Bloomberg BNA

Antitrust & Trade Regulation Report™

HEALTH CARE

Pharmaceuticals

The California Supreme Court's Opinion in *Cipro I* and *Cipro II*: What Does It Do for Antitrust?

BY KURT W. MELCHIOR

Earlier this year, the California Supreme Court unanimously issued a seminal opinion which will likely have significant impact nationally on antitrust law and on patent litigation although the opinion interpreted only state law, the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 et seq.

Briefly: the court held that settlements between patent holders and competitors who challenge the validity of those patents — such challenges being a purely federal arena for disputes — are subject to antitrust challenge under state law as well as federal law. The court then provided extensive, clear but very complex directions on how such challenges should be presented and evaluated under antitrust law: a subject which the United States Supreme Court had addressed only generally and which lower federal courts had likewise not developed.[1] That outline is likely to establish guideposts for the presentation of cases in this very hot area, in federal antitrust practice as well. This paper will examine some of the advances in the law that follow from the California Court's *Cipro* decision.

Kurt W. Melchior, a partner in the San Francisco, Cal., office of Nossaman, LLP, is an experienced antitrust and health care practitioner. He is a member of the California Trial Lawyers Hall of Fame. Melchior has tried many non-jury and jury cases to judgment and has been counsel of record in more than 70 published cases.

The two critical cases are the United States Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc.* (2012) 133 S. Ct. 2223, and the new California case *In re Cipro Cases I and II* (2015) 61 Cal. 4th 116.

First, a few technical comments about the *Cipro* opinion. It has long been an issue of contention whether California's antitrust law, the Cartwright Act, was or was not patterned after the federal Sherman Act. California high court decisions have gone both ways. *See California ex rel. Van de Kamp v. Texaco, Inc.* (1988) 46 Cal. 3d 1147 (Cartwright Act not based on Sherman Act); *Blank v. Kirwan* (1985) 39 Cal. 3d 311 (Cartwright Act is patterned after Sherman Act); *Union Carbide Co. v. Superior Court* (1984) 36 Cal. 3d 15 (same). The *Cipro* opinion comes down on the side that the Cartwright Act is based on laws of other states, not the Sherman Act, and that therefore federal antitrust cases are ''at most instructive, not conclusive, when construing the Cartwright Act'' (p. 142). But it discusses at length the fact that federal law controls interpretation of the patent laws, which are of course federal laws. In that part of the opinion which describes the Cartwright Act and its history, there is no mention at all of possible inconsistency between California's antitrust law and that of the nation. Rather, the court spends much time discussing the history of the interaction and frequent clashes between federal antitrust law and federal patent

[1] One federal court has called this case ''one of the most thorough and thoughtful discussions of *Actavis* yet issued by any court.'' *In re Aggrenox Antitrust Litig.* (D. Conn.) 2015 U.S. Dist. LEXIS 94516.

 ISSN 0003-6021

law. Clearly, despite its pro forma distinction between the two bodies of law, the *Cipro* opinion treats California antitrust law and federal antitrust law as a continuous whole and freely cites federal antitrust cases without distinction from state cases. The *Cipro* opinion is thus a hallmark for unified antitrust law interpretation under state and federal law for the future.

Actavis was the major decision of the United States Supreme Court which rejected the ''patent validity'' or ''scope of the patent'' line of argument which lower courts had widely followed and which, taken to the extreme, would immunize patent dispute settlements from antitrust attack as long as they contained no restrictions beyond ''the potential exclusionary scope of the patent—that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim,'' as the Eleventh Circuit had put it in the *Actavis* case before it went to the Supreme Court, *FTC v. Watson Pharms., Inc.* (2012) 677 F. 3d 1298, 1311.

Cipro discusses the theoretical bases of the pre-*Actavis* rulings in antitrust challenges of patent infringement case settlements at some length. An interesting point emerges: the majority opinion in *Actavis* is based on the proposition that all patents are challengeable and potentially invalid, a premise that allows questions about the patent owner's possible motivations to settle such challenges based on the possibility that the patent's validity might not be upheld.

The *Cipro* court calls this analysis ''in some sense probabilistic,'' citing ''a substantial body of scholarship suggesting patents are best understood this way'' (p. 144 fn. 9). The four Justices who had dissented in *Actavis* did not disagree that patent validity cases can be won or lost, but they stated their basic view that ''a patent is either valid or invalid'' and noted that ''[t]he parties of course don't know the answer with certainty at the outset of litigation; hence the litigation. But the same is true of any hard question yet to be litigated.'' (*Actavis* dissent, p. 13.)

