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February 14, 2014

Mr. Frank A. McGuire
Clerk of the Court
Supreme Court of California
350 McAllister St.
San Francisco, CA 94102-4797

RE: *In re Cipro Cases I & II*, No. S198616

Dear Mr. McGuire:

The Generic Defendants respectfully submit this reply pursuant to the court's December 11, 2013 order.

SUMMARY

Despite plaintiffs' argument that "*Actavis* supports application of a constrained rule of reason analysis ... or, in the alternative, a precisely formulated *per se* illegality rule" (Appellants' Supp. Br. 1 (Pls. Supp. Br.)), even a cursory review of the U.S. Supreme Court's decision shows that it does nothing of the sort.

- *First*, *Actavis* expressly concluded that antitrust challenges to Hatch-Waxman settlements must be proven "*as in other rule-of-reason cases*"—and expressly rejected both the per se approach and constrained "quick look" approach that plaintiffs demand. (*FTC v. Actavis, Inc.* (2013) 570 U.S. __ [133 S.Ct. 2223, 2237] (*Actavis*), emphasis added.) While plaintiffs may not like that *Actavis* rejected their proposed approaches, they cannot simply wish *Actavis* away.

- *Second*, plaintiffs' proposed approaches would create a federal preemption problem because they depend on the presumption that Bayer's patent was *in*valid. Federal law makes clear, however, that patents are presumed *valid* as a matter of law, 35 U.S.C. § 282, and the U.S. Supreme Court concluded in *Actavis* that the Rule of Reason provides the appropriate balance between patent rights and antitrust obligations. Subjecting Hatch-Waxman patent settlements to a per se rule or quick-look approach—through a new rule that applies only in California and in no other state—

would create a conflict with federal law and undermine a patent holder's lawful right to exclude under the federal Patent Act.

- *Third*, plaintiffs' contention that the superior court and the Court of Appeal granted "immunity" to the Cipro Settlement ignores what the decisions themselves actually say. While both of the lower court decisions considered the scope-of-the-patent test that other courts had applied at the time, both decisions went on to affirm the legality of the Cipro Settlement under the well-established Rule of Reason. As the Court of Appeal held, "the Cipro agreements do not violate the Cartwright Act under rule-of-reason analysis or the [scope of the patent] analysis." (Slip opn. 32-33, emphasis added; see also 11 AA 2690 [superior court decision concluding "that the agreement does not violate the Cartwright Act under the Rule of Reason"].)

Because both California law and federal law squarely reject plaintiffs' effort to short-circuit the traditional Rule of Reason, and because plaintiffs offer nothing more in this appeal, the lower courts' decisions should be affirmed.

ARGUMENT

I. Neither *Actavis* Nor California Law Supports Plaintiffs' Request to Treat Hatch-Waxman Patent Settlements as Per Se Unlawful or Presumptively Unlawful Under a Constrained Quick-Look Approach.

Plaintiffs' Proposed Per Se Rule. Plaintiffs assert that *Actavis* supports "a precisely formulated *per se* illegality rule" under which "proof of [a] payment [to a patent challenger] would suffice to establish a violation of California antitrust law" unless the payment could be "attributed to litigation costs or services provided." (Pls. Supp. Br. 1, 11.)

The problem for plaintiffs, however, is that the *Actavis* decision squarely rejected per se treatment. In declining the FTC's request for a per se rule, the U.S. Supreme Court concluded that Hatch-Waxman settlements that include monetary consideration from the patent holder to the patent challenger (so-called "reverse-payment" settlements) are neither presumptively lawful nor presumptively unlawful—much less per se illegal. As the court explained:

> [A]bandonment of the "rule of reason" in favor of presumptive rules ... is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." [Citations.] *We do not believe that reverse payment settlements, in the [Hatch-Waxman patent litigation] context we here discuss, meet this criterion.*

(*Actavis, supra*, 133 S.Ct. at p. 2237, quoting *California Dental Assn. v. FTC* (1999) 526 U.S. 756, 770, emphasis added.) In so holding, the court emphasized that the circumstances of each case warrant consideration—instead of applying a rule that presumes anticompetitive effects for this category of settlements as a whole. (See *ibid.*) In light of the court's express ruling that these types of agreements are to be judged under the Rule of Reason, plaintiffs' effort to manufacture a per se rule from the *Actavis* decision is nothing short of wishful thinking.

