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Reverse Payment Terms in ANDA Settlement Agreements

David F. Ryan · Wednesday, June 22nd, 2011

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Never ask for whom the bell tolls.

Computer and Internet lawyers should be following developments in the law affecting the rights of innovator and generic pharmaceutical manufacturers to settle their Hatch-Waxman patent infringement litigations on terms that include "reverse payment" provisions for three reasons: (1) because all industries must be sensitive to efforts by the antitrust enforcement authorities to limit the freedom of parties to patent infringement disputes to settle those disputes on economically acceptable terms; (2) because the same "asymmetries" in leverage that skew the economics of Hatch-Waxman settlements have parallels in several areas of patent litigation important to computer and Internet lawyers; and (3) because the Federal Trade Commission (FTC) already has attempted to interfere in an important litigation involving the settlement of such a dispute between parties to a research joint venture (RJV) and a significant standard setting organization (SSO) involving data storage media.

On March 7, 2011, the U.S. Supreme Court denied a petition for *certiorari* that sought review of the decision of the Court of Appeals for the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (*Cipro V*) (*Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, CCH 2010-1 Trade Cases ¶76,989 (2d Cir. 2010), *cert. denied sub nom., Louisiana Wholesale Drug Co. v. Bayer AG*, Dkt. No. 10-762). That petition represented a challenge by a number of direct purchaser antitrust treble damages plaintiffs to the twin determinations by the Second Circuit in *Cipro V* that "reverse payment" terms in settlement agreements terminating Abbreviated New Drug Application (ANDA) infringement litigations under the Hatch-Waxman Act were not presumptively unlawful, and that the Court of Appeals would adhere to the rule that it had announced in its decision in *In re Tamoxifen Citrate Antitrust* Litig. (466 F.3d 187, CCH 2006-2 Trade Cases ¶75,382 (2d Cir. 2006), *cert. denied sub nom., Joblove v. Barr Labs., Inc.* (2007)) more than five years ago.

The rule of *Tamoxifen*, sometimes referred to in this article as the "consensus rule," provides that, unless at least one of three types of misconduct can be established, reverse payment terms in Abbreviated New Drug Application (ANDA) settlement agreements will be upheld against challenges under the antitrust laws:

> Unless and until [1] the patent is shown to have been procured by fraud, [2] or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, [3] as long as competition is restrained only within the scope of the patent [citing *Cipro III*] (In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp.2d 514, 535, CCH 2005-1 Trade Cases ¶74,777 (E.D.N.Y. 2005)).

> We further agree with the Cipro III court that [3] absent an extension of the monopoly beyond the patent's scope * * * * and [1] absent fraud * * * * [2] the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits". (*Tamoxifen,* 466 F.2d at 213 (numerical brackets supplied), *citing Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60, CCH 1993-1 Trade Cases ¶70,207 (1993)).

As can be seen, the consensus rule announced by the Second Circuit in *Tamoxifen* explicitly engrafts the Supreme Court's holding in *PRE* onto the controlling test.

In *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus*. (*PRE*), the Supreme Court ruled that before initiation of an intellectual property infringement lawsuit can be proscribed under the antitrust laws, a two-part test must be satisfied:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . . . Only if challenged litigation is objectively baseless may a court examine the litigant's subjective motivation . . . . .This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

If the enforcement agencies elect to continue their campaign against reverse payment terms in ANDA settlements, they should be forced to finally come to grips with the *PRE* decision that they have already succeeded in avoiding for more than 10 years.

The denial of *certiorari* in *Cipro V* represents the final chapter of yet another setback story in the almost unbroken chain of Court of Appeals losses that the FTC has suffered during its campaign to establish the *per se* or presumptive illegality of reverse payment terms in ANDA settlements. In the courts, the FTC apparently had abandoned its initial advocacy for a per se rule before the end of 2003. The FTC also joined in the SG's 2004 brief to the Supreme Court in *Andrx v. Kroger*, which argued that, although the underlying *Cardizem* decision in the Sixth Circuit had purported to apply a per se rule, it was not really a per se case at all; rather, it involved a species of type (3) misconduct in which the terms of the settlement agreement extended to non-infringing formulations that did not fall within the scope of the claims. Elsewhere, however, the FTC appears less punctilious as evidenced by the very first numbered page of a recent staff study brochure,

which refers to the *Cardizem* case as holding "that such agreements were automatically (or per se) illegal." Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions—An FTC Staff Study (January 2010).

The public phase of this lengthy campaign, which has involved administrative litigations, consent judgments, *amicus* filings, and, most recently, support for legislation, celebrated its 11th anniversary just this month. It began on March 16, 2000, with the announcement of a proposed consent judgment in *In re Abbott Labs*. (FTC Dkt. No. C-3945) and the filing of an administrative complaint in *In re Hoechst Marion Roussel, Inc*. (FTC Dkt. No. 9293). The organization of the FTC's Web site has been vastly improved over the past several years. Whether or not that improvement can be attributed to the technological orientation of the Obama administration, it now seems superfluous to provide lengthy Internet citations to the specific locations of FTC docket entries and *amicus* briefs.

The denial of *certiorari* in *Cipro V* is also noteworthy because, amid a wave of publicity in 2009, the Department of Justice (DOJ) had announced that it would align itself with the FTC for the first time in *Cipro V* and seek application of a rule of presumptive illegality to ANDA reverse payment settlement agreements. Pursuant to this new stance, the DOJ filed a "Brief for the United States in Response to the Court's Invitation" on July 6, 2009, and a "Brief *Amicus Curiae* of the United States in Support of Rehearing *En Banc*" on June 3, 2010.

