JONES DAY

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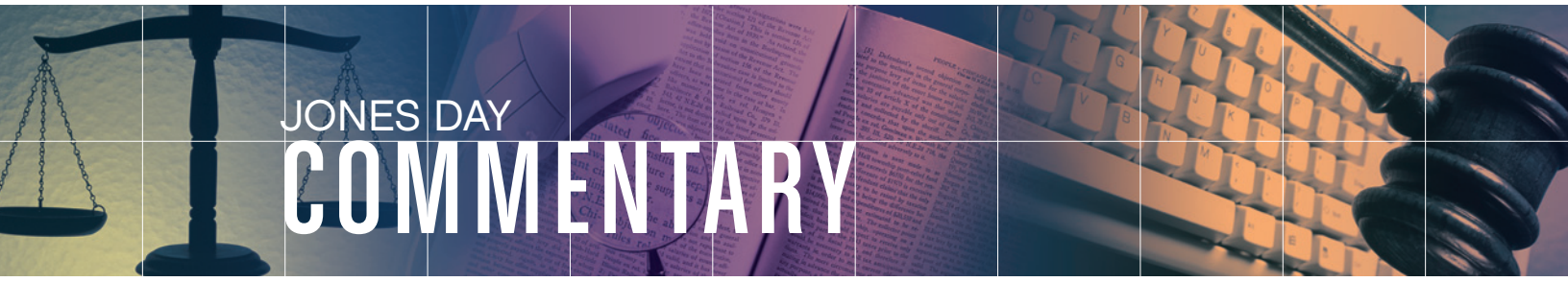

ANTITRUST RISKS IN SETTLING PATENT CASES: THE FTC AND CONGRESS CONTINUE THE ATTACK, WHILE THE COURTS CONTINUE TO BE UNIMPRESSED

On three consecutive days this month, new shots were fired in the ongoing battle over so-called "reverse payment" patent settlements in cases brought under the federal statute governing the introduction of generic pharmaceuticals.

- On February 2, 2009, the FTC filed a complaint in California federal court attacking as anticompetitive the settlement of a patent infringement claim involving AndroGel, a testosterone replacement drug. The FTC alleged that the patent holder had made reverse payments (disguised as a "co-promotion" arrangement) for the generic company's agreement to stay out of the market.
- On February 3, Senators Kohl, Grassley, Feingold, Durbin, and Brown echoed their support of the FTC by reintroducing a bill (which had languished in the last Congress) declaring all patent settlements under the Hatch-Waxman Act that contain reverse payments to be *per se* illegal under the antitrust laws.
- On February 4, however, yet another federal court opinion flatly rejected the FTC's position that settlements with reverse payments are necessarily anticompetitive. Echoing the Second, Eleventh, and Federal Circuits, the opinion stated that, as long as the infringement claim was brought in good faith (that is, was not "objectively baseless"), a settlement that excludes no more competition than the face of the patent itself cannot harm competition.

These events arise from a highly unusual set of circumstances and, many would say, unprecedented policy choices by the FTC. Taking the view that certain settlements of patent cases hinder the introduction of generic drugs, the FTC has aggressively sought to stifle them. In 2003, for example, the Commission conducted a full administrative proceeding and condemned a settlement as anticompetitive in a case against Schering-Plough. In litigation to enforce its views, however, the FTC has failed dismally to per-

suade the courts. The judges, both Democrat and Republican, and many highly distinguished, have observed that the FTC's theories of competitive harm prove too much and ignore the inherent effect of the patent right. Thus far, four appellate panels—including the one that reversed and vacated the FTC decision in *Schering-Plough*—have emphatically rejected the FTC view.

The FTC's woes continued when it sought Supreme Court review in *Schering-Plough* and could not persuade the Solicitor General to support its petition. The FTC promptly filed the petition on its own, only to have the Supreme Court impishly request "the views of the United States" on the FTC's petition. That led to the spectacle of one antitrust enforcement agency (the SG and the DOJ Antitrust Division) successfully opposing the cert. petition of the other.

The FTC has not taken this well. In 2007, it asked Congress to do something it has never done before: to declare *per se* illegal a specific practice (settlements with payments) in a specific industry (pharmaceuticals). There is no precedent for a federal antitrust agency seeking to enact its policy choices by statute when it has been unable to demonstrate that it has a competitive rationale for doing so. The bill that Congress has before it, moreover, would ban all Hatch-Waxman settlements that convey "anything of value" to the generic filer. The exceptions are so narrowly drawn that they would likely disqualify the bulk of Hatch-Waxman settlements whether or not they contain actual cash payments. The intent appears to be to severely limit the number of settlements overall and to convert the FTC into a close regulator of what settlements may or may not occur.