Nor does plaintiffs' proposed per se approach find any support in California law. California courts have long held that the Rule of Reason is "the prevailing standard of analysis" for evaluating whether a challenged practice violates the Cartwright Act. (*Bert G. Gianelli Distributing Co. v. Beck & Co.* (1985) 172 Cal.App.3d 1020, 1044 (*Gianelli*), disapproved on another ground in *Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal.4th 384, 394, fn. 2.) "Under the Cartwright Act, as under the Sherman Act, the 'illegal per se' designation is reserved for agreements or practices that have a pernicious effect on competition and *lack any redeeming virtue*. [Citations.]" (Slip opn. 32, citing, inter alia, *Corwin v. L.A. Newspaper Service Bureau, Inc.* (1971) 4 Cal.3d 842, 853; see also *Marin County Bd. of Realtors, Inc. v. Palsson* (1976) 16 Cal.3d 920, 930-931; 11 AA 2689 (*Marin County*).) As the superior court observed, "[p]laintiffs have cited no California case, nor is there one, supporting that a per se illegal analysis is applicable to" the type of agreement at issue here (11 AA 2689)—and this remains true today.

Plaintiffs' Proposed "Constrained Rule of Reason." Plaintiffs alternatively argue that the Cipro Settlement should be held presumptively unlawful, in what they have variously described as a "quick-look Rule of Reason" (Appellants' Reply Br. on the Merits 4 (Reply Br.)) or "constrained Rule of Reason" (Pls. Supp. Br. 1, 7). As plaintiffs explained in their opening merits brief, that approach would be "only slightly less stringent than the *per se* rule" (Appellants' Opening Br. on the Merits 37 (Opening Br.)) because it would *eliminate* the first step of the Rule of Reason, *assume* that the settlement had actual adverse effects on competition, and *shift the burden* to the defendants (see *id.* at p. 42; 11 AA 2581-2582).

Once again, however, plaintiffs' proposed standard finds no support in either *Actavis* or California law. The U.S. Supreme Court expressly rejected a presumptively unlawful or quick-look approach in *Actavis*:

> The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach, rather than applying a "rule of reason." [Citations.] *We decline to do so.*

(*Actavis, supra*, 133 S.Ct. at p. 2237, emphasis added.)

Actavis did not limit its holding to *some* types of settlements containing monetary consideration from the patent holder to the patent challenger, or suggest that *some* such settlements could be presumptively unlawful while others are not. Because such settlements could be subject to any number of "other justifications" even beyond the avoidance of litigation costs or compensation for other services (*Actavis*, *supra*, 133 S.Ct. at p. 2236)—and because the "existence and degree of any anticompetitive consequence may also vary" from one case to the next (*id.* at p. 2237)—the U.S. Supreme Court concluded that such settlements should be analyzed under a traditional Rule of Reason analysis "*as in other rule-of-reason cases.*" (*Ibid.*, emphasis added ["These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases."].) Plaintiffs do not and cannot cite a decision from any court that has adopted their proposed "constrained Rule of Reason" or "quick-look Rule of Reason"—apart from an earlier citation in their merits reply brief to the Third Circuit's now-vacated decision in *K-Dur*. (Reply Br. 4, citing *In re K-Dur Antitrust Litig.* (3d Cir. 2012) 686 F.3d 197, vacated *sub. nom. Merck & Co. v. Louisiana Wholesale Drug Co.* (2013) __ U.S. __ [133 S.Ct. 2849] [vacating *K-Dur* in light of *Actavis*].)

