Second Bites and the Search for a Standard: The DOJ's *Cipro* Brief

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LAST JULY, AT THE INVITATION OF the Court of Appeals for the Second Circuit, the Antitrust Division of the U.S. Department of Justice submitted an amicus brief in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, also known as *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.[1] The *Cipro* case is an appeal from a district court's determination that a "reverse-payment" settlement of a patent dispute between the manufacturer of a branded pharmaceutical product and a would-be generic entrant did not violate the antitrust laws. In its brief, the DOJ argues that reverse-payment settlements—which it had observed in previous cases are not necessarily anticompetitive—should be treated as "presumptively unlawful" because their "anticompetitive potential . . . is sufficiently clear."[2]

Consistent with its earlier amicus briefs and contrary to the Federal Trade Commission's current view that reverse-payment settlements should be banned as per se antitrust violations, the DOJ argues in the *Cipro* brief that such settlements must be reviewed under the rule of reason. Of course, the measure of the distance between "presumptive" and "per se" illegality is inversely proportional to the lengths to which defendants must go to rebut the presumption. In its *Cipro* brief the DOJ seeks to illuminate that space by articulating a standard that balances the public's interest in competition against private property rights, a standard that places a few extra stones on the public interest side of the scale, as shall be seen.

The *Cipro* case is not the first time the Second Circuit has wrestled with reverse-payment settlements; nor is it the first time the DOJ has commented on that Circuit's application of the antitrust laws to such settlements. Two years (and one administration) earlier, in a brief sbubmitted to the Supreme Court in response to the Court's "Call for the Views of the Solicitor General,"[3] the SG took issue with the standard that the Second Circuit applied in its *Tamoxifen* opinion.[4] As discussed further below, the DOJ recommended that the Supreme Court not grant cert in *Tamoxifen* because the case was a poor vehicle for resolving the questions presented. The DOJ nonetheless criticized the Second Circuit's standard as too weighted in favor of the rights of patent holders and the general interest in encouraging settlements.[5]

The FTC did not join that brief, and the case was one of several that found the DOJ and the FTC disagreeing about how the courts should address the issue of reverse-payment settlements. This disagreement had spilled into public view a year earlier when, in 2006, the SG recommended that the Supreme Court not review the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*.[6] That disagreement quickly broke down along partisan lines between the FTC and DOJ factions within the antitrust bar. On one side of the divide were those who tended to see antitrust issues in the pharmaceutical sector, including Hatch-Waxman settlements, as uniquely within the FTC's sphere of expertise and therefore entitled to great deference. On the other side of the issue were those who rejected the notion of industry-specific antitrust standards and who looked to the SG to balance competing public policy goals by encouraging, through judicious case selection, judicial development of clear, broadly applicable legal principles.

As in many partisan debates the focus tended to be on the implications of the dispute rather than on its substance. For example, there was never any disagreement between the agencies about whether reverse-payment settlements can be anticompetitive—every DOJ and FTC brief on the subject, including one that the agencies filed together,[7] clearly states that they can be. Rather, the issue was whether a standard could be devised for analyzing such settlements under the rule of reason that would enable antitrust condemnation of anticompetitive settlements while preserving an appropriate balance among the different policy goals of the U.S. Code, such as protecting competition, promoting innovation, and respecting intellectual property rights.

Against this backdrop, the DOJ's *Cipro* brief appears to have at least two goals: (1) fostering a public rapprochement with the FTC and (2) offering a standard according to which reverse-payment settlements may properly be examined under the antitrust laws. The first of these goals was a publicly stated intent of the Antitrust Division leadership that the new administration put in place in 2009. Jon Leibowitz, who had been a commissioner at the FTC before being elevated to Chairman in 2009 by President Obama, has repeatedly stated that under his leadership the elimination of "pay

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for delay" settlements—to use the FTC's preferred lexicon—will continue to be a top FTC priority.[8] When asked about the issue during her confirmation hearing before the Senate Judiciary Committee, Christine Varney—a former FTC commissioner herself and President Obama's nominee to be Assistant Attorney General in charge of the Antitrust Division—pledged to "work with the Department of Justice to align the Federal Trade Commission and the DOJ on the reverse payment issue."[9] So a DOJ brief that looks on reverse-payment settlements with great suspicion and refers favorably to the FTC's positions was to be expected.

The focus of this article is on the second of these goals, the standard that the *Cipro* brief advocates for evaluating such settlements. It rests on the theory—not found in the DOJ's earlier amicus briefs—that the public has an interest in the elimination of "undeserved patents" and that patent holders should therefore not be permitted to avoid the "statutorily imposed risk" of invalidation via litigation settlements.[10] Curiously, and in a sharp break from the DOJ's earlier amicus briefs, the *Cipro* brief also insists that examination of whether the patent holder likely would have prevailed had the litigation continued—which might indicate whether the patent may have been "undeserved" and thus whether the settlement's effect on competition goes beyond the scope of the patent—is "neither necessary nor appropriate."[11]

It is an extraordinary brief, especially when one considers what preceded it.

The Hatch-Waxman Act

The agreement at issue in the *Cipro* case arose in the context of the Drug Price Competition and Patent Term Restoration Act of 1984, better-known as the Hatch-Waxman Act,[12] which sought to facilitate generic entry while protecting the rights of IP holders. The Act makes it easier, faster, and cheaper for a generic firm to enter the market by allowing the filing of an "Abbreviated New Drug Application" (ANDA) that relies on the research and data previously provided to the FDA by the patent holder to establish the safety and efficacy of its product. The Act also established special procedures to resolve patent disputes. The development activity that precedes the filing of an ANDA, which might otherwise constitute an infringement of the patent holder's IP rights, was made exempt from infringement claims. But the filing of an ANDA was designated a constructive act of infringement so that the holder of the patent can take steps to enforce its rights before the generic hits the market.[13]

These procedures, which are unique to the pharmaceutical sector, re-allocate the risks inherent in all patent litigation. In other situations an entrant faces significant financial risks if it develops or markets a product that potentially infringes upon another's patent rights because the patent holder can wait until actual infringement occurs before taking legal action. Under Hatch-Waxman, a generic entrant can force the patent holder to initiate infringement litigation merely by filing an ANDA. Because at that stage it will not yet have made any infringing sales that would give rise to a claim for damages, nor incurred significant production or marketing costs that will have been wasted if the patent holder successfully blocks the generic's entry, the entrant's litigation risks are

Legislative Solutions?

■ THE DOJ FILED ITS *CIPRO* BRIEF DURING A TIME OF increased congressional attention to reverse-payment settlements. Bills such as the Preserve Access to Affordable Generics Act (S.369) and the Protecting Consumer Access to Generic Drugs Act (H.R. 1706), both of which would make such settlements per se violations of Section 5 of the FTC Act, have been introduced during the 111th Congress.

Although H.R. 1706 has not made it to the House floor as a stand-alone bill, a similar provision was included in the Affordable Health Care for America Act (H.R. 3962), the comprehensive health care reform bill that was approved by the full House on November 7, 2009. Section 2573 of that bill amends Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) to make reverse-payment settlements violations of the Act and grants the FTC the power to enforce the provision as if such settlements were violations of Section 5 of the FTC Act.

S.369, which enjoyed some bipartisan support, was introduced by Senator Herb Kohl, the Chairman of the Judiciary Committee's antitrust subcommittee and the senator who elicited AAG Varney's pledge to work to align the views of the DOJ and the FTC on the issue during her confirmation hearing. Although it was voted out of the Judiciary Committee on October 15, 2009, the bill has not yet been brought to the Senate floor for a vote and it was not included in the Patient Protection and Affordable Care Act, the health care reform bill passed by the full Senate last Christmas Eve.

On the day that the Senate approved its bill, Senator Kohl and several of his colleagues urged Senate Majority Leader Harry Reid to ensure that any final health care reform legislation include a provision like S.369. *See* Natasha Singer, *Deals to Restrain Generic Drugs Face a Ban*, N.Y. TIMES, Jan. 12, 2010. However, as this article goes to press it appears that this will not be possible. To avoid threatened Republican filibusters in the Senate the Democratic leadership in Congress has chosen to enact comprehensive health care reform via the Senate's budget reconciliation process. This requires the House to pass the Senate bill, which does not include the reverse-payment provision, so that the President can sign it into law and the Senate can then act on a separate package of "fixes" to address concerns that the House Democratic caucus has with the Senate bill. The House approved the Senate bill on March 21 and later that evening approved a package of fixes for the Senate to consider. That second bill did not include H.R. 3692's reverse-payment provision because the ban was not considered to be sufficiently budget-related to satisfy the Senate's reconciliation rules. *See* Christopher Norton, *Pay-for-Delay Ban Dropped from Health Care Bill*, LAW360, Mar. 18, 2010, *available at* http://www.law360.com/articles/156390. The ban could still move forward, of course, either as a stand-alone bill or in some other form, during this or a future Congress.

low. In contrast, the risks to the patent holder, whose IP rights could be invalidated as a result of the litigation it has been forced to initiate, are significant.

DOJ Views Pre-*Cipro*

The DOJ did not articulate its preferred standard in its pre-*Cipro* reverse-payment briefs. The *Andrx*,[14] *Schering*,[15] and *Joblove*[16] briefs were each CVSG briefs, in which the DOJ—specifically, the Solicitor General—provided the views of the United States regarding whether the Supreme Court should review an appellate court decision. In each brief the DOJ (joined by the FTC in *Andrx*) recommended against cert and the Supreme Court followed that recommendation. Had the Court granted cert and had it invited the SG to file a merits brief in any of those cases the DOJ likely would have laid out a standard, but that was neither necessary nor, arguably, appropriate in a series of "no cert" CVSG briefs.

Nevertheless, the DOJ did provide its general views about the issues raised by reverse-payment settlements and how they might properly be analyzed under the antitrust laws. For example, the DOJ argued that treating reverse-payment settlements as per se unlawful is inappropriate.[17] While supporting the proposition that settlements are generally to be encouraged, the DOJ also argued that such settlements are not per se lawful merely because they arise in the context of patent disputes. Outside such a context, the DOJ acknowledged, an agreement between two rivals pursuant to which one agrees not to compete with the other could well constitute an unreasonable restraint of trade.[18]

The DOJ was equally clear, however, that within that context such settlements are not necessarily anticompetitive. Indeed, "the settlement of a patent infringement claim will often involve restrictions on the sale of the product in question, and such a settlement is not necessarily impermissible or harmful to society."[19] Why not? Because "[a] patent grants the patent holder the lawful 'right to exclude others from profiting by the patented invention,'"[20] a right that allows patent holders lawfully to restrict competition by, e.g., "refus-[ing] to license competitors to produce the patented article" or "grant[ing] exclusive territorial or other limited licenses to one or more chosen licensees."[21]

Endowed with such rights, patent holders may nevertheless choose to narrow them when settling infringement disputes. Thus, as the DOJ explains in the *Joblove* brief, a patent holder might settle a Hatch-Waxman infringement action by agreeing that the generic challenger can enter the market prior to the expiration of the patent. It might also agree to give some other consideration, such as cash, to encourage the generic challenger to settle. The patent holder might reasonably do so, the DOJ offered, even if it believes that the likelihood of losing in court is small, because litigation is uncertain, the risks to the generic under Hatch-Waxman—and thus its incentive to settle—are very small, and the risks to the patent holder from patent invalidation are substantial.[22] The DOJ acknowledged that "[t]here may be particular reason for concern about the competitive consequences of a settlement that includes substantial payments from the patent holder to the alleged infringer" because "[s]uch payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market."[23] But it also observed that the Hatch-Waxman context creates a litigation dynamic that makes some reverse-payment settlements both expected and reasonable, even when the patent holder's claims may be strong.[24]

The fundamental premise that a valid patent gives its holder the lawful right to exclude others animates each of the DOJ's pre-*Cipro* briefs, as does the view that Hatch-Waxman creates incentives for reverse payments. However, the DOJ has also consistently recognized that the right to exclude is not unlimited, and that "competitive restraints adopted as part of a patent litigation settlement are subject to invalidation under the antitrust laws if the patent holder obtains 'protection from competition which the patent law, unaided by restrictive agreements, does not afford.'"[25] Thus, as the DOJ has repeatedly observed, "the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate patent holders' efforts to preserve weak patents." But "the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."[26]

While not proposing its own standard, the DOJ in these pre-*Cipro* briefs offered some thoughts in that direction. For example, in *Schering* the DOJ observed that the "competing considerations" described above "suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."[27] In *Joblove* the DOJ argued that before a court can condemn a settlement as a violation of the Sherman Act under the rule of reason the plaintiff must first establish that the agreement is "in fact unreasonable and anticompetitive."[28] If through the settlement the patent holder gained no more protection from competition than that afforded by the patent—if the terms of the agreement were within the scope of the patent's exclusionary power—the settlement likely did not violate the Sherman Act. Thus, examination of the limits of that exclusionary power is necessary. "[A]t a minimum," the DOJ said in *Joblove*, "[i]n determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court . . . should take into account the relative likelihood of success of the parties' claims, viewed *ex ante*."[29]

The DOJ's First Bite at the Apple: *Tamoxifen*

Three and a half years before the Second Circuit's *Cipro* panel invited the DOJ to submit its amicus brief, a different Second Circuit panel affirmed the Eastern District of New York's dismissal of an antitrust challenge to a Hatch-Waxman

settlement, focusing on the exclusionary scope of a patent and approvingly citing the Eleventh Circuit's *Schering* decision while doing so. In its *Tamoxifen* decision, the Second Circuit held that "so long as the patent litigation is neither a sham nor objectively baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly . . . ."[30] The court acknowledged that such a standard might lead to the preservation of "weak" patents, but noted that "the law allows the settlement even of [such] suits . . . with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly."[31]

Dissenting, Judge Pooler argued that the majority's standard was too deferential to the patent holder's rights and "insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws."[32] Judge Pooler argued that these different interests would be better served by application of a more stringent standard that focuses on "the strength of the patent as it appeared at the time at which the parties settled . . . ."[33] The majority rejected this approach, arguing that a review of the strength of the parties' competing patent claims would overly burden the review of a Hatch-Waxman settlement and thus "place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are to be encouraged."[34]

In its CVSG brief the DOJ agreed with the dissent's call for an examination of the parties' likelihood of success and noted that despite the majority's concerns "a limited examination of the merits of the claim . . . is hardly impossible."[35] Although it recommended against cert,[36] the DOJ argued that *Tamoxifen*'s "objectively baseless" standard was not sufficiently stringent and was too weighted in favor of the rights of patent holders and the general public interest in encouraging settlements.[37]

The *Cipro* Decision

Only months before the Second Circuit affirmed the district court's *Tamoxifen* ruling, a different judge in the same district issued the decision that has given the Antitrust Division's new leadership an opportunity to wade into the waters of Hatch-Waxman. Like the *Tamoxifen* appellate opinion, the district court's *Cipro* decision focused on the exclusionary power of the patent in granting summary judgment for the defendants, finding that "any adverse effects [of the settlement agreement that are] within the scope of the patent cannot be redressed by antitrust law."[38] Perhaps anticipating the Second Circuit's *Tamoxifen* decision, the district court, after reviewing other reverse-payment settlement cases (including the Eastern District of New York's *Tamoxifen* decision),[39] also eschewed as inappropriate any "after-the-fact inquiry into the validity of the underlying patent" and refused "to engage in an after-the-fact analysis of the patent's likely validity . . . ."[40]

The district court also refused "to discount the exclusionary power of the patent by any probability that the patent would have been found invalid."[41] This was a reference to an argument that the plaintiffs had put forward in response to the defendants' contention that as long as the settlement did not restrict competition beyond the scope of the patent it was within the bounds of the antitrust laws. Plaintiffs argued that "the exclusionary power of the patent for purposes of anticompetitive effects analysis should be tempered by its potential invalidity."[42]

These references to probabilities and potentialities can be traced to the FTC's *Schering* playbook. When it reversed the FTC in *Schering* the Eleventh Circuit emphasized that a valid patent gave Schering the lawful right to exclude infringing products from the market and that the settlements at issue were not unreasonable because their terms were within the scope of the patent's exclusionary power.[43] The FTC argued to the Supreme Court that such a "formalistic approach to the issue of the 'exclusionary potential' of [Schering's] patent ignores the most salient factor that gives rise to patent litigation and settlements, the existence of *uncertainty* regarding whether a patent is valid."[44] Drawing extensively on the work of economists Carl Shapiro and Mark Lemley,[45] the FTC argued that because any action brought to enforce a patent right could result in the invalidation of the patent, the property interest created by a patent is only a "probabilistic" right and thus "a patent is not a right to exclude, but rather a right to *try* to exclude."[46] Thus, for example, if there is a 50-50 chance that the patent will be invalidated, any settlement that includes an agreement that the generic will not enter the market for the remaining term of the patent, according to the FTC, denies consumers the expected value of "the 50 percent chance they had of enjoying the benefits of competition."[47]

Although the DOJ was only indirectly critical of "probabilistic patent" theory in its *Schering* CVSG brief,[48] the district court, presented with the argument that consumers have "a public policy right in the outcome of private lawsuits," was more direct. Such a theory, the court stated,

> does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (i.e., settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer.[49]

The district court also was not persuaded by plaintiffs' references to studies that purported to establish how probabilistic a patent right is by examining how patents tend to fare in litigation. To the district court, such an argument—absent any limiting principle—

> proves too much. To begin with the premise . . . that every patent is "a little bit invalid" results in undermining the presumption of validity that Congress has afforded patents. Moreover, [i]f [a reverse-payment settlement] is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty. . . . To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held

invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.[50]

The DOJ Takes a Second Bite: The *Cipro* Brief

In April 2009 the Second Circuit panel reviewing the *Cipro* decision invited the DOJ to address whether reverse-payment settlements violate the antitrust laws.[51] Precedents of a U.S. Court of Appeals may be overruled only by the full court en banc or by the U.S. Supreme Court, so it is not clear why the *Cipro* panel, bound as it is by the *Tamoxifen* decision, would seek to reopen that issue. The presence on the panel of Judge Pooler, author of the *Tamoxifen* dissent that the DOJ cited favorably in its *Joblove* brief, suggests that the panel may want to encourage the full circuit to revisit the *Tamoxifen* standard.

Whatever the panel's reasons, the DOJ's acceptance of the invitation was no surprise. As noted, the new leadership of the Antitrust Division had pledged to move the DOJ closer to the FTC's view on reverse-payment settlements. In that regard, while the *Cipro* brief stops short of embracing the per se standard favored by the FTC,[52] it comes closer to that standard than any of the DOJ's previous briefs. The DOJ, which once argued against subjecting reverse-payment settlements to "automatic or near-automatic invalidation,"[53] now argues that they "presumptively" violate Section 1 of the Sherman Act.[54]

In adopting that position, the DOJ appears to be seeking to rehabilitate the view that regardless of the scope of the patent at issue or the general public interest in encouraging settlements, private litigants' right to settle their cases must be tempered by the public's interest in the potential outcome of those cases. The DOJ's new embrace of this view may be explained by the fact that Carl Shapiro, one of the fathers of "probabilistic patent" theory, is now the Deputy Assistant Attorney General for Economics at the Antitrust Division.

The *Cipro* brief begins with the observation that animates the DOJ's previous reverse-payment settlement briefs: a patent gives its holder the right to exclude others. But whereas the earlier briefs then characterized the exclusionary power of a patent by referring to how the patent holder may lawfully restrict competition,[55] the *Cipro* brief instead—and immediately—notes that "[t]he Patent Act authorizes the patentee to enforce that right to exclude by filing an action for infringement."[56] This placement of the right to exclude into the context of a right to litigate is reminiscent of the FTC's *Schering* argument that a patent is only "a right to *try* to exclude." The DOJ thereby rejects the *Tamoxifen* standard because it upsets the balance struck in the Patent Act "between (1) encouraging innovation by providing for the enforcement of legitimate patent rights, and (2) protecting consumers' interest in a competitive marketplace by providing for the invalidation of undeserved patents."[57]

After then observing that settlements are generally to be encouraged,[58] the DOJ warns against going too far in that direction at the expense of competition: "This Court's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent . . . and offers no protection to the public interest in eliminating undeserved patents."[59] Citing an FTC study for support, the DOJ notes that "[t]here is a significant risk of invalidation through litigation" and that "patent litigation is inherently uncertain."[60]

Prior briefs reflected the DOJ's reluctance to infer anything from the fact that a settlement included a reverse payment; the DOJ repeatedly observed that such payments are to be expected in a Hatch-Waxman world and that they may be reasonable. The DOJ now believes that a reverse payment is best viewed as a "quid pro quo," the "quo" being the generic's agreement "to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation."[61] Quoting the FTC's *Schering* decision, the DOJ asserts that the "payment reveals the patent owner's lack of certainty about validity and its desire to avoid the risk of an invalidity determination. . . . '[T]he possible existence of a so-called 'reverse payment' [thus] raises a red flag that . . . mandates a further inquiry.'"[62]

But that inquiry is to be significantly truncated. Because "[t]he anticompetitive potential of reverse payments in the Hatch-Waxman context . . . is sufficiently clear . . . such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act."[63] Any daylight that might separate this standard from a per se rule is provided by the weak glow of defendants' right to rebut the presumption by showing that "the overall terms of the settlement did not 'impose[] an unreasonable restraint on competition' in view of their contemporaneous evaluations of the likelihood of an invalidity judgment."[64]

Under this standard a Hatch-Waxman settlement may still include some payment to the generic challenger. The DOJ explains that defendants clearly rebut the presumption if they can show that any such payment was commensurate with the patent holder's avoided litigation costs, which may include the costs of business disruption inherent in litigation.[65] But if the payment exceeds such costs, defendants will be unable to rebut the presumption if the settlement eliminates the possibility of competition prior to the expiration of the patent. In language reminiscent of Carl Shapiro's probabilistic patent theory, the DOJ observes that "[i]f all [Hatch-Waxman patent] cases were litigated to judgment, some would presumably [end in invalidity] thereby increasing generic competition in the aggregate."[66] Thus, according to the DOJ, the antitrust laws cannot permit a settlement that would restrict generic entry during the term of the patent, regardless of the patent's legal power to exclude such competition, because that would mean protecting undeserved patents from the risk of invalidity. To the DOJ, consumers' interests in potential invalidity judgments must be protected.

If the settlement (a) does not include a reverse payment in excess of the patent holder's avoided litigation costs and (b) provides for generic entry before the patent expires, defendants under the DOJ's proposed standard can rebut the presumption of illegality "by showing that the settlement preserved a degree of competition reasonably consistent with what had been expected if the infringement litigation went to judgment."[67] Thus, if the agreed generic entry date in the absence of any payment reflects the parties' contemporaneous and subjective evaluations of when generic entry might have occurred had the litigation continued to a judgment, the defendants may rebut the presumption.[68] The DOJ does not provide further guidance—e.g., whether defendant must waive applicable privileges and offer into evidence contemporaneous evaluations prepared by patent counsel—although it does state that it will not be enough for a defendant merely to show that it thought the patent's validity very likely would have been upheld or that its settlement would result in significant generic competition pre-patent expiration.[69]

The DOJ is quite clear, however, that it no longer thinks that the court should undertake an examination of whether the patent holder likely would have prevailed had the litigation continued. Although the DOJ had previously stated that "a court at a minimum should take into account the relative likelihood of success of the parties' claims,"[70] it now believes that such an examination is "neither necessary nor appropriate." Instead, "[l]iability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect."[71] In other words, the DOJ is taking the position that, because "all patents are at least a little bit invalid" and because the public has an interest in patent invalidation, no patent that becomes the subject of a dispute—or a settlement—can be presumed to be valid throughout its term to its expiration date. According to the DOJ's view the exclusionary scope of a patent, particularly its duration, does not describe the metes and bounds of what is permissible under the antitrust laws.

Conclusion

With its *Cipro* brief the DOJ's Antitrust Division has taken a strong position that reverse-payment settlements presumptively violate the antitrust laws. The new leadership has thereby fulfilled its pledge to move the DOJ closer to the FTC on this issue. It has also burnished some preferred theories that have not had an easy time in the courts thus far.

Advocating enforcement standards and sharing its views with the courts, the antitrust bar, the business community, the FTC, and the Congress (where legislation to ban reverse-payment settlements has been proposed—see sidebar), which the *Cipro* brief certainly does, is an important aspect of the Antitrust Division's mission. But competition advocacy aside, the practical relevance of the DOJ's *Cipro* brief is not clear. Should the Supreme Court decide to hear a reverse payment case sometime during the current administration, the brief may turn out to be a preview of what the SG, in consultation with the Antitrust Division, might say if invited by the Court to provide the views of the United States. In the near term, on the other hand, the views expressed by the DOJ in its *Cipro* brief may be more academic, because given the FTC's traditional role as civil antitrust enforcer for the pharmaceutical industry the DOJ will never actually evaluate a Hatch-Waxman settlement.

However, although the standard the DOJ offers in the brief is arguably targeted at such settlements, the policy that supports it—the idea that consumers have an interest in every patent suit that is equal to the expected value of the patent being invalidated—is not targeted. If the *Cipro* brief signals that the Antitrust Division intends to defer less to parties' intellectual property rights in the future and that the public's interest in eliminating undeserved patents limits litigants' freedom to settle patent disputes, the *Cipro* brief could prove to have relevance far beyond the relatively narrow Hatch-Waxman world.

Time will tell whether the *Cipro* brief is the next chapter in an ongoing antitrust saga, or merely its epilogue. ■

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1 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

2 Brief for the United States in Response to the Court's Invitation at 10, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, No. 05-2851 (2d Cir. July 6, 2009) [hereinafter *Cipro* Brief], *available at* http://www.justice.gov/atr/cases/f247700/247708.htm.

3 When the Court is considering whether to review a case that raises issues on which the views of the federal government might be relevant it will often invite the Solicitor General to file a "CVSG" brief expressing those views. Although characterized as an invitation from one branch of government to another, it is usually treated as tantamount to a command. *See, e.g.*, Richard L. Pacelle, Jr., *Amicus Curiae or Amicus Presidentis? Reexamining the Role of the Solicitor General in Filing Amici*, 89 JUDICATURE, May–June 2006, at 317, 319.

4 *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208–09 (2d Cir. 2005).

5 *See* Brief for the United States as Amicus Curiae at 14–15, Betty Joblove v. Barr Labs., Inc., No. 06-830 (S. Ct. May 2007) [hereinafter *Joblove* Brief], *available at* http://www.justice.gov/atr/cases/f223500/223525.htm.

6 402 F.3d 1056 (11th Cir. 2005).

7 Brief for the United States as Amicus Curiae, Andrx Pharm., Inc. v. Kroger Co., No. 03-779 (6th Cir. July 2004) [hereinafter *Andrx* Brief], *available at* http://www.justice.gov/osg/briefs/2004/2pet/6invit/2003-0779.pet.ami.inv.pdf.

8 *See, e.g.*, Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform 1 (The $35 Billion Solution), Remarks at the Center for American Progress (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.

9 *Nomination of Christine Anne Varney to be Assistant Attorney General in the Antitrust Division*, Hearing of the Senate Committee on the Judiciary, 111th Cong. (2009), 2009 WL 609975 (F.D.C.H.).

10 *Cipro* Brief, *supra* note 2, at 14.

11 *Id.* at 24.

12 Pub. L. No. 98-417, 98 Stat. 1585 (1984).

13 *See generally* Varma et al., *The FTC Reports on Follow-on Biologics and Authorized Generics: Applying Lessons Learned from Hatch-Waxman to Promote Competition*, ANTITRUST, Fall 2009, at 41, 41–42; *Cipro* Brief, *supra* note 2, at 1–3.

[14] *See supra* note 7. The *Andrx* case is perhaps better known by the brand name of the product at issue: Cardizem.

[15] Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., No. 05-273 (S. Ct. May 2006) [hereinafter *Schering* Brief], *available at* http://www.justice.gov/atr/cases/f216300/216358.htm.

[16] *See supra* note 5.

[17] *See, e.g.*, *Andrx* Brief, *supra* note 7, at 7 (per se rule "is reserved for conduct that has a predictable and pernicious anticompetitive effect"). Despite disapproving of the Sixth Circuit's per se standard the agencies recommended against cert in *Andrx* because in their view the case was not an appropriate vehicle for resolving the questions presented. The agencies noted that the district court had construed the agreement as covering not only the allegedly infringing products that were the subject of the patent litigation but also non-infringing products that were beyond the scope of the patent. The agreement was also an interim agreement that did not actually settle the dispute.

[18] *See, e.g.*, *Andrx* Brief, *supra* note 7, at 8; *Schering* Brief, *supra* note 15, at 8.

[19] *Joblove* Brief, *supra* note 5, at 9.

[20] *Andrx* Brief, *supra* note 7, at 8 (quoting Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980)). *See also* The Patent Act, 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant . . . of the right to exclude others from making, using, offering for sale, or selling the invention."); *Schering* Brief, *supra* note 15, at 8–9; *Joblove* Brief, *supra* note 5, at 9–10.

[21] *Andrx* Brief, *supra* note 7, at 8. *See also Schering* Brief, *supra* note 15, at 9; *Joblove* Brief, *supra* note 5, at 9.

[22] *See Joblove* Brief, *supra* note 5, at 9–10.

[23] *Schering* Brief, *supra* note 15, at 9. *See also Joblove* Brief, *supra* note 5, at 10; *Andrx* Brief, *supra* note 7, at 9.

[24] *See, e.g.*, *Schering* Brief, *supra* note 15, at 11; *Joblove* Brief, *supra* note 5, at 10.

[25] *Schering* Brief, *supra* note 15, at 9 (quoting United States v. Masonite Corp., 316 U.S. 265, 279 (1942)). *See also Andrx* Brief, *supra* note 7, at 9; *Joblove* Brief, *supra* note 5, at 10.

[26] *Schering* Brief, *supra* note 7, at 10. *See also Joblove* Brief, *supra* note 5, at 11.

[27] *Schering* Brief, *supra* note 7, at 11.

[28] *Joblove* Brief, *supra* note 5, at 12 (citing Texaco Inc. v. Dagher, 126 S. Ct. 1276, 1279 (2006)).

[29] *Id.* at 12. *See also Schering* Brief, *supra* note 7, at 11.

[30] *Tamoxifen*, 466 F.3d at 208–09.

[31] *Id.* at 211.

[32] *Id.* at 224 (Pooler, Circuit Judge, dissenting).

[33] *Id.* at 228.

[34] *Id.* at 212 n.26.

[35] *Joblove* Brief, *supra* note 5, at 13.

[36] *See id.* at 16–20. Among other reasons cited by the DOJ, petitioners' injunctive and declaratory Sherman Act claims had been mooted by the expiration of the patent, as a result of which the settlement agreement was no longer in effect.

