S198616

IN THE SUPREME COURT OF CALIFORNIA

Coordination Proceeding Special Title (Rule 1550(b)):

CIPRO CASES I & II

Judicial Council Coordination Proceeding Nos. 4154 & 4220

After a Decision by the Court of Appeal,
Fourth Appellate District, Division One

SUPPLEMENTAL REPLY LETTER BRIEF OF APPELLANTS ADDRESSING THE RELEVANCE OF *FTC V. ACTAVIS, INC.*

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I. SUMMARY OF REPLY

FTC v. Actavis, Inc. (2013) 570 U.S. __ [133 S.Ct. 2223], rejected the "scope of the patent" test and held that a payment delaying the risk of competition is anticompetitive. These holdings destroy the foundation of the lower court opinions in this action and mandate reversal. Further, *Actavis* supports adoption of a standard under which the Generic Respondents have no prospect for success given the facts of this case. The $398.1 million payment they received cannot be understood as buying anything other than their agreement to drop their patent challenge and delay the risk of generic competition. Such conduct is, according to *Actavis*, an antitrust violation.

The Generics resist this stark reality in two ways. First, they pretend that the U.S. Supreme Court embraced the conclusions of the lower courts here, when in fact it repudiated them. The Generics' argument conflates two very different versions of the rule of reason. The version adopted in *Actavis* constrains the permissible justifications for reverse payments. The version adopted by the lower courts below, in contrast, is in essence a rule of *per se* legality and would permit virtually any justification for a settlement that purports to remain within the scope of the patent. The Generics ignore this crucial distinction and the reasoning in *Actavis* generally.

No doubt sensing the weakness of this first argument, the Generics alternatively ask this Court to remand without giving the lower courts any guidance. Never mind that the Generics already made this request in a motion this Court denied. (See Section VII, *infra.*) Never mind that the Generics fail to identify any specific reason the record needs further development before the applicable legal standard could or should be clarified. The Generics would like the opportunity to reassert in the lower

courts all of the positions they now assert, without this Court's guidance on how they should be resolved.

Although the Generics prefer uncertainty and confusion, Appellants respectfully submit that the issue of reverse payments' illegality is ripe for decision, especially in light of *Actavis*. This case alone has been pending for over a decade. The litigants and the lower courts would benefit from a clarification of California antitrust law, and the clarification should be that a payment to delay the risk of competition violates California law.

II. THE GENERICS IGNORE THE HOLDINGS OF *ACTAVIS*

The Generics strain credulity with the following syllogism: *Actavis* said the rule of reason applies to reverse payments; the Court of Appeal below applied the rule of reason; therefore, under *Actavis*, the lower court rulings should be affirmed. The glaring flaw in this syllogism is that it ignores *how* each court applied the rule of reason. The legal standard of *Actavis* is diametrically opposed to the standard the lower courts applied in this case. *Actavis* endorsed a stringent standard that renders many reverse payments illegal, whereas the courts below adopted a toothless standard that would immunize almost all of them.[1]

If the Generics were right, *Actavis* would have affirmed rather than reversed the decision on appeal there. After all, the lower courts in *Actavis* applied the same version of the rule of reason—the "scope of the patent" test, 133 S.Ct. at p. 2227—as the lower courts did here, and according to the Generics, so did *Actavis* itself. But the Supreme Court did not affirm; it reversed. (*Id.* at p. 2238.) So should this Court.

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[1] (See Generics Letter Br. at p. 9 [conceding that *Actavis* may "warrant[] a more fulsome Rule of Reason analysis" than was applied below].)