* * * *

At bottom, the relevance of *Actavis* is that it *rejected* the very same arguments that plaintiffs have advanced throughout this appeal. Neither federal law nor California law supports plaintiffs' efforts to short-circuit the traditional Rule of Reason that is the "prevailing standard" in antitrust cases. (*Gianelli*, *supra*, 172 Cal.App.3d at p. 1044.)

II. Adopting Plaintiffs' Proposed Approaches Would Create a Federal Preemption Problem By Undercutting What It Means to Have a Patent Under Federal Patent Law.

Actavis also shows why adopting plaintiffs' proposed standards would impermissibly conflict with federal law and thereby create a preemption problem.

A. Plaintiffs' Preemption Arguments Are Irrelevant and Incorrect.

At the outset, it bears emphasis that plaintiffs' preemption arguments address the wrong preemption question. According to plaintiffs, the Court of Appeal improperly used federal preemption to reject their theory that Bayer's assertion of the patent against Barr constituted "sham litigation" that rendered the Cipro Settlement unlawful even under the scope-of-the-patent test. (Pls. Supp. Br. 13-16.) That argument is a red herring.

What plaintiffs fail to point out is that the Court of Appeal's disposition of their sham litigation theory actually turned on the observation that plaintiffs had failed to plead such a theory in their complaint. After reviewing the allegations in plaintiffs' operative complaint, the

Court of Appeal (like the superior court) found that "'[p]laintiffs *failed to allege* that Bayer's infringement suit was objectively baseless, [or] was sham litigation'" despite multiple rounds of amended pleadings. (Slip opn. 39, quoting 11 AA 2692, emphasis added.) Both courts further emphasized that "'[e]ven if such allegations were included in the [complaint], there is no evidence or legal support the [Bayer-Barr patent] suit was objectively baseless or was a sham.'" (*Ibid.*, quoting 11 AA 2692; see also *id.* at pp. 41-42.) It was only then that the Court of Appeal observed that a sham litigation claim would be preempted as well. (*Id.* at pp. 42-49.)

Even on its own terms, the Court of Appeal's preemption analysis was demonstrably correct.[1] After all, asking a state court jury to hold that Bayer's assertion of the patent was "objectively baseless" would invite a direct conflict with the holdings of multiple federal courts that *upheld* the validity of the patent—and with the Federal Circuit's conclusion that "no fraud occurred" in Bayer's procurement of the patent from the PTO. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Fed.Cir. 2008) 544 F.3d 1323, 1341 (*Cipro III*).) The Court of Appeal recognized this point, explaining that "'Bayer's success in its [patent infringement] litigations against Schein, Mylan, and Carlsbad forecloses any argument that its lawsuits were shams.'" (Slip. opn. 41, quoting *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2005) 363 F.Supp.2d 514, 547 (*Cipro II*).) "'A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore is not a sham.'" (*Ibid.*, quoting *Cipro II*, 363 F.Supp.2d at p. 547; accord *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, (1993) 508 U.S. 49, 61 fn. 5 [same].)

B. Plaintiffs' Proposed Approaches Would Conflict With Federal Patent Law.

If anything, the preemption doctrine shows why the decisions below should be affirmed and why plaintiffs' proposed approaches should be rejected.

As an initial matter, both a per se rule and a constrained quick-look approach would begin from the presumption that Bayer's patent was *in*valid, because the antitrust laws do not protect competition by would-be infringers, and it is undisputed that Barr's generic ciprofloxacin

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[1] Plaintiffs spend much of their preemption discussion on cases that actually address *jurisdiction*. (Pls. Supp. Br. 14.) Plaintiffs' reliance on this case law is misplaced. In any event, far from effecting a sea-change in federal jurisdiction as plaintiffs suggest, the U.S. Supreme Court's decision in *Gunn v. Minton* (2013) __ U.S. __ [133 S.Ct. 1059, 1065] (*Gunn*), simply restated (and actually quoted from) the substantial federal question test in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing* (2005) 545 U.S. 308 (*Grable*). (See *Gunn, supra*, 133 S.Ct. at p. 1065, quoting *Grable, supra*, 545 U.S. at p. 314.) Nothing about the Court of Appeal's consideration of *Grable* in *Lockwood v. Sheppard, Mullin, Richter & Hampton* (2009) 173 Cal.App.4th 675, has changed.

