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THE MONTHLY TAX JOURNAL

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A PANEL PUBLICATION
A DIVISION OF ASPEN PUBLISHERS, INC.

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Printed in the U.S.A.

ANTITRUST UPDATE

BY YEE WAH CHIN AND THOMAS G. KRATTENMAKER

Recent actions by the Federal Trade Commission (FTC) highlight the question of the appropriate antitrust standard for certain types of settlements of intellectual property disputes, settlements in which the apparent dominant rights holder pays a potential entrant who agrees not to compete with the rights holder. This article examines that issue in the context of two hypothetical settlements and three recent FTC actions. Additional actions, brought by state governments and private parties based on the situations addressed in the FTC actions, and apparently similar situations, are cited for further consideration.¹ In some instances, the courts found the alleged agreements *per se* illegal under the antitrust laws.²

The FTC actions arose in the distinctive context of the Hatch-Waxman Act, but there is no reason to limit the logic that the Commission appears to have applied in those cases to that particular context. The Commission's logic appears applicable to settlements of all intellectual property disputes where the rights holder makes payments to the alleged infringer—*i.e.*, where the money seems to move in the “wrong” direction—and, in fact, there are some indications that the FTC staff is now exploring such a broad rule.

In a recent speech, Commissioner Thomas B. Leary focused on the impact that the merits of the underlying patent litigation should have on the antitrust view of settlements of pharmaceutical patent disputes.³ Pharmaceutical patents are not intrinsically different from any other type of patent, and Commissioner Leary did not identify as material in his analysis any aspects unique to pharmaceutical patents.

This article analyzes the considerations that should inform the appropriate standard under which such agreements should be judged, proposes a standard,

and identifies factors counsel should consider in advising clients in similar contexts.

HYPOTHETICAL SETTLEMENTS

Case 1

Patent holder P1 has a very strong patent that still has 15 years left on its 20-year term. P1 has been selling its patented product and getting \$10 million in profits on \$30 million in sales monthly. Generic competitor G1 announces that it will introduce a competing product the following month. Based on past experience in the industry, P1 expects that its monthly profits will drop to around \$3 million, and monthly sales to around \$10 million, after G1 introduces its product. G1 will receive gross monthly profits of around \$1.5 million on about \$10 million in gross monthly sales of its product.

The total number of units of the competing products that will be sold by P1 and G1 together will be the same as the total sold by P1 alone. However, P1 does not plan to lower its unit price, while G1 expects to sell its product at half the price of P1's product. G1's costs are lower than P1's, but its profit margin is also lower since it cannot command the brand name premium that P1 does. These relative figures are consistent with the experience in the pharmaceuticals industry.⁴

P1 believes that G1's product infringes its patent and notifies G1 of that claim. G1 brings an action for a declaratory judgment that P1's patent is invalid and that, in any event, G1's product doesn't infringe P1's patent. P1 counters with a patent infringement claim against G1 and seeks a preliminary injunction to prevent G1 from introducing its competing product. The court denies a preliminary injunction on the basis that if G1 is ultimately found to have infringed P1's patent, P1 may collect royalties on all infringing sales, and instructs the parties to commence discovery and prepare for trial.

P1 estimates that it will take at least three years and \$10 million in legal fees to prepare for trial and to try the case. P1 is fairly confident that it will prevail at trial.

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However, during the three years of litigation, P1 will be losing \$7 million in profits monthly that it would otherwise make without G1's competition, and the time and resources of many of its senior business and technical staff will be diverted by the demands of litigation. While P1 could recover royalties from G1's sales if G1 were found to be infringing on P1's patent, those royalties on G1's anticipated \$10 million in gross monthly sales are unlikely to exceed \$1 million monthly.

Therefore, P1 and G1 reach an agreement that provides the following:

1. The parties will continue to litigate the issues of P1's patent's validity and G1's alleged infringement through final appeal;
2. G1 will not to introduce its competing product into the market place for the shorter of five years or until final appeal of the case;
3. P1 will pay G1 \$2 million monthly for the shorter of five years or until final appeal of the case.

Case 2

Patent holder P2 has a questionable patent that has only five years left on its 20-year term. P2 has been selling its patented product and getting \$10 million in profits on \$30 million in sales monthly. Generic competitor G2 announces that it will introduce a competing product the following month. As in Case 1, P2 expects that its monthly profits will drop to around \$3 million, and monthly sales to around \$10 million after G2 introduces its product, while G2 will receive gross monthly profits of around \$1.5 million on about \$10 million in gross monthly sales of its product.

P2 believes that G2's product infringes its patent and notifies G2 of that claim. G2 brings an action for a declaratory judgment that P2's patent is invalid and that, in any event, G2's product doesn't infringe P2's patent. P2 responds with a patent infringement claim against G2 and seeks a preliminary injunction to prevent G2 from introducing its competing product. The court denies a preliminary injunction on the basis that if G2 is ultimately found to have infringed P2's patent, P2 may collect royalties on all infringing sales, and instructs the parties to commence discovery and prepare for trial.

