Supreme Court Ruling will have significant impact on pharmaceutical industry

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For nearly a decade, the U.S. Supreme Court has declined to consider the question of whether so-called “reverse payment” or “pay-for-delay” agreements between branded pharmaceutical manufacturers and prospective generic competitors to settle patent infringement lawsuits violate federal antitrust laws. On December 7, the court finally granted *certiorari* on a petition by the Federal Trade Commission (FTC) in order to resolve a dispute between several of the federal circuit courts of appeals as to whether reverse payment agreements are lawful *per se*, as several appellate courts have held, or are presumptively anticompetitive.

Reverse payment agreements have increasingly become the mechanism of choice for settling patent infringement lawsuits between branded drug manufacturers – i.e., the patent owners – and generic manufacturers – i.e., the alleged infringers – instituted after the latter filed Abbreviated New Drug Applications (ANDA) seeking FDA approval to compete with previously-approved pioneer drugs. Where the pioneer drugs at issue are protected by U.S. patents, the generic manufacturers must include with their ANDAs a certification that the patents are invalid or the generic drugs do not infringe those patents. See 21 U.S.C. § 355(j)(2)(A)(vii)(VI). Based on the filing of such a "Paragraph IV certification," a patent owner can institute an infringement lawsuit against the ANDA filer. These lawsuits frequently have been settled by reverse payment agreements under which the patent owner pays the alleged infringer an amount of money (or extends some other benefit) in exchange for delaying the introduction of the generic product to the market.

Reverse payment agreements have been the subject of numerous lawsuits across the country challenging whether agreements between prospective competitors to limit competition violate antitrust laws. On their face, these would appear to be *per se* anticompetitive, but the analysis here is complicated by the fact that the branded drug manufacturers are entitled to protections from competition by their patents. Several jurisdictions – most notably the Second, Eleventh and Federal Circuits – have held that reverse payment agreements are presumptively lawful, and have upheld them, except where there is evidence that the underlying infringement lawsuit was a sham or where the agreement would extend the protection beyond that allowed by the branded manufacturers' patents. Meanwhile, at least one other jurisdiction – the Third Circuit – has deemed reverse payment agreements to be presumptively anticompetitive, and has held that they are not enforceable unless there is evidence of procompetitive effects of the agreement.

The FTC petitioned the Supreme Court after an adverse ruling by the U.S. Court of Appeals for the Eleventh Circuit in *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012). In that case, the Eleventh Circuit upheld an agreement between the manufacturer of AndroGel®, a synthetic testosterone treatment, and prospective generic competitors to settle patent infringement litigation. The holding followed that court’s established rule that, “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” 677 F.3d at 1312. The Supreme Court’s long-awaited resolution of this dispute among the appellate courts will have great significance within the pharmaceutical industry. According to the FTC, reverse payment agreements have the effect of delaying the introduction of generic bioequivalent drugs to the marketplace, which the FTC believes costs consumers billions of dollars each year. Drug manufacturers, though, argue that reverse payment agreements are necessary to ensure their patent monopolies for pioneer drugs, which are essential to recoup the billions of dollars spent on research and development. They argue that removing this incentive to invest in pioneer drugs raises concerns over whether they can afford to take the risks associated with research, development and testing in the future.

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