Notification Manual* (4th ed. 2007) (Interpretation No. 27).

⁶ Fed. Trade Comm’n, Notice of Proposed Rulemaking, *Premerger Notification; Reporting and Waiting Period Requirements*, (“FTC Premerger Notification Proposed Rulemaking”) at 7, available at <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>.

⁷ *Id.* at 16.

⁸ Several industries specifically are afforded exemptions from the HSR Act when a filing may otherwise be required. See, e.g., 16 C.F.R. § 802.2(e) (exempting acquisitions of hotels and motels) and (f) (exempting acquisitions of golf courses, swimming, and tennis clubs); § 802.3 (exempting certain acquisitions of carbon-based mineral reserves).

⁹ FTC Premerger Notification Proposed Rulemaking at 8.

¹⁰ *Id.* at 8.

¹¹ FTC amicus brief at 7, available at <http://www.ftc.gov/os/2012/08/120810effexoramicusbrief.pdf>.

¹² *Id.* at 5.

¹³ See Act of Dec. 8, 2003, Pub. L. No. 108-173, § 111(a) tit. XI, subtit. B, 117 Stat. 2461; see also Fed. Trade Comm’n, *Pharmaceutical Agreement Filings Overview*, available at <http://www.ftc.gov/bc/healthcare/drug/index.htm>.