WHY THE SUPREME COURT SHOULD DENY CERTIORARI IN *KING DRUG*

By Michael A. Carrier [1]

I. INTRODUCTION

In its 2013 decision in *FTC v. Actavis*, the U.S. Supreme Court held that agreements by which brand-name drug companies pay generic firms to settle patent litigation and delay entering the market could have "significant adverse effects on competition" and violate antitrust laws.[2] Since the decision, courts have wrestled with various issues. The question that has received the most attention is whether "payment" is limited to cash or encompasses non-cash forms of consideration.

The courts, including the Third Circuit in *SmithKline Beecham Corp. v. King Drug Co. of Florence* ("*King Drug*"), have uniformly held that payment includes non-cash transfers. Such a ruling is consistent with antitrust law's emphasis on substance over form and ensures that the settling parties, merely by adopting certain forms of anticompetitive settlements, cannot evade antitrust scrutiny.

Despite this uniformity, GlaxoSmithKline ("GSK") and Teva, the settling parties in *King Drug*, sought Supreme Court review of the Third Circuit's decision. The Supreme Court is currently considering this petition, and has requested the views of the Solicitor General,

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[2] 133 S. Ct. 2223, 2229, 2231 (2013).

indicating its serious consideration.

This article, which builds on a letter submitted to the Solicitor General on behalf of 61 professors, first summarizes the Third Circuit decision in *King Drug*. It next presents the argument of the petitioners. And it then offers four reasons why the Court should not grant certiorari: (1) drug patent settlements are not immune from antitrust scrutiny, (2) the arrangement at issue can induce delayed generic entry, (3) this is not an exclusive license, and (4) there is no circuit split or difficult issue presented.

II. *KING DRUG*

The Third Circuit in *King Drug* considered an agreement by which brand firm GSK promised not to market an "authorized generic" version of epilepsy- and bipolar-disorder-treating Lamictal that would have competed with the version offered by generic firm Teva.[3] Authorized generics ("AGs") are approved by the FDA as brand drugs but marketed as generics.[4] The significance of AGs is demonstrated by the Hatch-Waxman Act,[5] which governs competition in the pharmaceutical industry.

A central feature of the Act is a 180-day period of marketing exclusivity for the first generic to file a "Paragraph IV" certification claiming the brand's patent is invalid or will not be infringed by the generic.[6] During this period, the FDA cannot approve other generic applications for the brand drug.[7] Despite this prohibition, AGs can be introduced during the 180-day period.[8]

The introduction of an AG during the 180-day period has a significant effect on first-filing generics, which, on average, lose 25 percent of their market share and suffer revenue reductions of 40 percent to 52 percent.[9] First-filing generics often make the majority of their profits — potentially "several hundred million dollars" — during the period.[10] For that reason, settlements by which brands promise that they will not enter the market during a first-filing generic's 180-day period can be very valuable.

In *King Drug*, the Third Circuit recognized the significant competitive effects of settlements with no-AG promises. It stated that "no-AG agreements are likely to present the same types of problems as reverse payments of cash."[11] And it recognized that a no-AG

[3] *King Drug*, 791 F.3d 388, 397 (3d Cir. 2015).
[4] FEDERAL TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT 1 (2009).
[5] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified as amended at 21 U.S.C. §355 (2015).
[6] 21 U.S.C. § 355(j)(5)(B)(iv); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[7] See generally Michael A. Carrier, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, 67 RUTGERS U.L. REV. 697, 698-99 (2015).
[8] *Mylan Pharms. v. FDA*, 2005 WL 2411674 (N.D.W. Va. Sept. 29, 2005); *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).
[9] FEDERAL TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 57-59 (2009).
[10] *Actavis*, 133 S. Ct. at 2231.
[11] *King Drug*, 791 F.3d at 405.

agreement "may be of great monetary value to . . . the first-filing generic."[12]

The Third Circuit also tied the anticompetitive effects of no-AG agreements to the Supreme Court's concerns in *Actavis*, recognizing that "[i]f the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market)."[13] As a result, "a brand agreeing not to produce an authorized generic may thereby have 'avoid[ed] the risk of patent invalidation or a finding of noninfringement.'"[14] The Third Circuit also did not "believe the Court intended to draw . . . a formal line" between cash and non-cash transfers or "limit its reasoning or holding to cash payments only."[15]

