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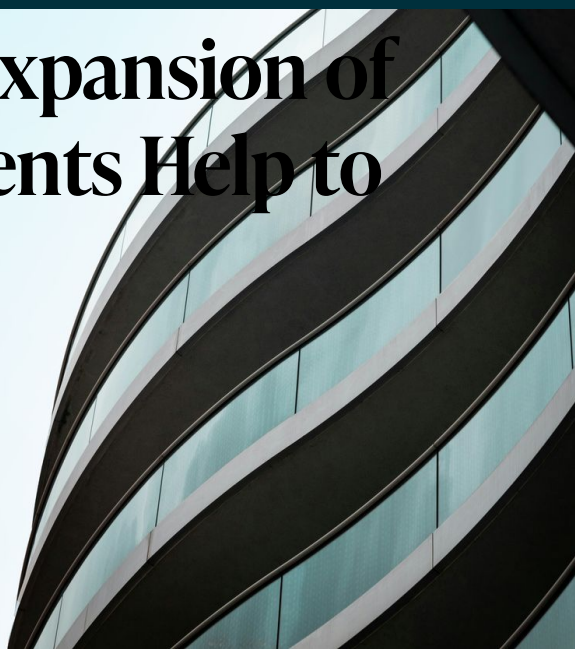
Will the PTO's Proposed Expansion of Filing Settlement Agreements Help to Reduce Drug Prices?



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By: Craig D. Minerva

In a recent Federal Register notice, the PTO announced a proposed rule requiring that any settlement agreement resolving a PTAB proceeding, even if such agreement occurs prior to a decision to institute an inter partes review (IPR), be submitted to the PTO. Prior to this rule, only post-institution settlements were required to be submitted, but the PTO noted that over half of all settlements occur pre-institution. The new rule is being proposed "to assist the Federal Trade Commission (FTC) and the Department of Justice (DOJ) in ensuring compliance with antitrust laws," pursuant to the Biden Administration's July 9, 2021 Executive Order, which encouraged government agencies to cooperate on policy anticompetitive practices.

The Biden Administration has certainly been applying more of an "all of government" approach in its attempts to lower drug costs and prevent potential patent abuses. We have written about the Administration's attempts to have FDA collaborate with the PTO on patent prosecution, develop a framework for HHS and the Department of Commerce to exercise "march-in" rights over pharmaceutical patents, and actively encourage the FTC to take action directed to patents that are improperly listed in the Orange Book. The PTO appears to be expanding those efforts with this new proposed rule.

That being said, will the proposed rule have a big impact when many of these settlement agreements are already being filed with the FTC and DOJ under the Medicare Modernization Act (MMA)? Under the MMA, patent-infringement settlement agreements involving a drug for

which the generic has submitted an ANDA with a Paragraph IV certification or that involve a settlement between a biologic innovator and biosimilar applicant must be filed with the antitrust authorities within 10 business days of the agreement.

It's certainly interesting to see yet another effort by a federal agency to tackle drug pricing, particularly where drug pricing has not traditionally been a part of its mandate. But it remains to be seen how much of an impact this proposed rule will have.

> **This proposed rule aligns with the policy set forth in Executive Order 14036, which encourages government agencies to cooperate on policing unfair, anticompetitive practices. In addition, having a depository for all settlement agreements in connection with contested cases, including AIA proceedings, in the USPTO would assist the FTC and the DOJ in determining whether antitrust laws have been violated.**

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