

FTC Expands Orange Book Patent Listing Challenges

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As discussed in [November](#) and [December](#), the FTC has placed improper Orange Book patent listings squarely in its crosshairs. Initially, based on its [September 2023 policy statement](#), FTC announced that it would “scrutinize improper Orange Book listings” and “use its full legal authority” to “tak[e] actions against companies and individuals that improperly list patents in the Orange Book that do not meet the statutory listing criteria.” Towards the end of last year, the FTC sent letters to 10 pharmaceutical companies, asserting that their listing of over 100 patents in the FDA’s Orange Book for a variety of products is improper, in addition to notifying the FDA of what it believed were [improper listings](#).

Since then, the FTC has been somewhat quiet, choosing not to sue any of these pharmaceutical companies on its own, but supporting the policy statement by filing two amicus briefs, [one](#) regarding the Lantus drug product and [the other](#) regarding asthma inhalers.

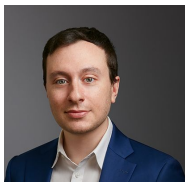
[Today](#), the FTC announced another set of 10 letters regarding 300 Orange Book patent listings across 20 different brand name products. It is unclear if the FTC will take action against these pharmaceutical companies or continue to file amicus briefs in cases where these patents are at issue. Time will tell whether the FTC’s actions result in any patent delistings or changes in the Orange Book. But it’s clear that the FTC intends to remain active in this area.



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