While not critical to *Cipro*, which after all arises from the fact that (in *Cipro's* words) the *Actavis* majority found the validity of patents ''probabilistic,'' that difference is worth a short detour. The difference between judges who view legal structures such as patents as inherently uncertain until an outside authority confirms that they are indeed enforceable,[2] and those who see a patent as binding until a challenge destroys its authority, seems basic to all elements of the social compact: by the *Actavis* majority's token a legal right is not binding until it is enforced in a specific context, and by the same reasoning a contract must be considered uncertain until a judge determines its meaning and validity. The minority, on the other hand, considers the social order, its laws and contracts, to be firm and settled and to have a clear meaning (but *what* meaning?) until some rebellious force manages to compel a contrary outcome. These are very different ways of seeing the world around us.

The probabilistic view of the world prevailed in the United States Supreme Court in *Actavis*, 5:4; it has now prevailed in *Cipro*, 7:0. The *Cipro* court wrote: ''The scope of the patent test is flawed precisely because it assumes away whatever level of uncertainty a given patent * * * may be subject to'' (p. 144). It concluded that ''State law must yield to federal, but we cannot under the guise of patent law carve into the Legislature's enactments a larger exception than federal law dictates, and *Actavis* shows such a broad exemption [concerning issues about patent validity] is not required'' (p. 145).

From that perspective, the *Cipro* court went on to ''consider what rubric courts should instead apply under state law to reverse payment patent settlements'' (*ibid.*).[3] In that process, it cited many California decisions interpreting the Cartwright Act but also frequently cited federal decisions under the Sherman Act.

How to apply antitrust law to actual trial issues in challenges to reverse payment patent challenge cases is something the *Actavis* court had not addressed: the subject was not before it. Nor does there appear to be any post-*Actavis* federal case that outlines how courts should approach the issues of proof that arise in reverse payment settlement cases: such issues have simply not yet arisen. **Thus, *Cipro*'s extensive directives about how such cases should be tried are a first, and will likely point the way for future cases both in federal and state courts. That seems to be *Cipro* 's true importance.**

As a first matter, the Court analyzed the standard by which the underlying facts should be reviewed. It started with the well-known fact that although the Cartwright Act purports to ban all restraints of trade, ''only unreasonable restraints of trade are prohibited.'' It next discussed the emergence of ''quick look rule of reason analysis'' in federal antitrust law, which ''makes equal sense for claims under the Cartwright Act'' (p. 147), and then turned to the question for which, besides adopting *Actavis*'s reasoning as the standard for evaluating patent challenge payments under California law as well, *Cipro* is likely to be remembered: how the analysis of such payments ''should be structured to most efficiently differentiate between reasonable and unreasonable restraints of trade in this context'' (*ibid.*).

The *Cipro* court noted that Hatch-Waxman patent litigation takes place in a special setting since Hatch-Waxman gives the first generic manufacturer to challenge a drug patent an exclusive period in which to market any generic substitute for the patented product if the challenge succeeds. Even where the patent is invalid (and due to the settlement, that question will not be answered), the features of such a settlement noted at

[2] In the patent field, that is in fact an overstatement since a ruling of patent validity is effective only against the challenger, whereas a finding of invalidity binds the patentee against the world. (*Blonder-Tongue v. University Foundation* (1971) 402 U.S. 313, 349-350, cited at *Cipro*, p. 143.)

[3] Briefly, a reverse payment patent settlement is one where a patent is challenged and the patent holder settles with the challenger by providing consideration, such as a money payment or (because money payments have been widely challenged by third parties such as buyers of the product in question) other considerations such as side purchase agreements, favored nation terms, etc., in return for dropping the challenge, thus continuing the patent holder's monopoly. The 1984 Hatch-Waxman Act, 21 U.S.C. § 355, was designed to accelerate generic substitutes for patented prescription drugs through several procedures, one of which allows a challenging generic manufacturer, if successful in its challenge, to accelerate its own manufacturing process and to gain a statutory lead time over its generic competitors. To date, reverse payment settlements are known primarily if not exclusively in the pharmaceutical patent wars, largely because of special features of the Hatch-Waxman process.

  ATRR ISSN 0003-6021

fn. 2, *supra* — challenge dropped and patentee exclusivity preserved, but its monopoly profits are shared with challenger — will keep the challenger out of the market. On the other hand, the patent holder may settle despite its belief in the strength of the patent, purely to avoid litigation costs, tensions and delays.

