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Important U.S. Developments Relating to "Reverse Payment" Patent Settlements

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There have been two key recent developments in the U.S. relating to the legal dispute over patent settlements including so-called "reverse payments." First, the U.S. Supreme Court has agreed to review an Eleventh Circuit decision dismissing a case brought by the Federal Trade Commission (FTC) challenging a patent settlement. Second, a district court in New Jersey issued the first decision to consider the legal treatment of a commitment by a brand name manufacturer to a generic company not to license any other generic companies the right to sell an authorized generic.

The Supreme Court's decision to weigh into the "reverse payment" dispute is a pivotal moment in the development of the U.S. law in this area, and provides the Court with an opportunity to provide crucial guidance on a legal issue that has been hotly debated for almost a decade – and which the FTC has frequently referred to as its top competition-related priority. Although the decision by the NJ district court is a lower-profile development, the authorized generic issue it considered is also of great importance because recent analyses from the FTC have illustrated that brand name manufacturers are regularly entering into patent settlements that include a commitment not to license other authorized generics. In fact, these types of settlement provisions are in practice more common than the direct payments that are at issue in *AndroGel*. The pharmaceutical industry and their legal advisors will, without doubt, be closely following these cases and anticipating the results.

AndroGel

On 7 December 2012, the Supreme Court granted certiorari to review the Eleventh Circuit's decision in *FTC v. Watson Pharmaceuticals*, which affirmed a district court's dismissal of the FTC's antitrust challenge to an alleged "reverse payment" patent settlement between Solvay Pharmaceuticals and several generic companies relating to Solvay's product AndroGel®. The FTC had alleged that because Solvay, according to the FTC, was "not likely to prevail" in the patent litigation, the settlements unlawfully restrained competition by extending a monopoly over AndroGel® that the patent laws did not authorize. The companies moved to dismiss, arguing that the FTC had failed to allege that the settlements imposed restraints on the generic companies that exceeded the scope of Solvay's patent for AndroGel®. The district court agreed, and granted the

companies' motion to dismiss.

The Eleventh Circuit upheld the dismissal, finding that the test for determining whether patent settlements are immune from antitrust attack focuses "on the *potential* exclusionary effect of the patent, not the *likely* exclusionary effect." (emphasis added). The court observed that, given the uncertainties of litigation and the varying reasons to settle, "it is simply not true that an infringement claim that is 'likely' to fail actually will fail." Until a claim actually fails, a patent retains its full potential exclusionary effect. And a settlement that imposes restraints less than that full potential effect could not, according to the court, be found to exceed the scope of the patent.

The decision in *AndroGel* followed prior decisions both in the Eleventh Circuit as well as the Second and Federal Circuits. However, a clear Circuit split was recently created when the Third Circuit adopted a legal standard that was aligned with the FTC's position. *In re K-Dur Antitrust Litig.*, No. 10-2079 (3d Cir. 2012). In *K-Dur*, the Third Circuit found the patent settlement to be prima facie unlawful based on the presence of a cash payment from the brand manufacturer to the generic manufacturer. This is in direct contrast with the decision in *AndroGel*, which found these very facts to be insufficient in light of the scope of the brand name manufacturer's patent.

In its petition for *certiorari* on behalf of the FTC, the U.S. Solicitor General forcefully argued for Supreme Court review of this issue of "great economic importance." The government emphasized the split between the *AndroGel* and *K-Dur* decisions, and argued that the *AndroGel* case was the superior vehicle for addressing the legal issues due, among other things, to the fact that the *AndroGel* case involved the FTC seeking injunctive relief and not private plaintiffs seeking damages. (Regardless of the standard used for liability, private plaintiffs would probably need to prove that the brand name manufacturer would have lost the underlying patent infringement case if they are to demonstrate that the patent settlement caused them damages).

In re Lamictal

On 6 December 2012, a New Jersey district court (which is in the Third Circuit) ruled that the strict legal standard set forth in the Third Circuit's decision in *K-Dur* should not apply to an antitrust challenge to a patent settlement that includes a provision pursuant to which the brand name pharmaceutical manufacturer granted the generic company the exclusive rights to sell an authorized generic. *In re Lamictal Direct Purchaser Antitrust Litigation*, Civ. No. 12-995. The court held instead that the *K-Dur* decision only applies to cash "reverse payments." The decision rejects the position that has long been advocated by the FTC that a commitment by a brand name manufacturer not to license other authorized generics provides the generic with value that effectively amounts to a "reverse payment" – which, in the FTC's view, should be considered *prima facie* unlawful under the antitrust laws.

Conclusion

In light of the Supreme Court's decision to review the *AndroGel* decision, in the short

term the “authorized generic” issue is likely to take a back seat to the more fundamental issues raised by the *AndroGel* appeal. However, in the longer term, it will also be important to follow closely the *Lamictal* case and its implications for the ability of brand name manufacturers to license exclusive authorized generics as part of a patent settlement agreement.

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