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Client Alert Commentary

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Supreme Court Denies Cert in Lamictal Pay-For-Delay Litigation

Third Circuit has previously ruled that non-cash payments to settle patent litigation may violate antitrust laws.

On November 7, 2016, the Supreme Court of the United States declined to hear the petition of GlaxoSmithKline LLC (GSK), Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals, USA (together, Teva) from the Third Circuit's ruling in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). As a result, the law in the Third Circuit is that non-cash payments made by the holder of a drug-patent to an infringer — to settle litigation over validity or infringement — may in some cases violate the antitrust laws.

Background: The District Court Proceedings

In around 2002, GSK introduced Lamictal, a breakthrough drug designed to treat epilepsy and bipolar disorder.[1] Later that year, Teva sought to produce generic versions of lamotrigine — the active ingredient in Lamictal — and, to that end, filed Abbreviated New Drug Applications (ANDAs) with the US Food and Drug Administration. As the first generic manufacturer to file an ANDA for lamotrigine, Teva would have been entitled to a 180-day period of exclusivity — during which it would have been the only generic manufacturer authorized to market the drug.[2] After Teva filed its ANDAs, GSK sued Teva for patent infringement, but when the court presiding over the patent litigation found the patent's main claim to be invalid, GSK and Teva agreed to settle the case.[3] As part of the settlement, GSK and Teva agreed that Teva would end its challenge to GSK's patent in exchange for early entry into the lamotrigine chewables market, and that, for a specified period, GSK would refrain from producing its own, "authorized generic" version of Lamictal tablets.[4] This latter part of the agreement is referred to as a "no authorized generic" agreement (or "no-AG agreement").

In 2012, a putative class of direct purchasers of Lamictal brought suit against GSK and Teva, contending that the no-AG agreement violated Sections 1 and 2 of the Sherman Act. The district court dismissed the complaint for failure to state a claim, and the plaintiffs appealed to the Third Circuit.[5] While the appeal was pending, the Supreme Court decided *FTC v. Actavis*, 133 S. Ct. 2223 (2013), which held that large, unexplained payments from the holder of a drug patent to settle patent litigation (a "reverse payment") "can sometimes violate the antitrust laws," and must be assessed under the rule of reason.[6] The Third Circuit remanded for further consideration in light of *Actavis*.[7] On remand, the district court again dismissed the Complaint, holding that "*Actavis* applies only to 'reverse payments' of money," and that the agreement would, in any event, "most likely" survive scrutiny under the rule of reason.[8]

The Third Circuit's Decision

On appeal, the Third Circuit once again vacated and remanded.[9] The court held that *Actavis* cannot "be limited to reverse payments of cash," and that "a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason."[10] In the court's view, a no-AG agreement could be of "great monetary value" to a generic challenger.[11] Using a no-AG agreement "to induce the generic to abandon the patent fight," the court explained, could have the same anticompetitive consequences as a monetary payment.[12]

The court rejected the argument — advanced by GSK and Teva — that no-AG agreements are immune from antitrust scrutiny "because they are in essence 'exclusive licenses'" authorized by the Patent Act.[13] In the court's view, the "right" that GSK and Teva were seeking was "not in fact a patentee's right to grant licenses, exclusive or otherwise," but rather "a right to use valuable licensing in such a way as to induce a patent challenger's delay," thereby eliminating competition.[14] Accordingly, the court held that the existence of a patent license does not immunize from antitrust scrutiny settlement agreements that are in substance "reverse payments to prevent generic competition."[15]

Finally, the court held that the complaint adequately pleaded a claim under the rule of reason, and remanded to the district court for reconsideration "under the traditional rule of reason, tailored, as necessary, to the circumstances of this case."[16] The court denied a subsequent request for rehearing en banc.[17]

The Supreme Court Proceedings

On February 19, 2016, GSK and Teva petitioned the Supreme Court for review of the Third Circuit's decision.[18] In their petition, they sought to distinguish their no-AG agreement from the "unusual" cash payment at issue in *Actavis*. In contrast to *Actavis*, they argued, there was no allegation of an "unusual" settlement here — only an allegation that "the patent holder granted the patent challenger a valuable exclusive license to market its product before the patent and its related exclusivities expired."[19] This type of licensing agreement, they explained, had been used routinely to settle patent disputes and, until recently, had not faced significant legal challenge.[20]

In the petitioners' view, the Third Circuit's decision had the potential to upend the established principle that "granting inventors the right to exclude competitors for a specified period is essential to encouraging innovation."[21] The petitioners warned of an avalanche of lawsuits by private plaintiffs and the FTC, "asking courts to scrutinize licensing agreements for potential antitrust liability."[22] And they urged a narrow reading of *Actavis*, one recognizing "a line between conduct that is authorized by patent law even though it might restrict competition in the near term . . . which is not subject to antitrust challenge . . . and the alleged unusual reverse payments at issue" in *Actavis*.[23] Finally, the petitioners stressed the need for guidance on the scope of *Actavis*, given "the confusion that has permeated the lower courts faced with interpreting" the decision.[24]

Pharmaceutical manufacturers and industry associations filed numerous amicus briefs in support of the petition, echoing the arguments advanced by the petitioners.