So, how can a court determine whether the payment to the challenger was an arrangement to keep competition out of the market improperly, rather than just a cost of doing a legitimate business which had the patent-based right to exclude competitors? Relying on economists' writings cited in *Actavis*, the *Cipro* court phrased the answer this way: ''What would the state of competition have been without the agreement? In the case of a reverse payment settlement, the relevant comparison is with the average level of competition that would have obtained absent settlement, i.e., if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination'' (p. 149). And importantly, for purposes of this analysis ''the period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought.''

This is a notable contribution. As the court explains, ''[i]f an agreement only replicates the likely average result of litigation, any exclusion is a function of the underlying patent strength**; if it extends exclusion beyond that point, this further exclusion from the marketplace – and the attendant anticompetitive effect – is attributable to the agreement**'' (pp. 149-150; emphasis supplied).[4] The court rejected defendants' argument that the effects of the agreement on competition must be judged by comparison to the unexpired term of the patent, which would have been another return to the *Actavis* minority's view that a patent is a firm pillar until it is actually invalidated.

Interestingly, though it is interpreting the Cartwright Act, the *Cipro* court bases this key reasoning wholly on federal precedents. So this is *Cipro*'s first extension of the *Actavis* ruling, which, it will be recalled, only ruled that a reverse payment settlement *can be* anticompetitive: ***here is a concrete formula which can and surely will be used by future courts to test whether an antitrust violation did or did not occur.***

And indeed the *Cipro* court went on to outline how the rule of reason should be applied to patent settlements in the future: ''how to identify whether the parties' settlement eliminates competition beyond the point at which competition would have been expected in the absence of an agreement,'' stating that *only at that point* ''is there an antitrust issue'' (pp. 150-151).

A plaintiff in such a case must prove four elements (actually five, by the court's own count) to make its prima facie case, according to the *Cipro* court (p. 151):

1. ''the settlement includes a limit on the settling generic challenger's entry into the market;''
2. there must be ''cash or equivalent consideration'' to the challenger;
3. that consideration must exceed ''the value of goods and services *other than any delay in market entry* provided by the generic challenger to the brand (emphasis supplied),''
4. plus the brand's expected remaining litigation costs if there had been no settlement.
5. (listed separately by the *Cipro* court) and of course there must be proof of the basic point, that the brand passed some consideration, monetary or otherwise, to the challenger.

The court observed that without anticompetitive restraints, ''one would expect rational parties that settle to select a market entry point roughly corresponding to their joint expectation as to when entry would have occurred, on the average, if the patent's validity and infringement had been fully litigated,'' citing an academic article (p. 151). That hypothetical entry point will be the referent for the antitrust inquiry: did the payment, in cash or other values, exceed the value of whatever products or services the generic was providing to the brand? If, but only if, that is the case, will the prima facie case of a combination in restraint of trade be made out.

The court considered this a prime indicator of antitrust concern because exchanges of goods and services between a brand and its generic competitors are rare, except in the context of settling access issues of this nature (p. 152). And since all these fact issues must be established to make out a prima facie case, the burden of proof is on the plaintiff in all these respects (p. 153).

However, the court noted another wrinkle: the burden of producing evidence may on occasion fall on a party other than that having the burden of proof (Ev. Code § 550); and although the plaintiff continues to have the burden of ultimate proof, where essential evidence ''lies peculiarly within the knowledge and competence of one of the parties,'' that party has the burden of going forward with the evidence. If a defendant in that position fails to provide evidence adequate to convince the trier of fact of its position, the plaintiff will have met its burden of proof, which is different from the burden of providing evidence and has never left the plaintiff.

Thus, once the plaintiff has shown an agreement involving a reverse payment and delay, the defense must come forward with exonerating evidence, or plaintiff will have met its burden of making out a prima facie case. But if the defense produces such evidence, then in order to meet its primary and persisting burden of proof, the plaintiff must show that the defendants' evidence is inadequate to justify the facts from the defense perspective, or rebut the evidence that the defense has introduced (pp. 153-154).