The Supreme Court's denial of *certiorari* in *Cipro V* was proper (1) because the Second Circuit merely reiterated the consensus rule of *Tamoxifen*, which it had announced more than five years ago; (2) because the petition raised no novel issues; (3) because alteration of the consensus rule might well undermine the Congressional purpose of maximizing patent challenges by generic pharmaceutical manufacturers under the Hatch-Waxman Act as well as the more general public policy objective of encouraging settlement of other types of patent litigation (at least in areas where similar asymmetries in settlement leverage are known to exist); (4) because predictions of success or failure in patent litigation are inherently uncertain and *post hoc* assessments of patent strength are even less reliable; (5) because lowering the bar for antitrust challenges to patent settlements inevitably would result in a chilling effect on such settlements that, in turn, might lead to across the board R&D budget reductions at both generic and innovator pharmaceutical manufacturers; (6) because the antitrust enforcement authorities have never proposed any realistic alternative to the *Tamoxifen* rule; and (7) because the FTC and DOJ have both refused to confront the fact that the *Tamoxifen* rule is itself inextricably intertwined with the Supreme Court's *PRE* decision and that, accordingly, any alteration of that rule might require that *PRE* itself be overruled or modified. Manifestly, no Court of Appeals would have the power to make such a change.

As yet, there has been no indication that the denial of *certiorari* in *Cipro V* will lead the FTC or the DOJ to acquiesce in the consensus rule of *Tamoxifen*. Indeed, remarks made by FTC Chairman Jon Leibowitz at Georgetown Law Center on September 21, 2010, indicate rather clearly that the FTC intends to press its campaign on both the legislative and litigation fronts. In any event, several high-profile FTC reverse payment ANDA settlement litigations are currently pending in at least the Third and Eleventh Circuits, and it is expected that prior legislative proposals to alter the consensus rule of *Tamoxifen* will be renewed before the current Congress.

Both of the enforcement agencies remain dissatisfied with the consensus rule of *Tamoxifen*, and indeed that dissatisfaction on the part of the DOJ may well have led to the belated support offered by the Antitrust Division for the FTC's fallback theory of presumptive illegality in 2009. Both of

the agencies likewise appear dissatisfied with the Supreme Court's decision in *PRE*, a decision that neither agency even attempted to deal with in any appellate brief for a period of more than 10 years. That 10-year period finally ended last summer with the filing of the FTC's *Watson* appeal brief with the Eleventh Circuit ("Brief for Plaintiff-Appellant Federal Trade Commission" in Fed. Trade Comm'n v. Watson Pharms., Inc., No. 10-12729-DD (11th Cir. Jul. 26, 2010)), almost five years after the Second Circuit had incorporated the holding of *PRE* into the consensus rule of *Tamoxifen*.

Almost incredibly, and apart from a single district court *amicus* submission by the FTC in 2002, it appears to the author that *PRE* likewise was never cited or briefed to any court by one of the antitrust agencies for the entire period from its citation in the Federal Circuit's *Xerox/ISO* opinion on February 17, 2000, until it was again cited by the FTC in *Watson* on July 26, 2010.

Apart from their short-lived and unsuccessful attempt to convince the Second Circuit to abandon the consensus rule of *Tamoxifen* in favor of the presumptively unlawful standard in *Cipro V*, the enforcement agencies have never proposed any judicial substitute for the consensus rule of *Tamoxifen*. The author respectfully submits that the enforcement agencies should be required (1) to set forth with specificity for the courts and Congress any proposals that they may harbor for replacement of the consensus rule of *Tamoxifen*, (2) to identify any areas of disagreement that they may have with that rule, and (3) to memorialize any objections that they may have to the Supreme Court cases, most particularly *PRE*, upon which the consensus rule of *Tamoxifen* is based.

* * *

Conclusions

Under the current consensus rule of *Tamoxifen*, in the absence of category (1) *Walker Process* fraud or a category (2) sham litigation or settlement that meets the requirements of *PRE*, the possibilities for establishing a category (3) Clayton Act § 4 antitrust claim or patent misuse defense would seem to be limited to assertions of temporal expansion predicated upon provisions impeding third-party generic Paragraph IV challenges and market entry by creating regulatory bottlenecks or assertions of subject matter expansion predicated upon provisions preventing generic marketing of formulations not covered by the claims.

Once the FTC and DOJ face up to *PRE*, they may try to get the Supreme Court to modify or overrule that precedent. Given that they have tried to hide the ball for more than 10 years, however, they may well have concluded that their chances for success with the Supreme Court are slim.

In any event, the enforcement agencies will continue to seek implementation of some alteration of the *PRE* standard from Congress. The change to a rebuttable presumption that reverse payment terms are unlawful would wreak havoc on the generic side of the industry and lead to a net reduction in Paragraph IV filings. The result on the innovator side probably would lead to a significant reduction in R&D budgets. Congress must be apprised of those facts.

The uncertainties of patent litigation and the dangers of incorporating subjective assessments into antitrust standards represent additional justifications for preserving the *PRE* standard, and Congress should be educated as to the reasons why the Courts of Appeal have repeatedly rejected the government's theories. Given its persistence in challenging reverse payment provisions in the Hatch-Waxman context, it can be expected that the FTC will press the positions it adopted in *Princo v. ITC* in other litigation involving patent settlements and clearance agreements in the

computer and Internet industries.

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