Finally, the *King Drug* court rejected the argument offered by the settling parties that a no-AG agreement merely constituted an "exclusive license" authorized by the patent laws. It explained that "the 'right' defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise," but "[i]nstead . . . is a right to use valuable licensing in such a way to induce a patent challenger's delay," which was "rejected" by *Actavis*.[16] Just because "the Patent Act expressly authorizes licensing does not necessarily mean it also authorizes reverse payments to prevent generic competition."[17] "[E]ven exclusive licenses," the court concluded, "cannot avoid antitrust scrutiny where they are used in anticompetitive ways."[18]

III. PETITION FOR CERTIORARI

Seeking to overturn the Third Circuit's *King Drug* decision, GSK and Teva filed a petition for certiorari. They raised three arguments.

First, they pointed to "disagreement and confusion among the lower courts about the breadth and meaning of *Actavis*."[19] The petitioners sought "[g]uidance . . . so that the lower courts, which routinely confront antitrust challenges to patent litigation settlements, do not further confuse the law."[20]

Second, they lamented that the *King Drug* ruling "strikes at the heart of patent law."[21] The Third Circuit asked if "a patentee is potentially using its patent rights in an anticompetitive manner," but "that is the very right granted to the patentee."[22] "[A]n indispensable part of that right," according to the petitioners, is "the ability to grant licenses, including those with exclusivity terms."[23] This case differed from *Actavis* since the agreement "merely reflected an

[12] Id.
[13] Id.
[14] Id. (citing *Actavis*, 133 S. Ct. at 2236).
[15] Id. at 405-06.
[16] Id. at 406-07.
[17] Id. at 407.
[18] Id.
[19] Petition for a Writ of Certiorari, *SmithKline Beecham Corp. v. King Drug Co. of Florence*, No. 15-1055, at 13 (U.S. filed Feb. 19, 2016).
[20] Id. at 15.
[21] Id. at 13.
[22] Id. (emphasis omitted).
[23] Id. at 14.

exercise of the patentee's express statutorily-granted right to grant an exclusive license."[24]

Third, petitioners worried that the Third Circuit's decision "will inflict immediate and far-reaching harm."[25] The opinion "calls into question the continued viability of any patent litigation settlement, as well as routine licensing agreements that are a critical part of the American economy across all industries."[26] Even worse, this "new *de facto* national regime" will mean that "parties to patent litigation will . . . settle their cases only at their own peril."[27]

In short, "[t]he opportunity is . . . ripe to grant review in order to resolve the confusion among the lower courts, to prevent the chilling of beneficial patent settlements and licensing arrangements, and to restore patent policy to its proper place."[28]

IV. REASON 1: NO IMMUNITY

There are at least four reasons why the Court should not grant certiorari in *King Drug*. First, the Court in *Actavis* made clear that drug patent settlements are not immune from antitrust scrutiny. The Court stated that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' — and consequently antitrust law immunity — that is conferred by a patent."[29] As it demonstrated in citing numerous of its precedents, "patent-related settlement agreements can sometimes violate the antitrust laws."[30] For that reason, "the Court has struck down overtly restrictive patent licensing agreements — irrespective of whether those agreements produced supra-patent-permitted revenues."[31]

It thus should not be a surprise that the lower courts have appropriately recognized that settling parties "cannot shield themselves with the argument that patent licenses are common and authorized, if such licenses disguise unlawful reverse payments;"[32] that "formally classifying an agreement a 'license' ought not halt further inquiry into the actual nature of the underlying arrangement;"[33] and that exclusive licenses "can be worth money, and granting them can thus be the equivalent of transferring money," which is why "[t]he issue is not whether the *form* of the payment was legal, but whether the *purpose* of the payment was legal."[34]

Frankly, it does not matter that the Patent Act "expressly authorize[s]"[35] licensing, as the *Actavis* Court focused not on what a patent holder could do under the Patent Act but on whether the brand firm "seeks to induce the generic challenger to abandon its claim" and makes a payment that "seeks to prevent the risk of competition."[36] Nor is it persuasive to

[24] Id.
[25] Id.
[26] Id.
[27] Id.
[28] Id. at 14-15.
[29] *Actavis*, at 2231.
[30] Id. at 2232.
[31] Id.
[32] *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 265 (D. Mass. 2014).
[33] Id.
[34] *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015).
[35] Petition, at 4.
[36] *Actavis*, at 2235, 2236.