Not only is the evidence of the five essential elements necessary, but the court cites extensive economic writings to conclude that such evidence will be sufficient to meet the plaintiff's burden: why — other than to maintain a monopoly it would not otherwise be able to retain — would a brand holder pay a challenger to stay out of the market for a period beyond that point which the court identified as the ''point of reason,'' meaning that point where the settlement paid to the challenger simply equaled the future litigation costs needed to retain the patent monopoly and keep competitors out of the market for the patent's remaining life? The only explanation for such a payment would be that it allows the patent holder to maintain an *improper* monopoly in the relevant product beyond such period as the facts of the

[4] As *Cipro* notes at p. 135, ''Rather than expend litigation costs on either side, the brand and generic can reach a settlement that reflects the likely validity or invalidity of the patent (stronger patent, smaller settlement; weaker patent, bigger settlement), grants the generic a share of monopoly profits, and leaves the brand the sole manufacturer of the product.''

patent strength warrant. In making such a payment to the challenger which would extend the patent monopoly beyond that ''point of reason,'' the patent holder and the challenger thus share improperly in the benefits of the brand's continuing monopoly position: the patent holder extends its monopoly beyond this ''point of reason,'' and the challenger shares in the monopoly benefits through the excess payment (pp. 135, 154).

The court goes on to rebut various arguments that would justify payments by the patent holder that would not result in market restraints, noting that small deviations will not support a claim of anticompetitive conduct but (quoting *Actavis*) that ''***if the basic reason*** [for a reverse payments settlement] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement'' (p. 156; emphasis supplied).

The court went on to state that if such a prima facie showing is made, the logic of that excess payment will also establish the needed proof of the parties' market power, because without market power there would be no motive to make the overpayment in order to preserve the patent holder's monopoly position (p. 157).

That is the end of the *Cipro* court's discussion of what a plaintiff must prove in order to support a claim that a reverse payment to a party challenging a patent will establish a restraint of trade.

The *Cipro* court next described the rebuttal that defendants in a reverse payment case might undertake. Plaintiffs argued that once a prima facie case has been made by the standards of proof just described, there could be no defense and the case was complete — presumably, subject to the quantification of damages. The *Cipro* court did not buy that argument: while skeptical of defenses (''this does not mean that any justification will do,'' p. 158), it rejected the defense's preferred argument that it might eventually prove that the patent was valid and relevant. Rather, the settlement must be analyzed *as of its date*, and at that time ''the patent's validity is unknown and unknowable.'' The only thing that matters is ''whether a settlement postpones market entry beyond the average point that would have been expected at the time in absence of an agreement'' (*ibid.*). Thus, even without citing any hypothetical picture that would justify a large reverse payment and negate its anticompetitive character, the court reserved an ungenerous opening for the defense by ''afford[ing] defendants the opportunity to demonstrate a given settlement is the exception'' to the rule that such settlements are by nature anticompetitive (p. 158). There is no suggestion as to how that claim could or should be proved, but the validity, vel non, of such evidence — evidence that this deal fostered competition, hard to imagine in the abstract given the anticompetitive nature of reverse payment patent settlements in general — seems to be the only recourse left to the defense where a prima facie case of reverse payments in the course of patent settlements as a restraint of trade has been made out.

The court concludes this section by summing up what it takes for the plaintiff to have made a showing of ''significant anticompetitive consequences.'' If he ''eliminates the possibility that litigation costs or other products or services could explain the consideration paid the generic'' and then dispels whatever evidence the defense might put forward in justification, plaintiff has made his case, showing conduct ''condemned by the Cartwright Act, as by federal antitrust law . . . .'' (p. 160).

A final section of the opinion rejects a defense claim that the entire field has been preempted by the federal patent laws. This argument presented no difficulty for the court, since ''state antitrust law ordinarily is fully compatible with federal law'' and *Actavis* had set a clear precedent as to how patent law and antitrust law can be reconciled in a reverse payment patent settlement case (pp. 160-161). The court provided a firm bar to the ''patent validity'' argument: ''Where the choice of a test [for anticompetitive conduct] rests solely on economic analysis, no patent law preemption concerns arise'' (p. 162).

In all this analysis, the *Cipro* court relied primarily on federal antitrust authorities, and of course on scholarly articles. Plainly, the court wanted to do more than simply rule on ''important unsettled questions of state antitrust law'' (p. 133). It freely, and surely deliberately, cited federal and state antitrust authorities with equal respect and deference, and it provided a road map for the analysis and disposition of antitrust challenges to reverse payment patent settlements all the way through the process of analysis and judgment. The court's work will likely prevail as the guiding standard for dealing with such important and conceptually very difficult cases for a long time to come.

  ATRR ISSN 0003-6021