would have infringed Bayer's compound patent—yet plaintiffs' proposals automatically would assume that the Cipro Settlement had an adverse effect on competition. (*Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.* (7th Cir. 1907) 154 F. 358, 364 ["[T]he public [i]s not entitled to profit by competition among infringers."]; *Hynix Semiconductor Inc. v. Rambus Inc.* (N.D. Cal. 2007) 527 F.Supp.2d 1084, 1096 ["[A]n infringer" has "no legal right to be competing in the product market."]); see also *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 107 (*Cipro IV*) [observing that "there could not be an ANDA-IV certification for a non-infringing version of [ciprofloxacin] since Bayer had a compound patent"].) Plaintiffs' contention that the Cipro Settlement was nothing more than a "naked payoff ... to suppress competition" presupposes that Bayer did not have a valid patent.[2] (Opening Br. 17.)

The problem for plaintiffs is that federal patent law commands that patents are presumed *valid.* (35 U.S.C. § 282; see also *Microsoft Corp. v. i4i Limited Partnership* (2011) __ U.S. __ [131 S.Ct. 2238, 2242] [holding that the presumption of patent validity can only be overcome "by clear and convincing evidence"].) As the Federal Circuit has explained, "[a] patent is born valid [and] [i]t remains valid until a challenger proves it was stillborn or had birth defects, or it is no longer viable as an enforceable right." (*Roper Corp. v. Litton Systems, Inc.* (Fed.Cir. 1985) 757 F.2d 1266, 1270, fn. omitted]; see also *Cipro III, supra,* 544 F.3d at p. 1337 [similar]). And it would be especially nonsensical to adopt a presumption of invalidity in this case, when Bayer defeated multiple challenges to the Cipro Patent—at trial and before the Federal Circuit—and the patent was reaffirmed upon re-examination by the U.S. Patent and Trademark Office ("PTO").[3] (See *Bayer AG v. Schein Pharmaceutical, Inc.* (D.N.J. 2001) 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306; *Bayer AG v. Carlsbad Technology, Inc.* (S.D.Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B) [opinions available at 1 RA 181-193, 195-227]; 2 AA 252 [plaintiffs' admission that PTO reexamination confirmed validity of Bayer's patent].)

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[2] Although plaintiffs repeatedly cite a paid expert's speculation about whether Barr would have earned more or less from settling versus litigating the patent case, the *undisputed facts* in the record demonstrate that the consideration Barr received under the settlement was *substantially less* than it would have earned had its patent challenge succeeded (3 RA 670), and that the settlement represented only 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the corresponding time period (1 RA 39).

[3] Plaintiffs' arguments about the preclusive effect of Bayer's subsequent patent victories (see Pls. Supp. Br. 11, fn. 8) are irrelevant. The relevant point is not whether plaintiffs are *bound* by Bayer's victories, but instead that the multiple decisions upholding the Cipro Patent demonstrate both the pro-competitive nature of the Cipro Settlement and the nonsensical nature of applying a presumption of invalidity to the patent in this case.