ignore, as petitioners did, (1) the actual right at issue: one to "pa[y] a competitor to respect its patent," and (2) the policy the *Actavis* majority invoked to reject inquiry based on the patent statute: one of "eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"[37]

In fact, any effort to distinguish the "routine" arrangement at issue from the "unusual" arrangement in *Actavis* falls apart under the slightest scrutiny.[38] The *Actavis* Court's reference to an "unusual" arrangement, responding to the FTC's allegation that (1) "in substance," (2) the plaintiff paid "many millions of dollars to stay out of its market," (3) "even though the defendants did not have any claim that the plaintiff was liable to them for damages,"[39] easily applies to the settlement here. For (1) the Court's reference to "substance" by definition reaches beyond one particular form of settlement, (2) the no-AG agreement at issue here was alleged to be "worth hundreds of millions of dollars,"[40] and (3) there is no claim that the generic in this case is liable for damages. Put differently, in substance, the generic here, with "no claim for damages . . . walks away with money simply so it will stay away from the patentee's market" rather than receiving a sum "equal to or less than the value of its claim."[41]

Nor does the application of antitrust law result in a rejection of innovation or patents, let alone the overstated, sky-is-falling threats of a "new *de facto* national regime" or the end of licenses "that are a critical part of the American economy."[42] Instead, it is the natural consequence of the rejection of the "scope of the patent" test, by which courts had immunized settlements and assumed that every challenged patent was valid and infringed. Even if the grant of a license is more competitive than the absence of a license, that is not an appropriate comparison after *Actavis*.[43]

V. REASON 2: ENTRY-DELAYING AGREEMENTS

The second reason the Court should deny certiorari is that arrangements like the one at issue here can induce delayed entry by providing significant consideration to a generic.[44] No-AG promises are immensely valuable, potentially worth "several hundred million dollars,"[45] as a first-filing generic that eludes competition with an authorized generic avoids market share losses and significant revenue reductions.[46] When "the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would

[37] Id. at 2233.
[38] Petition, at 11, 14.
[39] *Actavis*, at 2231.
[40] Brief in Opposition, *SmithKline Beecham Corp. v. King Drug Co. of Florence*, No. 15-1055, at 6 (U.S. filed May 2, 2016).
[41] *Actavis*, at 2233.
[42] Petition, at 14. The significant value of no-AG promises to first-filing generics also casts doubt on the "innovation" argument. See *Mannington Mills v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1071 (3d Cir. 1979) (explaining that licenses resulting primarily in benefits for the licensee "cannot be justified as a subsidy for the patentee's inventive activity").
[43] See *Aggrenox*, at 245.
[44] See, e.g. Complaint, *FTC v. Endo Pharms. Inc.*, Case 2:16-cv-01440-PD (E.D. Pa. filed Mar. 30, 2016).
[45] *Actavis*, at 2231.
[46] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 58-59 (2011).

have otherwise accepted," during which time "the brand's monopoly remains in force."[47] And presenting even more concern than cash payments, "[o]nce the generic enters, . . . it faces no competition with other generics at all."[48]

Not only is the generic encouraged to delay its entry from the bestowal of millions for doing nothing other than agreeing not to compete but also it is receiving something it could not obtain from successful patent litigation. When a generic receives a type of consideration it could not have obtained even if it had shown that the patent was invalid or not infringed, that rings alarm bells that the exclusion from the market is based on the payment, not the patent.[49] A generic winning patent litigation would be able to enter the market; it would not be able to receive an *additional* guarantee that the patent holder would not introduce a s*eparate* product not at issue in the litigation.

VI. REASON 3: NO EXCLUSIVE LICENSE

Third, the arrangement at issue is not even an exclusive license. As the antitrust agencies' IP licensing guidelines make clear, an exclusive license "precludes all other persons, including the licensor, from using the licensed intellectual property."[50] In this case, in contrast, even if GSK promises not to introduce its own generic, it is still able to sell the branded version of Lamictal. Such an arrangement provides a brand firm "with the kind of economic self-protection that . . . warrants suspicion."[51]

In addition to not being *exclusive*, the arrangement is not a typical *license* given that there is no agreement to currently enter production. As the leading antitrust treatise explains, "[u]ntil generic production commences . . . the agreement is simply a horizontal market division."[52] In fact, no-AG agreements "appear not to constitute a 'license' at all."[53]