P2 estimates that it will take at least three years and \$10 million in legal fees to prepare for trial and to try the case. However, it is uncertain that it will prevail at trial.

Moreover, during the three years of litigation, P2 will be losing \$7 million in profits monthly that it would otherwise make without G2's competition, and the time and resources of many of its senior business and technical staff will be diverted by the demands of litigation. While P2 could recover royalties from G2's sales if G2 were found to be infringing on P2's patent, those royalties on G2's anticipated \$10 million in gross monthly sales are unlikely to exceed \$1 million monthly. Moreover, by the time the litigation is resolved, there will be little if any time remaining on the term of P2's patent.

Therefore, P2 and G2 reached an agreement providing that . . .

1. The parties will withdraw their respective claims, with prejudice;
2. G1 will not to introduce competing product into the market place for five years;
3. P1 will pay G1 \$2 million monthly for those five years.

Analysis

How should these two settlements be viewed under the antitrust laws?

The staff of the Federal Trade Commission appears to favor the view that *any* payment by a patent or other intellectual property right holder to an alleged infringer, in connection with which the infringer withdraws from the market, is an unreasonable restraint of trade in violation of the antitrust laws. In fact, one Commissioner has stated that he is "tempted to support a presumption that reverse payments are illegal."⁵ The motivation for considering such a test is apparently at least in part to avoid burdensome, fact-specific inquiries into patent issues while removing from dominant firms the ability and incentive to buy off nascent rivals. "The question...is whether there is some proxy test...to decide present cases and provide prospective guidance, without a burdensome, fact-specific inquiry into issues of patent validity and infringement."⁶

However, in Case 1, the patent holder has a strong patent that still has 15 years in its term, while in Case 2, the patent holder has a questionable patent that has only five years left in its term. And in Case 2, the patent holder receives the benefit of the full term of its patent without having the merits decided by court, while in Case 1, the patent holder still faces the risk, however

slight, of having its patent invalidated and losing the benefit of the remaining term of the patent.

Should these two situations be considered equally illegal? Would a broad proscription against “reverse payments” in fact prevent only (or primarily) anti-competitive outcomes?

THE FTC ACTIONS

The Hatch-Waxman Act

The recent FTC actions arose in the distinctive context of the Hatch-Waxman Act, otherwise known as the Drug Price Competition and Patent Term Restoration Act of 1984.⁷ In a prime demonstration of the law of unintended consequences, this act created an incentive structure that may have increased the market participants’ motivation to act anti-competitively, and heightened the FTC’s interest in the situations. However, while these idiosyncrasies highlight the issues, they do not affect the core question considered in this article: what is the appropriate antitrust analysis of settlements of patent or other intellectual property rights disputes in which the rights holder pays the alleged infringer and the alleged infringer withdraws from the market?

The Hatch-Waxman Act was intended to encourage the introduction of generic alternatives to brand name pharmaceutical products by creating the Abbreviated New Drug Application (ANDA) process, under which generic drug makers need not satisfy the strict requirements of a New Drug Application before being permitted to sell their products. From the competition perspective, the Hatch-Waxman Act has these interesting attributes:

- So long as a generic drug applicant certifies [in a “Paragraph IV (¶14) certification”] that it is not infringing any patent of the branded drug or that the branded drug’s patent is invalid, the ANDA can proceed and be approved by the Food and Drug Administration if the other criteria for approval are met.
- The branded drug maker can challenge that certification by suing for patent infringement. Once that suit is filed, the generic applicant may not sell its drug until the earlier of 30 months or the final resolution of the lawsuit.
- Upon approval by the FDA of the first generic drug applicant’s application, that applicant has an 180-day exclusivity against all other generics that made the

same ¶14 certification, running from the earlier of the first day it actually markets the drug or the date of a court decision holding that the patent under the ¶14 certification is invalid or not infringed. Consequently, where there is no court decision against the patent under ¶14 certification, all later generic drug applicants cannot enter the market for the first six months that the first generic is in the market.

Therefore, the branded drug maker has every incentive to sue the first successful generic drug applicant for infringement, regardless of the merits of the claim, so long as its patent has not expired, because while the suit is pending, or up to 30 months, no generic drug by *any* manufacturer can go on the market. Moreover, the value of this delay to the branded firm (and hence the size of its incentive to ward off the first generic) can be seen in the large sums paid by the branded maker to the generic maker in the settlements of these types of cases, and in the fact that the branded maker can lose 70 percent of its sales in the first six months of the introduction of a generic version. At the same time, the first generic to be approved has the ability to exclude all other generics for several months, and might be able to sell that ability to the branded drug maker.

Abbott-Geneva

Abbott Laboratories Inc. is the maker of Hytrin, a hypertension and prostate drug with about \$540 million in U.S. sales annually. In January 1993, Geneva Pharmaceuticals filed an ANDA for the tablet form of a generic alternative to Hytrin. In December 1995, Geneva filed an ANDA for the capsule form of a generic alternative. In April 1996, Geneva filed its ¶14 certification that Abbott’s patents were not valid and that Geneva’s alternatives did not infringe Abbott’s patents. In June 1996, Abbott filed suit alleging that Geneva’s tablet product infringed its patents, somehow omitting Geneva’s capsule formulation. Therefore, the 30-month Hatch-Waxman stay that would end in December 1998 applied only to Geneva’s ANDA for its tablet formulation.