Actavis itself underscores the preemption problem that plaintiffs' proposed approaches would create. After all, the U.S. Supreme Court concluded that using the traditional Rule of Reason was the appropriate means of balancing patent rights against antitrust obligations, rather than holding Hatch-Waxman settlements either presumptively lawful or presumptively unlawful. (See *Actavis, supra*, 133 S.Ct. at p. 2237.) Now that the U.S. Supreme Court has cast the balance in that way, a rule subjecting such settlements to per se illegal treatment or a constrained quick-look approach would derogate the very balance that *Actavis* has cast—imposing a presumption of invalidity only in California and in no other state—and thus undermine the lawful right to exclude that a patent holder enjoys under the federal Patent Act. (See *United States v. Gen. Electric Co.* (1926) 272 U.S. 476, 485 ["It is only when ... he steps out of the scope of his patent rights ... that he comes within the operation of the Anti-Trust Act."]; see also *E. Bement & Sons v. Nat. Harrow Co.* (1902) 186 U.S. 70, 91 ["The fact that the conditions in the contracts keep up the [patent] monopoly or fix prices does not render them illegal."].) And it would be even more remarkable to subject the Cipro Settlement—which resolved a federal patent case in U.S. District Court for the Southern District of New York—to a new rule for Hatch-Waxman settlements applicable only in California and in no other state, especially when the Second Circuit and Federal Circuit upheld the very same settlement agreement in an MDL antitrust case that included California purchasers suing under California law. *See Cipro IV, supra*, 604 F.3d 98, cert. denied *sub nom. Louisiana Wholesale Drug Co. v. Bayer AG* (2011) __ U.S. __ [131 S.Ct. 1606]; *Cipro III, supra*, 544 F.3d 1323, cert. denied *sub nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2009) 557 U.S. 920; see also 1 AA 25 [Bayer's Motion for Summary Judg., explaining that the MDL case included California plaintiffs suing under the Cartwright Act and section 17200].)

Plaintiffs are simply incorrect in claiming that *Actavis* calls for courts to ignore the presence of a patent. (See Pls. Supp. Br. 10-11.) To the contrary, the U.S. Supreme Court repeatedly stated that in conducting the Rule of Reason analysis, courts must "consider[] traditional antitrust factors ... *and* potentially offsetting legal considerations present in the circumstances, *such as here those related to patents*." (*Actavis, supra*, 133 S.Ct. at p. 2231, emphasis added; see also *id.* at pp. 2230-2231 ["[W]hat the holder of a valid patent could do does not *by itself* answer the antitrust question," emphasis added].). Although the court made the unremarkable observation that it is not always "necessary to litigate patent validity to answer the antitrust question" in every case (*id.* at p. 2236), it expressly emphasized that "courts must 'balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the [antitrust laws] against combinations and attempts to monopolize'" (*id.* at p. 2231, quoting *United States v. U.S. Gypsum Co.* (1948) 333 U.S. 364, 390-391).

At bottom, the U.S. Supreme Court has long recognized that the patent rights conveyed by the federal Patent Act reflect a "carefully crafted bargain" put in place by Congress, and that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989)

489 U.S. 141, 152.) Against this backdrop, plaintiffs' per se rule and constrained quick-look approach cannot not be reconciled with the presumption of patent validity or with *Actavis* itself. This court should decline plaintiffs' invitation to go down this unprecedented path.

III. *Actavis* Confirms That the Decisions Below Should Be Upheld.

Plaintiffs' supplemental brief also argues that the superior court and the Court of Appeal improperly granted "immunity" to the Cipro Settlements by relying on the scope-of-the-patent test instead of the approach embraced by *Actavis*. (Pls. Supp. Br. 1-2.) In making this claim, plaintiffs again ignore the lower court decisions themselves.

To be sure, the lower courts considered the Cipro Settlement under the scope-of-the-patent test, as the Second Circuit and Federal Circuit had done in concluding that this very settlement was lawful. (See Slip opn. 37-38; 11 AA 2690.) Importantly, however, the lower courts *also* considered the settlement under the Rule of Reason and, in light of California precedent, including *Marin County* and *Gianelli*, found the settlement lawful under that standard. The superior court expressly concluded that "the [settlement] agreement does not violate the Cartwright Act *under the Rule of Reason.*" (11 AA 2690, emphasis added.) The Court of Appeal likewise held that "the Cipro agreements do not violate the Cartwright Act *under rule-of-reason analysis* or the [scope of the patent] analysis." (Slip opn. 32-33, emphasis added.) Rather than "immunizing" the Cipro Settlement as plaintiffs contend, the lower courts actually considered the Cipro Settlement under the Rule of Reason endorsed by *Actavis* and concluded that the settlement was lawful. That decision was eminently correct.