The Generics' Letter Brief says remarkably little about the reasoning of *Actavis* and its implications for how courts should analyze a reverse payment. It is as if the Supreme Court concluded that the rule of reason applies without any elaboration. However, as the Court's opinion makes clear—and as respected commentators have confirmed—*Actavis* did much more. (See, e.g., Edlin, Hemphill, Hovenkamp, and Shapiro, *Activating Actavis* (2013) vol. 28, No. 1, Antitrust 16.) *Actavis* recognized only two potential justifications for reverse payments—avoided litigation costs and a fair exchange for goods or services. (*Actavis, supra*, 133 S.Ct. at p. 2236.) Significantly, *Actavis* also held that the size of a reverse payment can supply evidence of both an antitrust violation and market power. (*Ibid.*) And the anticompetitive harm *Actavis* identified is avoidance of the *risk* of competition, the determination of which normally makes it unnecessary to assess the strength of the patent in question. (*Ibid.*) The Generics fail to grapple with any of these holdings.

They are, therefore, wrong to suggest *Actavis* applies the rule of reason *simpliciter*. Instead, *Actavis* placed severe constraints on the analysis that render many reverse payments illegal. The courts below, in contrast, held that virtually any settlement within the formal scope of a patent is automatically legal.

III. THE GENERICS MISCHARACTERIZE THE PAST PROCEEDINGS

The Generics succumb to wishful thinking when they claim that *Actavis* confirms the courts' rulings below. (Generics Letter Br. at pp. 4–5.) *Actavis* rejects the "near-automatic antitrust immunity" the lower courts applied. (*Actavis, supra*, 133 S.Ct. at pp. 2233, 2237 [disagreeing that "a patent holder may simply pay a competitor to respect its patent . . . without any antitrust scrutiny whatever."], internal quotation and alteration marks

omitted.) Because the Generics can find no support for their arguments in the text of the decision, they reinterpret the opinions below in line with *Actavis*, claiming the trial court and the Fourth District Court of Appeal applied a traditional rule of reason analysis. Yet the lower courts based their reasoning upon the very "scope of the patent test" *Actavis* repudiated.

To the extent the lower courts purported to apply the rule of reason, they applied a rule coterminous with the "scope of the patent" test. The Superior Court began and ended its inquiry with the boundaries of the '444 patent, stating that the key issue was "whether the agreement fell within the scope of the patent, because if it does, there is no antitrust violation." (Super. Ct. Order at p. 6, 11AA 2687.) The court rejected the evidence of anticompetitive effects—e.g., payment size and price increases—as being "within the rights of the patent holder" or "not relevant to the antitrust analysis." (*Ibid.*) In doing so, the trial court immunized the Cipro agreements on the grounds that "there are no anticompetitive effects on competition beyond the exclusionary scope of the patent itself." (*Ibid.*) Affirming this reasoning, the Court of Appeal held that where "the settlement restrains competition only within the scope of the patent," it is not unlawful because "an agreement is not unlawful under California and federal antitrust law if it restrains competition only within the exclusionary scope . . . ." (*In re Cipro Cases I & II* (2011) 200 Cal.App.4th 442, 449, 467.) The Court of Appeal therefore "conclude[d] that because the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the '444 patent, they do not violate the Cartwright Act." (*Id.* at p. 470.) Thus, the lower courts expressly applied the "scope of the patent" test, following the lower federal courts that permitted a drug company to engage in any type of malignant conduct so long as it claims a valid patent and the conduct does not purport to extend the patent's scope.

(*Id.* at pp. 457–466 [citing, *inter alia*, *In re Tamoxifen Citrate Antitrust Litig.* (2d Cir. 2006) 466 F.3d 187]; Super. Ct. Order at pp. 3–4, 11AA 2684–85 [same; "[f]ederal case law is not only instructive . . . it is dispositive."].)[2]

Actavis has required the Generics to reverse themselves. Previously, they defended the opinions below as having applied a rule of reason coterminous with the "scope of the patent" test. According to the Generics' Answer Brief, the lower courts held that Appellants "could not establish the first step of the Rule of Reason—showing an actual adverse effect on competition—because the settlement restrained no more competition than the exclusionary potential of the Cipro patent itself." (Generics Answer Br. at p. 15, citing Ct. App. slip op. at pp. 33–34; Super. Ct. Order at p. 10, 11AA 2691.) The Generics reiterated that Appellants consequently could not show an "actual adverse effect on competition" under the rule of reason "because the Cipro settlement limited no more competition than the patent already limited." (Generics Answer Br. at p. 17.)

