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ANTITRUST

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SOWING UNCERTAINTY: NAVIGATING PATENT DISPUTES AND ANTITRUST SCRUTINY POST *KING DRUG*

By Carl J. Schaerf and Benjamin D. Wanger

On June 26, 2015, the Third Circuit issued an opinion in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, (Case No. 14-1243). *King Drug*. The opinion, which already has been extensively commented on and scrutinized, purports to follow the Supreme Court's holding in *FTC v. Acatvis, Inc. Actavis* holds that patent dispute settlements consisting of reverse cash payments from a brand drug manufacturer to a generic drug manufacturer are subject to rule of reason scrutiny. *King Drug* holds that, similarly, non-cash settlements in which a patentee drug manufacturer agrees to relinquish its right to produce an "authorized generic" of the drug (a "no-AG agreement") to compete with a first-filing generic drug's 180-day exclusivity period, are subject to antitrust scrutiny under a "rule of reason analysis."

Although the Third Circuit's holding in *King Drug* answers (at least within the Third Circuit) the much-debated question about whether *Actavis* should be strictly limited to settlements involving cash-payments, the opinion ultimately raises more questions than it answers. Both *King Drug* and *Actavis* create roadblocks to the structuring of settlements of patent disputes. Accordingly, the resolution of a substantial number of patent disputes may be subject to antitrust scrutiny, a result which may chill the voluntary resolution of such matters.

King Drug involved the drug Lamictal, which was produced by GlaxoSmithKline (GSK) to treat epilepsy and bipolar disorder. In 2002, Teva was the first company to file an abbreviated new drug application (ANDA) with the FDA to market the generic version of the drug – Lamotrigine. As required by the FDA, Teva's ANDA application alleged that GSK's patent on Lamictal was invalid or not infringed. To incentivize patent challenges like this, the Hatch-Waxman acts affords "first filers," such as Teva, a 180-day exclusivity period to market its generic drug if it succeeds in its invalidity claim. Soon thereafter, GSK sued Teva in federal court for infringing on its patent. After the parties tried the patent case in January 2005 in the United States District Court for the District of New Jersey before Judge John W. Bissell, Judge Bissell issued an opinion stating that GSK's main patent claim, for the invention of Lamotrigine, was invalid, and that it was "highly likely that Teva would prevail with respect to the remaining patent claims." In February 2005, however, before Judge Bissell could rule on the validity of GSK's remaining patent claims, GSK and Teva reached a settlement pursuant to which in return for Teva ending its challenge to the validity GSK's patent, GSK would allow Teva to market Lamotrigine by no later than June 1, 2005 – 37 months before GSK's patent was scheduled to expire on July 22, 2008. Moreover, GSK agreed to a no-AG agreement, pursuant to which it would not market its own authorized

generic version of Lamictal until after January 2009, when Teva's 180-day exclusivity period was set to expire. Judge Bissell approved this settlement.

In February 2012, however, direct purchasers of Lamictal from GSK filed the *King Drug* action, alleging that GSK and Teva's settlement violated the Sherman Antitrust Act. Although the district court dismissed the *King Drug* plaintiffs' antitrust action because it found that, *inter alia, Actavis* only applied to reverse payments of cash (as opposed to GSK and Teva's no-AG agreement), the Third Circuit reversed, holding that no-AG agreements should be subject to antitrust scrutiny under the full rule of reason framework adopted in *Actavis*. Specifically, the Third Circuit opined that any commitments like no-AG agreements, flowing from a patent holder to an alleged infringer can be considered "an unusual, unexplained reverse transfer of considerable value" that the Supreme Court in *Actavis* held was subject to a rule of reason analysis. The Third Circuit drew no distinction between *Actavis*-type reverse settlements consisting of cash payments and *King Drug*-type reverse settlements that do not involve the transfer of cash, *per se*, but are costly to the patent holder and may be of "great monetary value" to the alleged patent infringer. Additionally, the Third Circuit rejected the argument that a no-AG agreement is simply an exclusive license – something that is specifically permitted under patent law – and therefore was not "unusual" under the *Actavis* framework. The court reasoned that just because a patent holder may have the right to grant a license, that "does not mean it also has the right to give a challenger a license along with a promise not to produce an authorized generic—i.e., a promise not to compete—in order to induce the challenger" to drop its patent challenge.

Assuming that other courts agree with the Third Circuit's holding that *Actavis* is not strictly limited to ANDA settlements involving cash payments and no-AG agreements are distinguishable from the exclusive licenses that patent law expressly permits, *King Drug* raises a genuine question as to whether it is possible for parties to structure an ANDA settlement in such a way as to avoid antitrust scrutiny.

The practical implications of *King Drug*, both from a litigation and counseling standpoint, are disturbing. The underlying resolution between Teva and GSK was court-approved, and obviated the need for future trial court work and a presumably complex appeal. Any expansion of the antitrust scrutiny invited by *Actavis* is potentially problematic. Looking at the problem in the broadest sense, there is no way to settle an intellectual property dispute and agree that one party has the rights asserted under patent, copyright or trademark law without an argument of collusion being at least theoretically possible. As a matter of course, in all of these types of cases, the infringer was in competition with the owner. If the infringer now agrees that the owner has rights, and limitations are placed on the infringer by virtue of an agreed upon license, or other arrangement, such agreement, in a very real sense, limits competition. Such limitations on competition are imposed by intellectual property law in any event. If there are valid trademark rights, there cannot be unfettered competition. Therefore, to analyze any intellectual property dispute under an antitrust analysis can lead to an erosion of the law of intellectual property, and the protections granted to such a holder.

Antitrust law is often a litigant's wishing well. The rules are complex and fact intensive, particularly in rule of reason cases (which is how such claims are to be judged under *Actavis*), and can be expensive. There is a natural tension between intellectual property rights, which are legal monopolies, and antitrust law which seeks to erase and limit concentrations of economic power. There is serious danger in allowing third-party antitrust challenges to voluntary resolutions of intellectual property disputes. In our view, while we understand the rationale of *Actavis* concerning why a reverse payment settlement might be ripe for scrutiny, *King Drug* illustrates why *Actavis* places intellectual property disputes on a slippery slope. The resolution of many intellectual property

disputes now needs to be considered and vetted by antitrust counsel in addition to intellectual property counsel.

Traditional antitrust defenses, most specifically market definition and market power, will remain. However, given the uniqueness of many of the drugs (which is why these types of settlements are meaningful and valuable), it is difficult to imagine any early resolution of a pleaded antitrust matter that alleges a very specific "one product" market definition. If there were "reasonable substitutes," there is likely going to be a meaningful question over the very validity of the patent in the first place.

For the Courts to leave for the future some very meaningful questions about the intersection of two entirely disparate fields of legal inquiry, antitrust and intellectual property, is to potentially invite chaos and uncertainty. From a counseling standpoint, it will likely mean that many intellectual property disputes must be litigated to completion, and that counsel to settle those disputes must be done with only the most hesitation and trepidation. We certainly understand the goals the Supreme Court and Third Circuit were trying to advance, but they have done so at the expense of valid and well-recognized intellectual property precedent. Perhaps the Courts have created new business for lawyers, but they have sown much uncertainty for the business community in the process.◆

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