Nor, to state the obvious, is a no-AG arrangement an "early entry" settlement that merely allows entry before the end of the patent term. Such benign agreements do not involve consideration beyond the strength of the patent, such as a brand offering on a silver platter a "180-day monopoly over the generic market."[54] As the Third Circuit has recognized, "a no-AG agreement is no more solely an early-entry licensing agreement than the settlement in *Actavis*

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[47] *King Drug*, at 405; see also *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014); Motion for Permanent Injunction, *In re Nexium (Esomeprazole) Antitrust Litig.*, Case 1:12-md-02409-WGY, Ex. D (D. Mass. Jan. 7, 2015) (AstraZeneca counsel conceded that generic "will want a settlement that . . . guarantees [] exclusivity against authorized generic competition," and as a result "may be willing to agree to a relatively late entry date").

[48] *King Drug*, at 405.

[49] See Reply Brief for the Petitioner, *FTC v. Actavis*, No. 12-416, at 11 (U.S. filed Mar. 2013) (reverse-payment settlements "give the generic manufacturer an economic benefit that it could not obtain even by winning the lawsuit"); Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 9 (2014) (articulating test based on whether "the brand conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit").

[50] U.S. DEP'T OF JUSTICE AND FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY ¶ 5.7 (1995).

[51] *Nexium*, 42 F. Supp. 3d at 265.

[52] AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 2046d6 (2015 Supp.).

[53] Id.

[54] *King Drug*, at 408.

itself, where entry was permitted 65 months before patent expiration."[55] The Third Circuit reasonably concluded that "the antitrust problem was that . . . entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered."[56]

VII. REASON 4: NO CIRCUIT SPLIT OR DIFFICULT ISSUE

Fourth, there is no issue worthy of certiorari. For starters, there is no circuit split. In fact, with the two district courts that had adopted a constricted view limiting payment to cash now overruled, all twelve courts to consider the issue have unremarkably found that payment includes non-cash forms of consideration.[57]

In addition, not a single court has adopted petitioners' argument that arrangements like this one are exclusive licenses immune from antitrust liability. The Third Circuit in *King Drug* most fully considered this argument before unambiguously, and correctly, rejecting it. The court understood that "[t]he 'right' defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise, [but] [i]nstead . . . a right to use valuable licensing in such a way as to induce a patent challenger's delay," which "[t]he *Actavis* Court rejected."[58] Just because a patent holder "may generally have the right to grant licenses, exclusive or otherwise, 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 respect its patent and quit [the competitor's] patent invalidity or noninfringement claim without any antitrust scrutiny.'"[59]

Finally, there is no difficult question here. The facts and language of *Actavis*, value of the no-AG clause to the generic, brand profits from authorized generics, preference in antitrust law for substance over form, provision of more than the generic could have received in patent litigation, and presence of market division (as the generic agrees to delay entry and the brand agrees not to introduce a generic version) make the question of whether valuable no-AG promises are subject to antitrust scrutiny the easiest of the post-*Actavis* issues.[60] Petitioners' arguments are merely a version of the scope-of-the-patent test soundly rejected in *Actavis*.

VIII. CONCLUSION

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[55] Id.
[56] Id.
[57] *King Drug*, at 403-06; *In re Loestrin Antitrust Litig.*, 814 F.3d 538, 549-50 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 2016 WL 521005, at *7 (N.D. Ill. Feb. 10, 2016); *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015); *Aggrenox*, at 242-43; *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (Lidoderm)*, 74 F. Supp. 3d 1052, 1069-70 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca*, 2014 WL 4933025, at *3 (E.D. Pa. Oct. 1, 2014); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 542 (D.N.J. 2014); *Niaspan*, 42 F. Supp. 3d at 751; *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-02431, slip op. at 4 (E.D. Pa. Jan. 17, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).
[58] *King Drug*, at 407.
[59] Id. (citing *Actavis*, 133 S. Ct. at 2233).
[60] Carrier, *Eight Reasons*, at 706-20.

Among the complex issues courts have considered after *Actavis*, the question of whether payment is restricted to cash (and, relatedly, whether an "exclusive license" is immune from antitrust scrutiny) is easy. Rather than opening a completely avoidable can of worms that could lead to mischief by which drug companies disguise anticompetitive settlements in unwitting court-blessed packages, the Court should deny certiorari in *King Drug*.