The Generics are now speaking out of the other side of their mouths. Having previously equated the rule of reason in this context with a "scope of the patent" understanding of anticompetitive effects, they now suggest the Court might view the two standards as distinct. (Generics Letter Br. at pp. 4–5.) But the rule applied below no longer holds sway, and the rule of reason that replaced it for federal claims rejects an immunity based on patent scope. (*Actavis, supra*, 133 S.Ct. at p. 2231.)

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[2] The lower courts also misapplied existing California case law. (See Appellants' Reply Br. at pp. 9–11 & fn. 5 [discussing, *inter alia*, *Vulcan Powder Co. v. Hercules Powder Co.* (1892) 96 Cal. 510, and *Fruit Machinery Co. v. F. M. Ball & Co.* (1953) 118 Cal.App.2d 748].)

IV. THE CIPRO AGREEMENTS LACK ANY PROCOMPETITIVE JUSTIFICATION

The "unjustified anticompetitive harm" on display in this factual record resulted from agreements by which Bayer shared "monopoly profits to avoid the risk of patent invalidation . . . ." (*Actavis, supra*, 133 S.Ct. at p. 2236.) The Generics, however, mischaracterize the record with the claim that "far from preventing competition, the Cipro settlement was *pro*-competitive." (Generics Letter Br. at p. 6.) There was nothing procompetitive about this pay-for-delay agreement. The record shows Bayer paid Barr nearly $400 million, for no purpose other than delay. The settlement injured consumers and other purchasers such as the insurance companies in this certified class by denying them a competitive Cipro market and imposing high monopoly prices for years. These harmful effects were not offset by any of the exceptions to antitrust condemnation *Actavis* identified.

Bayer's $398.1 million cash agreement with the Generics evidences none of the "traditional settlement considerations, such as avoided litigation costs or fair value for services," that the Supreme Court stated might be "legitimate justifications" for such an agreement. (*Actavis, supra*, 133 S.Ct. at pp. 2235–2236.) The Generics make no attempt to address this part of the Court's analysis—nor could they. Their cash settlement vastly exceeded Bayer's remaining litigation costs in defending its patent from Barr's challenge, and the Generics have no plausible claim that the payment provided fair value for services rendered by them on Bayer's behalf. Simply put, the Generics do not and cannot show that the reverse payment covered costs or services.

The Generics still refuse to acknowledge the Cipro agreements' negative effects on consumers, who had to pay much higher prescription drug prices if they could afford their medicine at all. (See Appellants'

Opening Br. at p. 28.) The evidence shows that because of the Cipro settlement, prices went up for seven consecutive years. Before this settlement, Bayer's annual rates of price increases on the three major Cipro dosages were 4.56%, 4.85%, and 4.33%, but in the seven years that followed the settlement—and because of it—Bayer accelerated price increases at annual rates of 10.53%, 11.66%, and *74.83%*. (6AA 1208.) Absent the Cipro agreements, consumers would have paid only $1.10 per generic pill; under the improperly fortified monopoly, consumers paid upwards of $5.30 for the same dose. (5AA 1093.)

It is nonsense for the Generics to assert a procompetitive effect from Barr's entry six months before the patent expired. (Compare Generics Letter Br. at p. 3, with Appellants' Letter Br. at p. 12, fn. 10.) Under the limited license that permitted Barr to market and sell Bayer-manufactured Cipro, Barr was required to purchase the drug from Bayer at 85% of its current price—which Barr then re-sold at prices that equaled or *exceeded* Bayer's prices. (5AA 999, 1037; 6AA 1207–08.) Consumers in no way benefited from this arrangement. Bayer and the Generics alone profited.

V. THE GENERICS FAIL TO DISTINGUISH *ACTAVIS*

Having failed to establish that *Actavis* supports the decisions below, the Generics next argue *Actavis* is inapposite. (Generics Letter Br. at pp. 7–8.) Yet their effort to distinguish the case is no more successful than their argument that *Actavis* dictates affirmance of the decisions on appeal.

