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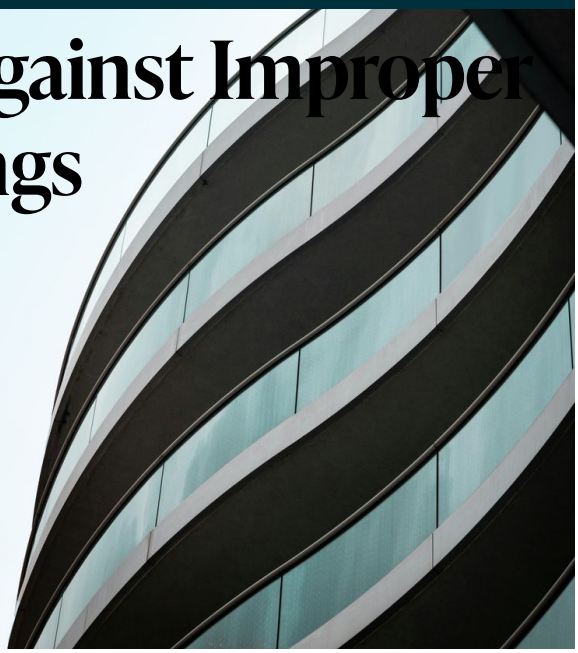
FTC Takes Up the Battle Against Improper Orange Book Patent Listings



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By: Daniel K. Oakes

Attempting to put some teeth into the policy statement that it issued last month, the FTC sent letters to 10 pharmaceutical companies, asserting that their listing of over 100 patents in FDA's Orange Book for a variety of products is improper. The products include certain asthma inhalers and epinephrine autoinjectors, including EpiPen, and the letters were sent to: AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, Impax Laboratories, Kaleo, Mylan Specialty, and subsidiaries of Glaxo-Smith Kline and Teva.

Delays in entry of generic competition can reduce patient access to drugs and increase health care costs. The FTC has long been concerned that improper Orange Book listings may be driving up drug costs by imposing 30-month stays of FDA approvals of generic drugs and requiring generic drug companies to unnecessarily challenge patents through Paragraph IV patent litigation. In its September policy statement, the FTC declared that it viewed the improper listing of patents in the Orange Book as constituting an unfair method of competition in violation of Section 5 of the FTC Act, or even a claim of illegal monopolization under Section 2 of the Sherman Act.

While FDA has taken the position that its role in the patent listing process is merely ministerial, the FTC has now made the first move to challenge – and publicly call out – companies for questionable patent listings. In doing so, the FTC initiated the FDA's regulatory dispute

process, which will likely lead FDA to seek further certification that the patent listings are correct.

Perhaps foreshadowing FDA's intent to follow this process, FDA Commissioner Robert M. Califf, M.D., stated: "The FDA reminds all NDA holders they are obligated to ensure that patent listings comply with statutory and regulatory requirements and to substantively respond to statements of dispute provided under the FDA's patent listing dispute process."

It will be interesting to see if any company removes patents from or changes use codes or other information in the Orange Book as a result of this action. In addition, these letters are likely to spur interest from the antitrust class action bar and may lead generic companies to evaluate whether to bring patent delisting counterclaims in Paragraph IV patent litigations.

It remains to be seen how far FTC will take this effort to quash certain patent listings. But this is likely just the first shot across the bow – the letters expressly reserve the right to take further action including investigation under Section 5.

> **"Wrongfully listed patents can significantly drive up the prices Americans must pay for medicines and drug products while undermining fair and honest competition," said FTC Chair Lina M. Khan. "The FTC's action today identifies over 100 patents that we believe are improperly listed, affecting products ranging from inhalers to EpiPens. We will continue to use all our tools to protect Americans from illegal business tactics that are hiking the cost of drugs and drug products."**
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> FTC www.ftc.gov/...

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