In its response brief, King Drug Company of Florence Inc. (King) cast the question presented as whether "a reverse payment must be in cash" in order to fall foul of *Actavis*.[25] In King's view, the interpretation the petitioners offered would allow a patent-holder to circumvent *Actavis* so long as the patent-holder's settlement payment was made in non-monetary form — here, a promise by the patent-holder "not to market its own less expensive 'authorized generic' product in competition with the challenger's generic product."[26] Arguing against review, King pointed to the absence of a circuit split on the question

presented (given the novelty of the holding in *Actavis*, the issue had only just begun to percolate at the district court level, and aside from the Third Circuit, only one other court of appeal, the First Circuit, had addressed it).[27] In addition, King argued, even if the question presented "might warrant review by this Court at some point," this case was "an especially poor vehicle for addressing it" because the alleged "exclusive license" in question was due to begin one day before the patent was scheduled to expire. As a result, the settlement's alleged benefit to the patent challenger "was not an assignment of a right in the patent but instead a purported waiver of 'pediatric exclusivity,' a regulatory benefit arising from a special statutory provision with its own distinct text and purposes."[28]

On June 6, 2016, the Supreme Court invited the Solicitor General to submit a brief expressing the views of the United States.[29] The Acting Solicitor General submitted an amicus brief on October 3, supporting the position of the respondents and recommending that the Court deny the petition.[30] In the view of the United States, agreements of the kind at issue were on the same footing as the payment in *Actavis*: they warrant antitrust scrutiny because they raise a "concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement" by "inducing the generic challenger to abandon its claim with a share of the monopoly profits that would otherwise be lost in the competitive market."[31] That concern would be the same whether the manufacturer chooses to "share its profits in cash, or instead through some non-cash consideration."[32] Accordingly, the United States argued, there is no basis for limiting the rule in *Actavis* to monetary payments.

The United States also rejected the argument that a reverse-payment settlement involving a no-AG agreement is immune from antitrust scrutiny because no-AG agreements are "exclusive licenses" that are "expressly authorized by the Patent Act."[33] In the view of the United States, this argument was misplaced for two reasons. First, because GSK's promise not to launch an authorized generic would extend six months after the expiration of its patent, that promise could not plausibly be characterized as a "patent license."[34] Second, as the Third Circuit held, even a no-AG agreement that falls entirely within the patent term will not be immune from antitrust scrutiny because "[t]he anticompetitive consequences of such agreements may be as harmful as those resulting from reverse payments of cash."[35] Like the respondents, the United States also emphasized the absence of a circuit split on the issue presented,[36] and questioned the suitability of the case as a vehicle for deciding the issue.[37]

On November 7, the Court denied the petition[38] without stating the reasons for its decision (as is customary).

Conclusions

The Supreme Court's denial of certiorari has no precedential effect, and little can be gleaned from the Supreme Court's denial of review here: the decision was likely premised on the novelty of the issue presented, and the difficulty with using this case as a vehicle for deciding it, rather than any substantive view of the merits. But for now, one can safely assume that the holding in *Actavis* will be extended beyond cash payments, and may include a range of other valuable consideration offered by a patent-holder to an infringer to limit competition. Although the district court concluded that *Actavis* does not extend beyond cash payments, not even the petitioners pressed that argument before the Supreme Court, and the argument is unlikely to be a fruitful basis for challenge going forward. What appears to matter — in the opinion of both the Third Circuit and the United States — is not the form of the consideration offered, but rather, whether the patent holder is offering a right of significant "value" in exchange for an agreement not to compete (in the drug-patent context, an agreement to delay entry of a generic). In the words of the United States, the "risk of serious anticompetitive harms[] is the same whether the manufacturer agrees to share its profits in cash or instead through some non-cash consideration, such as stock, real property, product inventory, or (as here) a reciprocal agreement not to

compete."[39] District courts will now need to identify those non-cash settlements that escape antitrust scrutiny, and — perhaps more significantly — those that survive antitrust scrutiny. And for the time being, the courts will need to do that work unassisted, without further guidance from the Supreme Court.

