# New FTC Initiative to Expand Premerger Filing Requirements for Pharma Patents

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## FTC also expanding use of monetary remedies

Perhaps buoyed by the Third Circuit's recent decision adopting its position that payments by a pharmaceutical patent holder to a generic patent challenger who agrees to delay entry into the market is prima facie evidence of an unreasonable restraint to trade (*see In re K-Dur Antitrust Litigation,* 686 F.3d 197 (3d Cir. 2012), the Federal Trade Commission recently announced two new policy initiatives that will expand its reach in competition matters.

### The FTC Proposes To Expand Premerger Filing Requirements for Transfers of Pharmaceutical Patent Rights

Under the premerger notification rules, proposed acquisitions of patents, like other assets, may be subject to reporting requirements and waiting periods under the Hart-Scott-Rodino Act. In addition to the general dollar value thresholds for size-of-persons and the size of transaction, in the patent area questions arise concerning when grants of licenses will constitute an asset acquisition. In an August 13, 2012 Notice of proposed rulemaking, the Federal Trade Commission ("FTC") has proposed changes to the premerger notification rules that will clarify and expand the patent transactions potentially reportable in the pharmaceutical industry. The Notice and proposed rules are available here.

As set forth in the Notice, the Premerger Notification Office ("PNO") staff had long taken the position that a transfer of exclusive rights to a patent - typically by an exclusive license - was potentially reportable. The proposed rules clarify this policy only for transactions involving pharmaceutical patents, based on the FTC's view that unique incentives exist as to pharmaceutical patents. Thus, the proposal applies only to patents within NAICS Industry Group 3254, which encompasses manufacturing of medical, botanical, pharmaceutical, biological and in-vitro diagnostic substances. The proposed amended rule 801.2(g) states:

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> (2) The transfer of patent rights covered by this paragraph constitutes an asset acquisition; and (3) patent rights are transferred if and only if all commercially significant rights to a patent, as defined in §801.1(o), for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. All commercially significant rights are transferred even if the patent holder retains limited manufacturing rights, as defined in §801.1(p), or co-rights, as defined in §801.1(q).

Rather than "exclusive licensing", the proposed rule refers to "all commercially significant rights." Proposed Rule 801.2(g)(3). This phrase in turn is defined to mean "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.)" Proposed Rule 801.1(o). The commentary indicates that this formulation was intended to ensure substance prevailed over form: whether a transaction agreement is labeled "exclusive license" is not dispositive. Moreover, the application to therapeutic area or a specific indication within a therapeutic area comports with PNO staff positions that exclusive licenses within a field of use constituted asset transfers.

As stated in the Notice, PNO staff generally had viewed exclusive licenses in which the patent holder retains the right to manufacture the product as non-reportable events because the license appeared to be a distribution agreement, not an asset acquisition. In changing this outcome under the proposed rules, the FTC commented that in the pharmaceutical industry, the patent holder often retains the right to manufacture, albeit exclusively for the licensee. Because the focus of pharmaceutical licensing arrangements frequently is to obtain FDA approval for a compound and then, if successful, to market and sell it, retention of manufacturing rights is typically less significant. Accordingly, the patent holder's retention of the right to manufacture the pharmaceutical covered by the patent (a "limited manufacturing right") will no longer avoid treatment as an asset acquisition.

The other provision - that retention of certain "co-rights" by the patent holder does not take the patent transaction out of the rule - accords with PNO's current practice. As defined under the proposed new rule: "The term co-rights means 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. These co-rights include, but are not limited to co-development, co-promotion, co-marketing and co-commercialization." Proposed Rule 801.1(q). Because, under this circumscribed definition of co-rights, the licensor does not retain the right to use the patent in the same therapeutic area, these co-rights, which may assist the licensee in maximizing sales (and thereby increase the licensor's royalties), do not render the license non-exclusive.

Comments on the proposed rules may be submitted through October 25, 2012. The Notice specifies the procedures for submitting comments, including how to seek confidentiality for a submission.

## FTC's Withdrawal of its 2003 Policy Statement on Monetary Equitable Remedies In Competition Cases

On July 31, 2012, the Federal Trade Commission withdrew its Policy Statement on Monetary Equitable Remedies in Competition Cases. The Policy Statement had been adopted in 2003 to provide guidance concerning the circumstances in which the FTC would seek disgorgement or restitution in competition cases. In its Statement explaining the change, which is available here , the FTC asserted that the 2003 Policy Statement had created an "overly restrictive view of the Commission's options for equitable remedies." In particular the FTC pointed to two of the three factors cited in the Policy Statement - (1) whether the underlying violation is "clear" and (2) whether "other remedies are likely to fail to accomplish fully the purposes of the antitrust laws" - as potentially imposing unwarranted constraints on the FTC. (The third factor, relating to whether there is a reasonable basis to calculate the remedial payment was described as simply reflecting existing law.)

The FTC's withdrawal Statement noted that the FTC had sought monetary equitable remedies in only two competition cases since the 2003 Policy Statement was adopted. Limiting monetary remedies to "exceptional cases," the FTC stated, was not appropriate. Instead, going forward, the FTC will evaluate disgorgement and restitution remedies through the framework of existing case law.

The withdrawal of the Policy Statement follows other signals that the FTC intends to seek monetary remedies more aggressively. Prior to his elevation from FTC Commissioner to Chairman, Jon Leibowitz had issued a concurring statement in *FTC v. Ovation Pharmaceuticals, Inc*.,supporting the disgorgement remedy sought in that case. His concurrence available here noted that recent literature supported seeking disgorgement more frequently and stated: "I strongly agree the Commission should use disgorgement in antitrust cases more often."

If you have any questions or would like to discuss these developments or other competition issues, please contact:


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