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Antitrust Considerations in Pharmaceutical Life Cycle Management

By Carl W. Hittinger

Efforts to extend the life cycle of pharmaceutical products frequently involve innovations and improvements in product design, formulation, route of administration, and treatment indications. In addition, negotiation of agreements with competitors, including generic and biosimilar manufacturers, is frequently employed as part of a life cycle management strategy. However, recent changes in patent, regulatory, and antitrust laws have introduced greater complexity and higher risk into these strategies.

On October 23, 2015, a distinguished panel of BakerHostetler partners led an exclusive seminar in person and online at which they discussed these and related issues and provided suggestions for developing successful life cycle management strategies. Here, Carl W. Hittinger addresses potential antitrust considerations.

Carl Hittinger's portion of the presentation addressed certain antitrust considerations raised by pharmaceutical life cycle management strategies. Hittinger first noted the inherent historic tension between exclusivities – including patent exclusivity – and antitrust law, which in part seeks to prevent or control monopolies. This tension was recently addressed by the U.S. Supreme Court in *FTC v. Actavis*, a 2013 opinion that Hittinger described as a "game changer." In *Actavis*, the Court addressed the antitrust implications of "reverse payment" settlements of Abbreviated New Drug Application (ANDA) litigation under the Hatch-Waxman Act. This type of settlement involves payment from the plaintiff (the patent holder) to the defendant (the generic company accused of infringement) – even though the defendant has no claim for damages. The Federal Trade Commission (FTC) has long believed such settlements are often anticompetitive because they are, in substance, agreements between competitors to share a branded company's monopoly profits in exchange for a generic challenger's agreement to abandon its patent challenge and stay out of the market. In a 5-4 opinion, the *Actavis* Court held that such settlements may violate the antitrust laws, rejecting the view adopted by some Circuits that settlements within the "scope of the patent" were immune from antitrust scrutiny. As Hittinger explained, the import of the decision was reflected in the powerful dissent by Chief Justice John Roberts, who believed that the precedential decision undermined established relationships between patent law and antitrust law and would weaken incentives to innovate. Since the decision, courts have addressed the question of whether *Actavis* applies to non-cash payments. The Third Circuit held earlier this year that *Actavis* does apply to a non-cash settlement involving a branded company's agreement not to market its own "authorized generic" during the first ANDA filer's 180-day exclusivity period. Such an agreement may have extremely significant financial value to the generic company, though it is not a straightforward transfer of money. Hittinger also noted that post-*Actavis*, companies should be prepared to justify "side deals" accompanying settlement. Such deals may be scrutinized by the FTC to assess whether they reflect genuine business transactions for fair value, as opposed to a cover for an anticompetitive payment unrelated to the litigation at issue. Finally, Hittinger suggested that the *Actavis* analysis might also be implicated by settlements of *inter partes* reviews or post-grant reviews involving competitors, since, as in the Hatch-Waxman context, these would also involve a transfer of value from the patentee to a challenger with no damages claim.

Hittinger next discussed recent cases involving antitrust claims based on "product hopping" – a term used to describe the strategy of moving customers from an older drug product losing exclusivity to a similar modified product for which exclusivity is still available. The key case in this area is the Second Circuit's decision earlier this year in *New York v. Actavis*. In that case, the defendant manufacturer Forest Laboratories had removed from the market an older, immediate-release version of its Alzheimer's drug Namenda in connection with the launch of a new, extended-release version with patent protection until 2029. Notably, the older product was withdrawn from the market before generic competition entered, preventing existing patients from moving to a generic version of the

drug under state laws requiring automatic substitution when a generic is available. Instead, patients would be switched to the extended-release form, which would not be subject to generic competition for many years. The Second Circuit upheld an injunction issued by the district court that required the manufacturer to continue to make the older product available. While noting that courts are generally skeptical about claims that product design changes are anticompetitive, the Second Circuit held that such a change may raise antitrust issues when it "coerces customers and impedes competition." The court found that generic companies were entitled to a fair opportunity to take advantage of generic substitution laws. Importantly, Hittinger noted, the court suggested that certain "soft switch" tactics, such as discounts, rebates, or refocusing of promotional efforts, would be permissible. In Hittinger's view, the takeaway of the case for the industry is that actions taken to move customers to a new, modified product must be persuasive, not coercive.

Hittinger also discussed the 2014 case from the Eastern District of Pennsylvania involving the drug Suboxone, in which an antitrust claim based on product hopping survived summary judgment even though the older drug was not taken off the market before generic entry. The plaintiff alleged various other actions, including filing a "sham" citizens' petition that raised false safety concerns about the older drug. In the aggregate, the court believed, these allegations sufficiently evidenced conduct intended to stymie competition in violation of the antitrust laws. By contrast, in the recent *Mylan v. Warner* case, also from the Eastern District of Pennsylvania, the court there dismissed the generic plaintiff's antitrust claims based on repeated incremental product changes over a series of years, coupled in some cases with the withdrawal of the earlier product from the market. The *Mylan* case is now on appeal to the Third Circuit, where the FTC has filed an amicus brief highly critical of the district court's decision.

Hittinger noted that an FTC official recently made comments on product hopping, and identified two elements of a product hopping scheme that may raise concerns – product changes that are "only minor" and conduct by the drugmaker that is intended to destroy the market for the older product. In Hittinger's view, the FTC is likely to bring an enforcement action related to product hopping. Importantly, he noted, the FTC has broader powers than the Justice Department or private litigants under the Sherman Act because it can act against "unfair methods of competition" under Section 5 of the FTC Act, which, the agency maintains, reaches some conduct that would not otherwise constitute an antitrust violation under established Sherman Act precedent.

Finally, Hittinger discussed antitrust claims that have been brought based on alleged abuses of Risk, Evaluation and Mitigation Strategies (REMS) programs. In two cases from the District of New Jersey in recent years, plaintiffs raising such claims have survived motions to dismiss antitrust claims. In both cases, the plaintiffs alleged that branded manufacturers used REMS restrictions and related safety concerns as a pretext to refuse to provide drug samples to potential generic competitors, who needed the samples to undertake required bioequivalence testing. By contrast, in the Suboxone case, discussed earlier in connection with product hopping, the court did not allow a claim based on allegations that the defendant refused to cooperate in good faith with the plaintiff, a generic competitor, in developing a shared REMS program, per the Federal Drug Administration's instructions. That court pointed out that the Federal Food, Drug, and Cosmetic Act expressly prohibits manipulating the REMS process for purposes of delay and that this provision lessens the need for judicial antitrust scrutiny.

Hittinger was asked why so many important cases in this area seem to come out of the Third Circuit. He responded that both the FTC and private litigants view the Third Circuit as a favorable jurisdiction, in part based on *In re K-Dur*, a "reverse payment" case predating *FTC v. Actavis* in which the Third Circuit held that reverse payments were presumptively anticompetitive and illegal. Though that position did not ultimately prevail, there remains a perception that the Third Circuit is receptive to plaintiffs' arguments, as well as being experienced and sophisticated with regard to antitrust issues.

In closing, Hittinger suggested an approach that he acknowledged might be "counterintuitive." When entering into settlements or other actions involving competitors that might implicate antitrust issues, companies should consider being proactive and asking for the FTC's views through their relatively expeditious formal FTC letter review procedures before engaging in questionable conduct. If the conduct is approved by the agency, this can potentially spare the company the battle and expense of litigation that might otherwise follow. Being perceived as a "good corporate citizen" in the eyes of antitrust regulators can be a good long-term investment, he stressed.