There is considerable tension between the principle the petitioners favor — that "granting inventors the right to exclude competitors for a specified period" is a necessary exception to "the general rule against monopolies"[40] — and the broad view the United States and Third Circuit favor — that even a no-AG agreement falling "entirely within the patent term would not be immune from antitrust scrutiny."[41] Courts will continue to consider the relationship between these principles; as of October, only one other court of appeals, the First Circuit, had considered whether *Actavis* extends beyond cash payments (as in the Third Circuit, the conclusion was that it does).[42] But the breadth of the reading favored by the United States likely indicates that the FTC — which submitted an amicus brief raising many of the same arguments in the proceedings below — intends to pursue an aggressive interpretation of *Actavis* in the patent-settlement context. Private plaintiffs will likely follow the same course.

Whether the holding will hinder the settlement of patent litigation going forward is open to question. Although no-AG agreements have been used with frequency in the patent-settlement context, data that the United States cited in its amicus brief suggests that the number of no-AG commitments fell significantly in 2013 and 2014 — after *Actavis* was decided — without a corresponding decline in the number of patent settlements. (According to the United States, the 160 settlements recorded in 2014 is the largest number on record.[43]) Putting aside the deterrent effect of threatened litigation, there is nothing to suggest that agreements of this kind are a dead letter under the Third Circuit's ruling; as the court emphasized, they are not *per se* violations of the antitrust laws.[44] But what is clear is that parties entering into such agreements as part of a patent settlement should be prepared to advance compelling business rationales that outweigh any anti-competitive effects perceived to flow from the delayed entry of competing generics.

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Endnotes

[1] *See Lamictal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action (In re Lamictal Direct Purchaser Antitrust Litig.)*, 18 F. Supp. 3d 560, 561 (D.N.J. Jan. 24, 2014).

[2] *Id*.

[3] *Id*.

[4] *Id*.

[5] *In re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580 (D.N.J., Dec. 6, 2012).

[6] *Id*. at 2227.

[7] *See Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. at 563.

[8] *Id.* at 566, 567.

[9] *King Drug Co. of Florence*, 791 F.3d at 413.

[10] *Id*. at 403.

[11] *Id*. at 404.

[12] *Id*. at 405.

[13] *See id*. at 406-7.

[14] *Id*.

[15] *Id*. at 407.

[16] *Id*. at 413.

[17] *SmithKline Beecham Corp. v. King Drug Co. of Florence*, No. 14-1243 (3d Cir. Sept. 23, 2015).

[18] *See SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.*, 791 F.3d 388 (3d Cir. 2015), petition for cert. filed 2016 WL 704916 (U.S. Feb. 19, 2016) (No. 15-1055).

[19] Brief for Petitioner ("Pet. Br.") at 2, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.* (No. 15-1055), 2016 WL 704916 (U.S. Feb. 19, 2016).

[20] *Id*.

[21] *Id*. at 1.

[22] *Id*. at 2.

[23] *Id*. at 3.

[24] *Id*.

[25] Brief for Respondent ("Resp. Br.") at 1, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.* (No. 15-1055), 2016 WL 1745527 (U.S. May 2, 2016).

[26] Resp. Br. at 1.

[27] Resp. Br. at 1.

[28] Resp. Br. at 2.

[29] *SmithKline Beecham Corp. v. King Drug Co. of Florence*, 136 S. Ct. 2428 (2016).

[30] *See* Brief of the United States as Amicus Curiae (U.S. Br.), *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.* (No. 15-1055), 2016 WL 5765167 (U.S. Oct. 3, 2016).

[31] *Id*. at 10-11 (internal quotation and alterations omitted).

[32] *Id*. at 11.

[33] *Id*. at 11-12.

[34] *Id*. at 12.

[35] *Id*. at 15 (internal quotation omitted); *see also id.* at 7.

[36] U.S. Br. at 8-9, 14-15.

[37] *Id*. at 20-21.

[38] *SmithKline Beecham Corp. v. King Drug Co. of Florence*, No. 15-1055, 2016 WL 696150 (U.S. Nov. 7, 2016).

[39] U.S. Br. at 11.

[40] Pet. Br. at 1.

[41] U.S. Br. at 12.

[42] *See Loestrin 24 Fe Antitrust Litig., In re,* 814 F.3d 538 (1st Cir. 2016) (cited in U.S. Br. at 20).

[43] *See* U.S. Br. at 19.

[44] *See King Drug Co. of Florence,* 791 F.3d at 404.