The first distinction the Generics attempt to draw is that the Federal Trade Commission brought the claims in *Actavis* while private plaintiffs brought this case. But there is no authority, cited or otherwise, suggesting that a different substantive legal standard for adjudging a reverse payment applies to government as opposed to private plaintiffs. Nor does the reasoning in *Actavis* give so much as a hint that a different standard should

apply to private litigants. To the contrary, the Court vacated and remanded the Third Circuit's decision in *K-Dur*, a private case, making it clear that *Actavis* applies to private claims. (See *Merck & Co. v. Louisiana Wholesale Drug Co., Inc.* (June 24, 2013) 133 S.Ct. 2849 [vacating and remanding "for further consideration in light of [*Actavis*]"]; *Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.* (June 24, 2013) 133 S.Ct. 2849 [same].)

The Generics alternatively claim that, even if the same standard applies to government and private plaintiffs challenging a reverse payment, private plaintiffs must satisfy two additional elements: antitrust injury and causation. This claim is dubious; federal courts have applied both elements to government plaintiffs as well as to private ones.[3] More important, the claim is irrelevant. The decisions on appeal addressed only liability, concluding that as a matter of law, Appellants failed to show a Cartwright Act violation. (*Cipro Cases I & II, supra*, 200 Cal.App.4th at p. 470.) Indeed, the Generics themselves admit that the issues of antitrust injury and causation played no role in the lower courts' decisions and are not currently before this Court. (Generics Letter Br. at p. 8 ["[T]he lower courts had no occasion to consider whether plaintiffs could satisfy the antitrust injury and causation requirements, and these issues are not before the court."].) In other words, the Generics admittedly offer a distinction without a difference.

Similarly unpersuasive is the Generics' argument that this case diverges from *Actavis* because the patent at issue here was upheld in other litigation, even though such litigation did not involve these Appellants.

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[3] (See, e.g., *Rambus, Inc. v. FTC* (D.C.Cir. 2008) 522 F.3d 456, 463, 467 [reversing a Federal Trade Commission judgment for failure to show defendant caused harm to competition]).

First, this argument contradicts the predicate of *Actavis*. The Supreme Court held that the anticompetitive effect of the reverse payment is to eliminate *the risk of competition*. (*Actavis*, *supra*, 133 S.Ct. at p. 2236 [prohibiting payments "to avoid the *risk* of patent invalidation or a finding of noninfringement"], italics added.) A reverse payment eliminates that *risk* at the time a generic company drops a legal challenge in exchange for payment. (*Ibid.*) The Court therefore concluded that it is generally not necessary to assess patent strength to determine whether a reverse payment violates federal law. (*Ibid.* ["[I]t is normally not necessary to litigate patent validity to answer the antitrust question."].) Second, any determination regarding the Cipro patent does not bind Appellants in this action. Appellants were not parties or privies to any Cipro patent litigation, as they would have had to be for collateral estoppel to apply. (*In re Swanson* (Fed.Cir. 2008) 540 F.3d 1368, 1377.) Third, the patent at issue in this antitrust litigation is not the same one that was upheld in post-settlement patent litigation. (See Section VI, *infra*.)

Finally, policy considerations weigh against this Court departing from *Actavis* and allowing non-binding patent assessments to inform litigation over a reverse payment. Plaintiffs in antitrust reverse payment cases would then have strong incentive to intervene—and complicate—cases directly challenging the patent at issue in the antitrust case. And courts adjudicating antitrust reverse payment claims could become immersed in evaluating past litigation over a patent and perhaps collateral patent issues themselves. Hence, by directing courts to focus on the anticompetitive effect of reverse payments *at the time they are made*, *Actavis* is not only theoretically sound but also practically wise.