In the meantime, the FTC has employed its administrative power to achieve its goals even without judicial support. The FTC staff thus continues to monitor all such patent settlements, effectively ending the use of reverse payments through the threat of expensive and burdensome "investigation." Even in the absence of cash, moreover, the FTC will often characterize the other terms of a settlement (such as cross-licensing other products, or even making the generic an exclusive licensee) as a "reverse payment" subject to condemnation.

What these latest developments reflect is that the antitrust debate over reverse payments in particular, and patent settlements in general, will rage on, especially during the early years of the Obama administration. Nevertheless, the Court decisions continue to demonstrate that the FTC will need a new statute if it is ever to win this war. So far, the antitrust laws, which proscribe only injuries to the competitive process, have not been enough.

WHAT IS A REVERSE PAYMENT?

To define a "reverse payment" settlement requires a general—here, quite simplified—description of the FDA's Hatch-Waxman procedures. When a branded drug company obtains FDA approval of a new drug application ("NDA") for a branded or "pioneer" drug, it lists any patents that claim the drug in the FDA's register, known as the "Orange Book." When another company seeks approval to market a generic copy of that drug, it need only file an *abbreviated* new drug application ("ANDA"), establishing that the generic is bioequivalent to the branded drug. If the ANDA filer seeks approval to market the generic drug prior to the expiration of any listed patent, it must make a so-called "ANDA IV certification" that the patent is invalid or not infringed.

Upon notice of the ANDA IV filing, the branded company has 45 days to file an infringement suit. If it does so, the FDA may not grant final approval of the ANDA for 30 months, unless the generic should win the patent suit beforehand. The reverse payment settlement occurs when the parties to the patent case settle, with the generic agreeing not to enter the market for a period of years (or until the patent expires) and the branded company providing the generic with payments. Because these payments flow from the patent holder to the challenger, unlike royalty payments—which flow from the licensee to the patent holder—they are labeled "reverse" payments.

For the FTC and others opposed to reverse payments, such settlements are little more than market division agreements, in which a competitor pays a potential entrant to stay out of the market. In such settlements, they argue, consumers

should be given the benefit of any uncertainty as to whether the patent would have been able to exclude the generic product. The presence of cash payments, in their view, necessarily means that generic entry will occur later than it otherwise would. Because earlier entry would be better for consumers, payments that necessarily defer entry are presumptively anticompetitive.

The opposing group, including the majority of judges to address the issue, challenges both the assumptions and conclusions of the first view. A patent by its nature excludes infringing competition, and virtually all agreements to market a patented good (including all licenses) would be *per se* illegal but for the patent. The antitrust laws, however, do not protect competition that infringes an intellectual property right, and they place the burden on the plaintiff to show that the competition allegedly excluded would have been lawful. Thus, the issue is whether the settlement agreement, like any other patent agreement, excludes more competition than would enforcement of the patent. As one court put it, "Whether [the attack on reverse payments] is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass*, 289 F.Supp. 2d at 994. Under this view, neither the fact nor amount of cash from the branded company matters if the competition would not have been permitted in the first place.

THE COURTS HAVE THUS FAR REJECTED THE FTC VIEW

The Courts have overwhelmingly accepted the defendants' view that a "reverse payment" settlement within the exclusionary effect of the patent does not harm competition. At this date, decisions in favor of the settling defendants have been rendered by the Eleventh Circuit in two separate cases (*Valley Drug* and *Schering-Plough*), by the Second Circuit (*Tamoxifen*), and by the Federal Circuit (*Ciprofloxacin*). In addition, the influential Judge Richard Posner, while sitting by designation as a District Judge, dismissed a similar complaint (*Asahi Glass*).

Recognizing that all settlements involve the exchange of consideration to eliminate litigation risk, these courts have pointed out that reverse payments are not "reverse" at all, but a "natural by-product" of Hatch-Waxman, which allows the generic to challenge and perhaps set aside a valuable patent with no risk of paying damages. Accordingly, they have focused not on the payments, but on the "exclusionary" scope of the patent. They have rejected the plaintiffs' theory that every patent should be considered "a little bit invalid," and that the antitrust laws give consumers a "property right" in the chance that the patentee might have lost the litigation. "This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right." *Ciprofloxacin*, 363 F. Supp. 2d at 532. They have also rejected the FTC's theory that, if payments were not permitted, the patent case would have settled with earlier entry dates. An agreement is not unreasonably anticompetitive under the antitrust laws simply because one can imagine a more competitive agreement, and hence "consumers have no right to second-guess whether some different agreement would have been more palatable."

