Update on a Recent Supreme Court Antitrust/ Intellectual Property Case: “Reverse Payment” Settlement Agreements under FTC v. Actavis, Inc. (June 17, 2013)

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Since the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), "pay for delay" or "reverse payment" settlement agreements have become commonplace in the brand-name drug industry. The practice, and its purpose, is fairly straight-forward: In the setting of pharmaceutical drug regulation, a generic manufacturer challenges the validity or scope of the brand-name company's patent as a step towards launching a generic product. In order to preserve a pioneer drug's market position in the face of such a challenge from the would-be generic entrant, the pioneer drug company pays the generic drug company a substantial sum of money to delay the entry of the generic drug into the market for a specified number of years, while typically permitting entry before the normal expiration of the pioneer drug company's patent. Outside of the patent context, this type of agreement would appear facially to stifle competition and thus raise significant antitrust concerns. Within the patent context, however, this type of agreement has found support under the Patent Act and Hatch-Waxman Act.

The co-existence between the antitrust and patent laws has always been controversial, if not a bit awkward. While the antitrust laws seek to protect competitive markets in order to promote consumer welfare, the patent laws seek to encourage innovation by granting a patent holder the legal right to exclude others from that very market. "Reverse payment" settlement agreements amplify the inconsistencies inherent in the two fields of law.

In examining the practice of "reverse payment" settlement agreements, a number of federal courts, including the Second, Third, Sixth and Eleventh Circuits have reached conflicting conclusions. Some federal circuits have found the practice to presumptively violate the antitrust laws under a "quick-look" rule of reason analysis. Other federal circuits have found the practice to be immunized from antitrust scrutiny under the scope-of-patent protections afforded under the Patent Act and Hatch-Waxman Act. The logic defending the position that the practice of settling patent cases has immunity rests on the premise that if the patentee is acting within the exclusionary power conferred by the scope of the patent, then the realm of antitrust law should not be invoked. This logic in favor of immunity of patent cases from antitrust, however, was

recognized did not prevail.

A new U.S. Supreme Court opinion in the case of *FTC v. Actavis, Inc*. resolves the debate - at least for the time being - and is of great significance to pioneer drug patent holders and generic manufacturers alike. As background, the Federal Trade Commission ("FTC") brought an antitrust action against several drug companies seeking to enjoin a "reverse payment" settlement under its authority under Section 5 of the FTC Act. Section 5 equips the FTC with exclusive authority to enjoin conduct alleged to constitute an "unfair method of competition," a far less demanding standard than what would apply to a violation of other areas of federal antitrust law, including the Sherman Antitrust Act (unreasonable restraint of trade) or Clayton Antitrust Act (substantial lessening of competition). After carefully considering the split in the circuits below, the Supreme Court resolved the antitrust-patent tug-of-war by holding that "reverse payment" settlement agreements are not immune from antitrust scrutiny. While not presumptively unlawful, the Supreme Court held that such agreements are subject to antitrust evaluation under the "rule of reason" analysis (requiring a balancing of the various competitive factors to determine whether competition has been unduly harmed). In doing so, the Supreme Court effectively shifted the burden to the lower federal courts to inquire into and weigh the benefits achieved by settlement agreements in the context of the intellectual property laws against omnipresent antitrust concerns.

Significantly, this decision opens the door to potential antitrust exposure to all parties involved in "reverse payment" settlement agreements, including pioneer drug patent holders and generic manufacturers. Parties to "reverse payment" settlement agreements should expect careful government scrutiny in the future.

Lathrop Gage LLP has a strong team of practitioners, having a variety of deep backgrounds, serving clients in the life sciences. Please feel welcome to contact us if you would like to discuss this case or any aspect of intellectual property law.

Links to case opinion via the U.S. Supreme Court website; *FTC v. Actavis, Inc*. (June 17, 2013):

http://www.supremecourt.gov/opinions/slipopinions.aspx?Term=12 (search for "Actavis"); http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf