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ANTITRUST

ALERT

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CALIFORNIA SUPREME COURT DECISION IN *CIPRO* HIGHLIGHTS THE LACK OF PREDICTABILITY IN ANTITRUST JURISPRUDENCE AND COUNSELING

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On May 7, 2015, the Supreme Court of California issued an opinion in *In re Cipro Cases I & II*, a case centered on pay-to-delay settlements between drug makers and generic manufacturers. The Court found the existence of an issue of fact as to whether a settlement in which the branded manufacturer paid generic manufacturers to stay out of the market until the expiration of the patent on the branded drug violated California state antitrust law. At issue in the case was a 1997 settlement agreement between Bayer and Barr Pharmaceuticals, pursuant to which Bayer paid Barr approximately $400 million to delay marketing a generic version of Cipro – a drug produced by Bayer – until Bayer's patent on Cipro expired in late 2003.

The legality of pay-to-delay settlements and the relationship between patent law and antitrust law was previously examined in the United States Supreme Court's 2013 decision in *Federal Trade Commission v. Actavis, Inc.* In *Actavis,* as a matter of federal law, the United States Supreme Court refused to find that reverse payment settlements made by a brand manufacturer to a generic manufacturer to resolve pending patent litigation were presumptively unlawful under federal antitrust law, opining that such bright line rules are only appropriate when the anticompetitive effects of a challenged practice are readily apparent – and that pay-to-delay settlements do not meet that criterion. The Supreme Court remanded the case to the Court of Appeals, directing the Circuit Court to analyze the potential anticompetitive effects of reverse payment settlements under a rule of reason approach, pursuant to which the court should balance the competing interests of federal antitrust law and patent law.

The United States Supreme Court's holding in *Actavis*, however, only addressed the extent to which pay-to-delay settlements should be assessed under federal antitrust law, necessarily leaving open the question as to how such settlements would be viewed in the context of various states' antitrust laws. Typically, states do follow suit with federal antitrust policy in the interest of consistency and predictability of outcome. A decision suggesting a different result under state antitrust law than under federal law raises issues concerning counseling: Can an attorney recommend a pay-to-delay settlement that is subject to challenge under state, as opposed to federal, law?

In *Cipro*, the Supreme Court of California analyzed the settlement under what it called a "structured rule of reason approach" which requires a third-party plaintiff to establish four elements in order to make out its prima facie argument under the

Cartwright Act: (1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services *other* than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement. The court explained that once a third-party plaintiff establishes these elements, the burden shifts to the defendants to produce evidence of the collateral goods and services provided by the generic challenger to the brand and the brand manufacturer's expected litigation costs absent settlement. The *Cipro* court held that if the defendants make this showing, the burden of persuasion shifts back to the third-party plaintiff, which must prove that the amount of the settlement at issue exceeds the combined value of the collateral goods and services and litigation costs.

Although the Supreme Court of California claims that its holding in *Cipro* "is in harmony with *Actavis*, which offered only broad outlines and explicitly left to other courts the task of developing a framework for analyzing the anticompetitive effects of reverse payment patent settlements," there are significant differences between the two decisions that are very material from a client counseling standpoint. For example, whereas the Court in *Actavis* explicitly rejected the notion of analyzing reverse payment patent settlements under bright-line or presumptive standards, the Supreme Court of California's holding in *Cipro* requires the use of such standards. Indeed, under *Cipro*, if a plaintiff can establish that the amount of the proposed settlement exceeds the combined value of the collateral goods and services provided by the generic challenger to the brand and the brand's expected remaining litigation costs absent settlement, the burden shifts to the defendants to make the Herculean (and perhaps impossible) showing that the settlement actually *promotes* competition rather than hinders it. Given the extreme unlikeliness that defendants will be able to make such a showing (assuming they want to take on the litigation risk at all by reaching such a settlement), it appears that in *Cipro*, the Supreme Court of California effectively adopted precisely the type of bright-line rule that the United States Supreme Court rejected in *Actavis*. Moreover, unlike the Court in *Actavis*, in *Cipro*, the court held that evidence concerning the validity of the brand manufacturer's patent is immaterial to the analysis of whether a particular reverse payment settlement violates antitrust law.