Even the one appellate decision in favor of the plaintiffs—the Sixth Circuit's decision in *Cardizem*—involved a settlement that the court found to extend the patent's exclusionary effect. (That is, the formulation patent at issue excluded only *some* generic versions of the drug, but the settlement allegedly provided that the ANDA filer would refrain from entering with *any* generic version.) While some plaintiffs argue that *Cardizem* represents a *per se* rule against payments, the subsequent courts have easily distinguished it as involving a settlement beyond the scope of the patent. Indeed, the FTC later stated, in a brief to the Supreme Court in *Cardizem* itself, that the decision should not be read as a *per se* rule against reverse payments because any such holding would be "erroneous."

The most recent appellate Court to subscribe to the prevailing view was the Federal Circuit in its October 2008 decision in favor of Jones Day client Bayer AG (*Ciprofloxacin*). At this point, the clear majority rule is the one first articulated

by Judge Posner in *Asahi Glass*, and since echoed by the Eleventh, Second, and Federal Circuits: "unless and until the patent is shown … to be 'objectively baseless,' there is no injury to the market … as long as competition is restrained only within the scope of the patent." *Tamoxifen*, 466 F.3d at 213.

THE FTC ATTACK CONTINUES

The FTC has been undeterred by these losses. As a practical matter, the FTC can pursue its own view of the law until every Circuit has ruled against it. The Commission has stated publicly, therefore, that it is seeking ways to obtain a decision from a different Circuit consistent with its view of reverse payments. In the meantime, the FTC staff has undertaken a broad program to scrutinize Hatch-Waxman settlements.

FTC Staff "Investigations." In 2003, Congress amended Hatch-Waxman to require all parties settling ANDA litigation to give notice to the FTC within 10 days, disclosing the terms of the settlement and any related agreements. This notification is after the fact: The FTC is neither required nor willing to give prior approval to a settlement. The FTC is simply free to make whatever subsequent inquiries or other investigation it deems fit. The effect of this process has been to place most settling parties in a suspended state of "investigation" by the FTC staff, which will periodically ask for more information or raise new questions. There is no set procedure and generally no point at which the staff concedes that it has concluded its review.

The FTC reports to Congress annually on the quantity and nature of the settlements filed with it. In recent reports, it has asserted that many of the settlements reflect a "return" of reverse payments, a development it attributes to the Court decisions in favor of the settling parties. The irony is that, to our knowledge, none of the settlements they so characterize contain actual cash payments of the kind that the FTC has condemned and the courts have approved. (Hatch-Waxman litigants understand that the inclusion of such payments will result in a burdensome investigation, and thus we have seen no use of actual direct payments since the early 2000s.) Instead, the FTC has discovered "payments" in the other terms of a settlement, such as cross licenses or other provisions unrelated to the generic's starting date. Members of the staff have stated publicly that even a license may be regarded as a reverse payment if the patentee makes it wholly exclusive by agreeing not to market its own authorized generic.

FTC Litigation. Despite its level of concern and activity, the FTC has filed few actual complaints against settlements, and it has issued only one opinion, in *Schering-Plough*. Since its defeat in that case, the FTC has eschewed its own administrative process, acknowledging that most respondents could successfully appeal any order the FTC would issue to the Second or Eleventh Circuits. It has opted instead to file direct actions in federal district courts located in other Circuits. The first of these was its complaint in early 2008 against Cephalon, the maker of Provigil, filed in the District of Columbia. The reverse payments there consisted of various cross-licenses to four generic challengers alleged to be pretexts for direct payments. However, the D.C. court promptly transferred *Cephalon* to the Eastern District of Pennsylvania, where private cases attacking the same settlement had long been pending. (The FTC's objection to the transfer on the ground that its choice of forum should be sacrosanct was undermined by its public statements that it was shopping for a forum where it might win.)

***FTC v. Watson Pharmaceuticals*, No. CV09-00598 (C.D.Cal.).** The second such complaint was filed by the FTC on February 2, 2009, in the Central District of California. It attacks a patent settlement by Solvay with Watson and two other generic companies concerning the branded drug AndroGel. The FTC alleges that the settlements' "co-promotion agreements" constituted a reverse payment and that the settlement harmed competition by eliminating the "potential" for three things: (1) that the generic challengers would have gone to market "at risk" during the pendency of the patent case; (2) that the generics would have won the patent case had it been tried; and (3) that the parties would have entered into a different settlement with an earlier entry date for the generic.