[37] *Id.* at 14–15 ("While it is true that the law generally encourages settlements, the Patent Act does not embody a policy of promoting the interests of patent holders at all costs.").

[38] *Cipro*, 363 F. Supp. 2d at 524.

[39] *Id.* at 524–30.

[40] *Id.* at 530, 539.

[41] *Id.* at 539.

[42] *Id.* at 524.

[43] *See* Schering-Plough Corp. v. FTC, 402 F.3d at 1066.

[44] Petition for a Writ of Certiorari at 15, FTC v. Schering-Plough Corp., No. 05-273, 2005 WL 2105243 (S. Ct. Aug. 29 2005) [hereinafter FTC *Schering* Petition).

[45] *See, e.g.*, Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP., Spring 2005, at 75.

[46] FTC *Schering* Petition, *supra* note 44, at 16 (quoting Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1761 (2003) (citations omitted)).

[47] *FTC Schering* Petition, *supra* note 44, at 17–18.

[48] *See Schering* Brief, *supra* note 15, at 11–12. The DOJ avoided a direct assessment of the theory's merits and argued that the Supreme Court could as well, because the theory had not yet been considered by the courts of appeals—neither by the Eleventh Circuit in the case below nor in any other circuit. *Id.* at 16.

[49] *Cipro*, 363 F. Supp. 2d at 531–32. The court further stated that "[r]equiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest . . . is, as a practical matter, tantamount to establishing a rule requiring litigants 'to continue to litigate when they would prefer to settle' and 'to act as unwilling private attorneys general . . . .'" *Id.* at 532 (quoting Nestle Co., Inc. v. Chester's Market, Inc., 756 F.2d 280, 284 (2d Cir. 1985)).

[50] *Cipro*, 363 F. Supp. 2d at 533.

[51] *See Cipro* Brief, *supra* note 2, at 1. The court also asked for the government's views regarding whether the court had jurisdiction over the appeal if the decision would involve a determination of the validity of a patent. The court had earlier transferred one of the three cases that had been consolidated into the *Cipro* case to the Federal Circuit because it involved a *Walker Process* claim. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965). The Federal Circuit held that a reverse payment settlement that has no anticompetitive effect outside the scope of the patent does not violate the antitrust laws. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008). On June 22, 2009, two weeks before the DOJ filed its amicus brief regarding the portion of the *Cipro* case that is still pending before the Second Circuit, the Supreme Court declined to grant cert in the Federal Circuit portion of the case.

[52] *See, e.g.*, Statement of FTC Chairman Jon Leibowitz in response to Senate Judiciary Committee's Passage of Preserve Access to Affordable Generics Act (S. 369) (Oct. 15, 2009) (supporting legislation that would make per se unlawful any patent settlement in which the ANDA filer receives "anything of value" in exchange for "agreeing not to research, develop, manufacture, market, or sell the [generic] for any period of time"), *available at* http://www.ftc.gov/opa/2009/10/pfdvote.shtm.

[53] *See Joblove* Brief, *supra* note 5, at 11.

[54] *Cipro* Brief, *supra* note 2, at 22.

[55] *See, e.g*, *Joblove* Brief, *supra* note 5, at 9; *Andrx* Brief, *supra* note 7, at 8; *Schering* Brief, *supra* note 15, at 9.

[56] *Cipro* Brief, *supra* note 2, at 11.

[57] *Id.* at 13.

[58] *Id.* at 13–14.

[59] *Id.* at 14–15.

[60] *Id.* at 15, 16.

[61] *Id.* at 22. *See also id.* at 19 ("a substantial payment for an agreement to withdraw a patent validity challenge strongly implies that the payor recognized a significant risk of patent invalidation through litigation").

[62] *Id.* at 26–27 (quoting Schering-Plough Corp., 136 F.T.C. 956, 991 (2003), *vacated*, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005)).

[63] *Id.* at 10.

[64] *Id.* at 28 (internal citations omitted).

[65] *Id.* at 28–29.

[66] *Id.* at 30.

[67] *Id.*

[68] Id. at 30–31.

[69] *Id.* at 31.

[70] *Joblove* Brief, *supra* note 5, at 12. *See also Schering* Brief, *supra* note 15, at 11 (same).

[71] *Id.* at 24, 25. In a footnote, the DOJ refers to its suggestion, in its *Joblove* brief, "that a court should conduct a limited evaluation of the claims in the settled patent litigation" and acknowledges "some tension between statements" made in that brief and its "current views." *Id.* at 26 n.9.