As an initial matter, plaintiffs cannot establish an adverse effect on competition as the first step of the Rule of Reason requires. Plaintiffs try to satisfy this test by arguing that Barr *would have won* the underlying patent litigation absent the settlement—or that Bayer and Barr *would have reached* an alternative settlement on different terms. (See, e.g., Br. of Appellants to Ct. of Appeal 54-55; 1 AA 213 [Pls. Summary Judg. Opp'n].) Both of those theories are far too speculative to support plaintiffs' claims. (See, e.g., *Casey v. Perini Corp.* (2012) 206 Cal.App.4th 1222, 1237 ["Mere speculation or conjecture ... is insufficient to demonstrate the existence of a triable issue of fact to preclude summary judgment."]; *Saelzler v. Advanced Group 400* (2001) 25 Cal.4th 763, 775-776 ["[W]hen the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, *it becomes the duty of the court to direct a verdict for the defendant.*' [Citation.]"].)

As the superior court recognized, it would be rank speculation for a California jury to try to determine whether a New York court hearing the patent case in 1997 would or should have found the patent invalid, especially when every court to have considered the merits has found the patent valid. (See 11 AA 2692 ["Plaintiffs' allegations that Barr would have won the patent challenge are speculative, and are dismissed as, 'little more than dubious expectations or

desires.' [Citation.]"].) "[L]itigation is at best uncertain" (*In re Adoption of Joshua S.* (2008) 42 Cal.4th 945, 954), and "[t]he litigation process ... is fraught with complexities, uncertainties, delays, and risks of many kinds," including that "[d]ifferent judges and juries may respond in different ways to the same evidence and argument" (*Neary v. Regents of Univ. of Cal.* (1992) 3 Cal.4th 273, 280). As such, this court—like others across the country—has held that what the outcome of a hypothetical trial or appeal might be "is a matter of pure speculation that should not serve as a basis for tort liability." (*Forbes v. County of San Bernardino* (2002) 101 Cal.App.4th 48, 59; see also *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (2003) 344 F.3d 1294, 1308 ["Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages...."].)

It would be even more speculative for a California jury to decide whether Bayer and Barr would (or could) have settled on different terms that would have allowed for earlier generic entry. Simply put, there is no way that a jury could assess how a hypothetically different settlement negotiation would have unfolded, whether that negotiation would have succeeded, what the terms of a different settlement structure would have been, and how those terms would or would not have benefited indirect purchasers of Cipro. (See *Stare v. Tate* (1971) 21 Cal.App.3d 432, 440 [reversing as "based solely on conjecture" the trial court's finding that a party would have entered into a settlement agreement, and observing that "[s]ettlement negotiations of the kind that were had between the parties are usually nothing but a high stake[s] game of poker"].) Plaintiffs cannot cherry-pick between the parts of the Cipro Settlement they like and the parts that they do not, and then ask a jury to assume that Bayer and Barr would have agreed to that hypothetical alternative. As another court has explained in rejecting an antitrust challenge to a different Hatch-Waxman settlement, such a claim fails because it "relies on speculation as to what might have been negotiated in a hypothetical agreement," and because "[t]he antitrust laws are not designed to ensure the most productive competition or the most procompetitive agreement."[4] (*Kroger Co. v. Sanofi-Aventis* (S.D.Ohio 2010) 701 F.Supp.2d 938, 959; see also *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP* (2004) 540 U.S. 398, 415-416 [explaining that the antitrust laws do not require "that a monopolist alter its way of doing business whenever some other approach might yield greater competition"].)