While no new theories of competitive harm appear in the complaint, the FTC continues to broaden the range of legal grounds for relief. Whereas prior cases have focused on

Section One of the Sherman Act, which proscribes conspiracies in restraint of trade, the AndroGel complaint also bases its claims on Section Two (for monopolization by Solvay alone), Section 5 of the FTC Act (for unfair methods of competition), and California state statutes concerning antitrust and unfair competition.

WILL IT TAKE AN ACT OF CONGRESS?

On the day after the FTC's *Watson* complaint, several senators expressed their support by introducing a bill to ban reverse payments altogether. S.369 is essentially identical to a bill proposed in the last Congress, which had been voted out of Committee but never acted upon. There is no doubt that the FTC has been the driving force behind this legislation. Commissioner Leibowitz, likely the next FTC Chairman, testified in 2007 on the need for such a bill before it ever existed. And the Senate bill later drafted contains language taken verbatim from the FTC's vacated order in *Schering-Plough*.

That language, moreover, is exceptionally broad. It would amend the Clayton Act to prohibit any agreement resolving a "patent infringement claim" in which "an ANDA filer receives anything of value." S.369, §29(a)(1). The term "patent infringement claim," in turn, is defined to include any allegation, in public or in private, that an ANDA product would infringe any patent held by the branded company. By their terms, those provisions arguably would outlaw all ANDA settlements and a high proportion of private licenses, which are often negotiated when one party asserts a patent with respect to the licensed product.

The only exception in the statute is for a settlement that has a single negotiated provision: the date on which the generic challenger may enter with the ANDA product. Beyond that, the statute gives the FTC authority to promulgate rules that would "exempt certain agreements" it finds competitively acceptable.

Whether this bill will pass in its current form is unclear. If enacted as written, it would likely curtail Hatch-Waxman settlements severely. The settlements it permits—based on splitting the remaining patent term—are often infeasible because the parties value the time granted under a license differently. That is, the branded company loses far more profit by giving up a year at higher prices than the generic gains by adding a year at lower prices. Yet any other provision that seeks to close the gap by limiting the license or by cross-licensing other products will convey "value" that the statute forbids. And converting the FTC in this context from its historical role as an antitrust law enforcer into a regulator—governed by only the vaguest of standards—will add great uncertainty and risk to any ANDA patent litigation.

THE COURTS REMAIN UNMOVED

The third consecutive day in this series of Hatch-Waxman events brought a stark reminder that it may take a new statute to create a legal ban on reverse payments. On February 4, a Special Master assigned to the private antitrust class actions involving the potassium supplement K-Dur issued an opinion recommending summary judgment in favor of the settling defendants. *In re K-Dur Antitrust Litigation*, C.A. No. 01-1652 (JAG) (D.N.J. 2009). This opinion is noteworthy because the case arises from the very same settlement that the FTC struck down in *Schering-Plough*, only to be reversed by the Eleventh Circuit.

The Special Master (a former federal district judge once nominated by President Clinton to the Third Circuit) concluded that a settlement within the scope of a valid patent cannot harm competition. The Master "decline[d] to adopt the 'FTC/Hovenkamp' framework proposed" by the plaintiffs in which payments are presumptively illegal, because it "effectively discounts the fact that Schering's '743 Patent gave it the right to exclude infringing competitors. Moreover, it essentially requires a presumption that if the patent holder pays money to the generic company, the patent at issue must be either invalid or not infringed." The Master also "decline[d] to discount the exclusionary power of Schering's patent based on the *possibility* that it was not infringed." Finally, the Master declined "to conduct an ex post inquiry into the infringement issues that were resolved by the parties' settlement." Such issues would be considered "only [as necessary] to determine whether Schering's patent lawsuits were objectively baseless."

The Special Master's recommendation will be considered by the District Court and, if adopted, may be appealed to the Third Circuit. There is no guarantee that the Third Circuit will agree with the Circuits that have ruled to date. What is clear is that a reversal of the current opinion in *K-Dur* would be a result that "the weight of authority counsels against."

CONCLUSION

Parties settling any patent litigation, but most especially Hatch-Waxman ANDA litigation, face serious antitrust risks. Simply avoiding the use of direct payments is no safe harbor, because government enforcers continue to find payments in other, cashless provisions that—unsurprisingly—convey "value." This trend will only be heightened by the new administration, which will no doubt encourage, rather than provide a check on, the FTC's views in this area. And the proposed legislation in Congress could make the possibility of a legally safe Hatch-Waxman settlement remote indeed. To date, however, the courts have continued to remind all involved that, whatever the problem with reverse payments may be, it is not an antitrust problem.

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