The Generics nonetheless attempt to resist *Actavis*' holding that "it is normally not necessary to litigate patent validity to answer the antitrust

question . . . ." (133 S.Ct. at p. 2236.) How? They rewrite the sentence, suggesting that the Supreme Court held "it is not *always* 'necessary to litigate patent validity to answer the antitrust question' *in every case*." (Generics Letter Br. at p. 6, fn. 2, italics added.) But judicial opinions are not subject to after-the-fact editing by litigants. Moreover, the Generics fail to explain how their revisionist approach could avoid the routine, improper assessment of patent validity. Indeed, under their approach, defendants in antitrust reverse payment cases would *normally* assert patent validity as a defense. This is precisely what *Actavis* bars.

The Generics further contend that the Supreme Court acknowledged the foundational need to balance the privileges of patent holders against antitrust prohibitions. (*Ibid.*) True. But the Supreme Court was merely explaining its reasoning in striking the proper balance in this context. It was not extending an invitation to parties—or lower courts—to do so afresh in every case. The balance the Supreme Court struck placed significant constraints on the antitrust analysis, limiting the justifications for reverse payments. And the desire "to avoid the risk of patent invalidation or a finding of noninfringement" is foreclosed as a justification. (*Actavis, supra*, 133 S.Ct. at p. 2236.) That is "the very anticompetitive consequence" the Supreme Court prohibited. (*Ibid.*)

The Court's ban on payments that avoid the *risk* of a patent challenge has a critical implication. It implies that what matters is the effect of the reverse payment agreement *at the time it is made*, not any later determination about the validity or scope of a patent. (1 Herbert Hovenkamp et al., IP and Antitrust (2013 Supp.) § 15.2a1[D], p. 15-44 ["[D]ecisions prior to *Actavis* have made clear that the right time for assessing the competitive effects of the settlement is at the time of settlement, not afterwards. . . . Thus, we are skeptical that subsequent

evidence of validity or invalidity ought to carry much weight in the rule of reason inquiry."].) The Generics' contention that antitrust fact finders in reverse payment cases should take into account later, non-binding rulings on patent validity would in effect rewrite *Actavis*.

VI. THE CIPRO AGREEMENTS AND BAYER'S CONDUCT RESULTED IN THE SEALING OF PRIOR ART EVIDENCE THAT WAS UNAVAILABLE TO SUBSEQUENT LITIGANTS

Even were this Court inclined to find that special circumstances may warrant taking into account whether a patent has survived a litigated challenge in a different proceeding, this case would be a poor vehicle to address that issue. That is so because of the strong evidence that Bayer's patent was unenforceable and that Bayer recognized the Generics were in a particularly strong position to mount a challenge to its patent. Bayer's actions—paying off would-be horizontal competitors, concealing prior art, sealing evidence, and narrowing its patent in a reexamination proceeding—demonstrate Bayer's belief that the original Cipro patent was highly vulnerable.

The Generics lean too heavily on Bayer's success in defending the narrowed '444 patent in post-settlement lawsuits, failing to inform the Court that the challengers in these suits did not have access to key evidence unearthed by Barr's attorneys concerning the Cipro patent's unenforceability. (See Generics Letter Br. at p. 6.) The express terms of the Cipro agreements required Barr to "collect and destroy, other than one copy, which shall be held by [Barr's patent lawyers], all Documents [including attorney work product] in the possession of or under the control of any of the foregoing"—effectively entombing the evidence of Bayer's bad faith conduct from future litigants. (4AA 704–05.) Bayer also made sure the Generics' counsel were muzzled and their work product concerning the prior art kept secret, through the cross-retention of Barr's

lawyers in order to obtain attorney-client privilege—and concomitant silence—on why the patent was unenforceable. (7AA 1467–68; 6AA 1173.) In this regard, "[t]he issue of inequitable conduct was not adjudicated in any of the actions." (*In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Fed.Cir. 2008) 544 F.3d 1323, 1329.)[4]