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[4] The speculative nature of plaintiffs' theories also underscores why plaintiffs would be unable to demonstrate antitrust injury and causation—to show that it actually was the settlement, and not the patent itself, that caused any alleged harm. Because plaintiffs could not satisfy the first step of the Rule of Reason by demonstrating an adverse impact on competition, the proceedings below had no occasion to address whether plaintiffs could satisfy these additional elements of an antitrust claim. *Actavis* also did not consider these requirements because it was a case brought by the FTC under the FTC Act, which does not require the government to establish either element to prevail. (See Generic Defs. Supp. Br. 7-8.)

Moreover, the Cipro Settlement had significant pro-competitive effects. The settlement enabled Barr to sell a competing ciprofloxacin product six months *before* the challenged patent expired and a full year before Bayer's FDA exclusivity ended—during which time Barr achieved significant market penetration, resulting in increased competition and lower drug prices.[5] (2 RA 374-375, 378-380.) By contrast, Mylan, Schein, and Carlsbad pursued their own challenges to Bayer's patent. All of them lost in court and could not sell ciprofloxacin until *after* Bayer's exclusivity ended—a year after Barr was able to enter. The Cipro Settlement also provided certainty to Barr and the other Generic Defendants by removing the inherent uncertainty of litigation and freeing up resources to develop other products and pursue additional patent challenges. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2003) 261 F.Supp.2d 188, 252 (*Cipro I*) [recognizing that Hatch-Waxman patent settlements facilitate the challenge of additional patents by generic pharmaceutical companies].)

All of this underscores why the lower courts' decisions should be affirmed. Throughout this case, plaintiffs have demanded nothing short of a per se rule or quick-look approach that deviates from the traditional Rule of Reason analysis. (Reply Br. 4.) *Actavis* rejects the reasoning behind plaintiffs' proposed approaches, both of which would disregard patent rights and the policies favoring settlement altogether. Because the lower courts expressly applied the Rule of Reason—and plaintiffs fail to offer anything beyond their now-rejected approaches—the decisions below in this 14-year-old case should be affirmed.

CONCLUSION

For the foregoing reasons, the Generic Defendants respectfully request that the court affirm the decision below or, in the alternative, remand the case without decision to the Court of Appeal with instructions that the case be remanded to the superior court for further proceedings.

Sincerely,

Jay P. Lefkowitz, P.C.

[5] Although plaintiffs assert that Barr sold ciprofloxacin "at prices 5-10% higher than" Bayer's prices (Pls. Supp. Br. 12, fn. 10), the very testimony that plaintiffs cite confirms that Barr in fact set the price of its competing product "eight percent lower" than Bayer's price. (5 AA 996.) Plaintiffs' real complaint is that wholesalers, retailers, and other indirect purchasers did not pass all of those savings along to consumers. (See 5 AA 999.) Plaintiffs cannot premise their claims against the Generic Defendants on the decision by resellers to keep some or most of the savings to themselves.

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CERTIFICATE OF WORD COUNT

Pursuant to the California Rules of Court and the modified word limit in this court's December 11, 2013 Order, the undersigned certifies that the foregoing supplemental letter brief contains 4,501 words, exclusive of tables, certificates, and attachments, as counted by the Word Count feature of Microsoft Word.

Jay P. Lefkowitz, P.C.

DECLARATION OF SERVICE

Case Name: ***In re Cipro Cases I & II***

Case No.: S198616

I am over the age of eighteen years and not a party to this action. My business address is 555 California Street, San Francisco, CA 94104. On February 14, 2014, I served the attached Supplemental Reply Letter Brief of the Generic Defendants by placing it in a sealed envelope with postage fully prepaid, in the United States mail at Kirkland & Ellis LLP, 555 California Street, San Francisco, CA 94104 addressed as set forth below. I am familiar with Kirkland & Ellis' practice for collecting and processing correspondence for mailing. On the same day that the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Dated February 14, 2014.

Janaya Guerrero

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Superior Court of California Clerk of San Diego County Superior Court 330 West Broadway San Diego, CA 92101	**By U.S. Mail**
California Court of Appeal Fourth Appellate District, Div. One Symphony Towers 750 B Street, Suite 300 San Diego, CA 92101	**By U.S. Mail**