Predictability is an important value in law, particularly in antitrust law. Conduct that can be viewed as anticompetitive in one light is often the quite competitive in another light (predatory pricing, discount programs, vertical integration, etc.). Making sure that rules are applied consistently and logically is important to our business community and to our ability as lawyers to intelligently and accurately counsel our clients.

A recent amicus brief from the National Association of Manufacturers (NAM) illustrates the point and the problem, albeit in a different context. NAM is encouraging the United States Supreme Court to grant certiorari in *Motorola Mobility, LLC v. AU Optronics*, a case involving the extent to which U.S. antitrust laws apply to certain foreign transactions. There is a current conflict between how the Seventh and Ninth Circuits interpret the Foreign Trade Antitrust Improvement Act of 1982 (FTAIA). 15 U.S.C. § 6a. NAM takes no position on what the right outcome should be, but does express, most eloquently, the problem caused by lack of predictability and risk of inconsistent outcome:

> Needless to say, the risks (or benefits) of potential U.S. antitrust liability (or protection) and the financial consequences of getting it wrong are tremendous. Whether it is foreign suppliers or affiliates of U.S. companies seeking to minimize their legal risk or U.S. manufacturers seeking the protection of U.S. antitrust laws for their imports of intermediate

> manufacturing inputs, it is important for companies to know precisely how to accomplish such goals or to more effectively incorporate the risks and costs of foregoing those goals in the bargaining process.
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> Whatever the rule turns out to be, businesses must know such rule in advance in order to bargain for its application or avoidance. While bargaining is, of course, possible in situations of uncertainty, it is far more time consuming, expensive, and of uncertain effect when the application of the antitrust laws remains a matter of chance and judicial venue. The transaction costs of such uncertainty (and the consequences of error) are so high that they could put a meaningful damper on trade and increase the price of goods for U.S. manufacturers and consumers alike.

Amicus brief at 7-8.

In *Cipro*, as the conflict is between federal and state law, the United States Supreme Court cannot be expected to resolve any dispute[1]. If a pay-to-delay settlement is violative of any law (particularly the law of California, the largest state in the Union) then it is effectively something that any lawyer has to consider long and hard before counseling a client to proceed with (The Supreme Court's decision in *Actavis* suggested that parties could proceed with such settlements, albeit with caution). If so, how can anyone ever settle a case involving the intersection of intellectual property rights and antitrust? Are all such cases to be fought through trial and through appeals, or is there some way for the parties to cut the litigation Gordian Knot without running afoul of *Cipro*? The Supreme Court of California's ruling in *Cipro*, therefore, presents a significant problem, and one that cannot be remedied except by the California legislature.

It also stands as a timely reminder that when analyzing the risk that a planned course of action could subject a party to legal liability, a potential litigant must not only perform such an analysis under federal law ***but also*** under applicable state law. Although federal preemption law does not permit state laws to ***conflict*** with federal laws, potential litigants cannot assume that state courts will apply state laws in the same manner that federal courts have applied analogous federal laws. The states are generally free to apply their own laws in different fashion than the analogous federal antitrust law, and the differences can be quite material. For example, despite the fact that in 2007 in *Leegin Creative Leather Products, Inc. v. PSKS Inc.,* the United States Supreme Court applied a rule of reason approach in its analysis of whether resale price agreements violate federal antitrust law, in 2012, in *O'Brien v. Leegin Creative Leather Products, Inc.*, the Kansas Supreme Court held that any arrangement, contract, agreement, or combination "designed to" advance, reduce, or control prices, or that "tends to" advance, reduce, or control prices, is illegal and constitutes a *per se* violation of Kansas state antitrust law. Accordingly, cases like *Cipro* and the Kansas *Leegin* decision present cautionary tales for all who counsel clients on antitrust matters. State laws, as well as unresolved federal conflicts, remove predictability from the legal landscape.◆

[1] Though conflict preemption may always be argued, even in the absence of express or implied preemption, the Supreme Court cast serious doubt on the viability of such arguments when applied to differences between federal and state antitrust statutes in *California v. ARC America Corp.*, 490 U.S. 93 (1989).

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