Additionally, the Cipro patent at issue in the follow-on patent cases was different and substantially narrower than the patent at issue in this case. After the Cipro agreements, Bayer re-submitted the Cipro patent via a new PTO petition that voluntarily terminated certain claims, narrowed other claims, added new claims, and finally disclosed the German '850 and '070 applications Bayer had earlier withheld. (7AA 1471–75, 1482–88.) As patent expert Michael Jester explained, "Bayer's voluntary disclaimer of certain naphthyridine claims of the '444 Cipro patent followed by the substantial narrowing of claims (including Claim 1) during reexamination, coupled with the belated disclosure of the German '070 and '850 publications during reexamination, [implies] Bayer's concern that the patentability of at least some of the original broad claims of the patent over the prior art (including German '070 and '850) was in serious doubt . . . ." (8AA 1855–56, footnote omitted.) It is of little moment that, with time running out on its term, this narrowed patent survived validity attacks. (See Appellants' Opening Br. at p. 62.) It is the broader, since-abandoned patent Bayer asserted against Barr that led to their reverse payment settlement.

[4] Bayer's German patent agent, Dr. Simon, admitted the company knew that the German '850 patent application was disqualifying prior art. (8AA 1853.) Rather than deny its deception, Bayer attacked its employees. It attested that Dr. Simon suffered from depression that impaired his abilities, and that another of its attorneys who admitted Bayer knowingly concealed prior art also suffered from a degenerative mental disease. (7AA 1478–80.)

The Generics also avoid any mention of the nearly $400 million settlement amount, justifiably fearful of illustrating the *Actavis* Court's rule of thumb that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . ." (*Actavis, supra*, 133 S.Ct. at pp. 2236–2237.) The simple size of this payoff refutes the Generics' assertion of Bayer's faith in the patent's enforceability and likely success against Barr's attack. Bayer's actions in paying off not just the Generics but also a subsequent challenger, Ranbaxy (see 7AA 1522–30, 1591–93), reveal a strategy of co-opting strong claimants—and hiding their evidence—while choosing to litigate weaker claims.

VII. THE COURT SHOULD ARTICULATE A STANDARD TO GUIDE THE LOWER COURTS

The Generics' final suggestion in their brief—that this Court might remand without providing any guidance to lower courts—reflects a strategic maneuver to sow confusion and cause further delay. The Generics would not ask this Court to remand without explaining *Actavis* if that case lent any support to their position. They seem to recognize that uncertainty and inefficiency are their best hope.

In fact, the Generics' suggestion represents an improper attempt to relitigate an issue they have already lost. After Appellants settled with Bayer, the Generics on July 2, 2013, moved this Court to transfer the case as a whole to the Court of Appeal with instructions to remand it to the Superior Court. (See Generics' Mot. Transfer Without Decision.) This Court denied that motion. (Order of July 10, 2013.) The Generics should not be permitted to renew the same request again.

Moreover, the Generics' request for remand without guidance would cause needless delay. They are arguing before this Court that the decisions of the lower courts should stand under *Actavis*. They would no doubt do

the same on remand and in any subsequent appeals. No additional discovery is necessary to resolve this argument. Were the Court to grant the Generics' request to avoid the central issues in this appeal, the coordinated California Cipro litigation would continue for many more years, and could end up before this Court once again in a posture little different from today.

This litigation has already been pending for over a decade. The passage of time has allowed the Generics to retain their ill-gotten gains at the expense of California consumers. Appellants respectfully submit that it is time to clarify the legal standard that applies to reverse payments, so the trial court can adjudicate these claims and California courts can do the same in other reverse payment cases.

Accordingly, the Court should reverse the grant of summary judgment and hold that a payment to delay the risk of competition violates California law.

Dated: February 14, 2014

Respectfully submitted,

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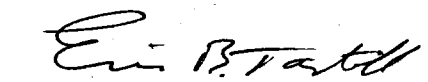
By: 

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CERTIFICATE OF WORD COUNT

[California Rule of Court 8.204(c)(1)]

Pursuant to the California Rules of Court and this Court's Order of December 11, 2013, counsel of record certifies that this Supplemental Reply Brief uses 13-point Roman type and contains 4,107 words, including footnotes. Counsel relies on the count of the computer program used to prepare this Brief.

Dated: February 14, 2014

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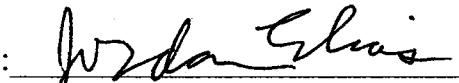
By: 
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