In April 1998, the ANDA for Geneva’s capsule formulation was approved, and Geneva informed Abbott that it would launch that product. Abbott estimated that it would lose about \$185 million, or 70 percent of its sales of Hytrin, in the first six months of such a launch.

At that time, the parties reached a confidential agreement that was not disclosed to the court, under which Geneva agreed . . .

1. Not to market its generic alternatives until the earlier of the final resolution of the patent infringement lawsuit or the entry into the market of another generic version of Hytrin;
2. Not to forfeit or transfer its 180-day exclusivity, assuming it had the ability to do so.

In return, Abbott agreed . . .

1. To pay Geneva \$4.5 million monthly until the federal district court decided the case;
2. If Geneva prevailed before the district court, to place \$4.5 million monthly in escrow pending the final disposition of the case, after which the prevailing party would receive the escrowed sums.

There is some indication that Abbott's payments were estimated to exceed Geneva's likely profits from sales of its generic products.

The parties continued to litigate the case, and in September 1998 Geneva won summary judgment on the claim that Abbott's patent was invalid. Geneva did not enter the market and Abbott continued to make payments, now into escrow, while the case was appealed to the Federal Circuit. The Federal Circuit affirmed the trial court decision in July 1999. The parties maintained the status quo pending U.S. Supreme Court review.

Shortly thereafter, the FTC's investigation of the confidential pre-trial agreement became known. Geneva terminated the agreement and entered the market in August 1999. In the meantime, at least one other generic manufacturer had filed an ANDA that was approved, but was prevented from entering the market because of Geneva's 180-day exclusivity.

The settlement that was reached with the FTC⁸ in March 2000 provided that . . .

1. Geneva would waive its 180-day exclusivity for the tablet formulation;
2. The parties would not enter into such agreements in litigation without express court approval;
3. The parties would notify the FTC of such agreements.

The FTC indicated that it might seek disgorgement in future prosecutions of this type.

Aventis-Andrx

In September 1995, Andrx Corp. filed the first ANDA for a generic alternative to Cardizem CD, Hoechst's leading hypertension and angina medication with U.S. sales of over \$700 million annually. Andrx thus became eligible for the 180-day exclusivity period under Hatch-Waxman. Hoechst AG (a predecessor to Aventis SA) filed a patent infringement suit against Andrx that started the 30-month stay of FDA approval, which would end in July 1998. Hoechst apparently forecast that a generic substitute such as Andrx's product would cause it to lose about 40 percent of its Cardizem sales in the first year.

An agreement was reached in September 1997 that did not end the action, but provided that . . .

1. Andrx would not market its product after its ANDA was approved in July 1998 at the end of the 30-month Hatch-Waxman stay;
2. Andrx would not forfeit or transfer its 180-day exclusivity;
3. Andrx would not market any non-infringing generic that it may develop.

In return, Hoechst would pay Andrx...

1. Ten million dollars per quarter beginning from the time the ANDA was approved;
2. An additional \$60 million annually beginning July 1998 until the lawsuit was finally decided.

The agreement did not settle the case and end the Hatch-Waxman 30-month stay of FDA approval, but did provide an incentive for Hoechst to prosecute and end the case after the 30 months by more than doubling its payments to Andrx at that point.

The FTC investigated and brought an administrative proceeding against Aventis and Andrx.⁹ The settlement that became final in May 2001...

1. Barred agreements that restricted relinquishing the 180-day exclusivity right or restricted entry into the market of a non-infringing product;
2. Required approval by the court and notice to the FTC of interim settlements of patent litigation involv-

ing payments to the generic manufacturer and the generic manufacturer temporarily refraining from marketing its product;

3. Provided notice to the FTC of similar agreements in other contexts.

The FTC stated in its Analysis of the proposed consent order that the agreement between Hoechst and Andrx did not appear to have delayed the entry of a generic version of Cardizem into the market.¹⁰

Schering-Plough - Upsher-Smith - American Home Products

Schering-Plough Corporation makes K-Dur 20, a prescription potassium chloride supplement used to treat low potassium levels, with annual sales of over \$220 million. Upsher-Smith Laboratories filed an ANDA for a generic version of K-Dur 20 in August 1995 and submitted a ¶14 certification. Schering sued Upsher-Smith in December 1995 for patent infringement, triggering the 30-month Hatch-Waxman stay that would end in May 1998.

In June 1997, Schering and Upsher-Smith settled the litigation, and Upsher-Smith agreed...

1. Not to enter the market until September 2001 with any version of K-Dur 20, infringing or non-infringing;
2. To license Schering to market five Upsher-Smith products.

In return, Schering agreed to pay Upsher-Smith \$60 million.

Following the settlement, Schering never sold four of the five products licensed from Upsher-Smith and sold only minimal amounts of the fifth, without expectations of making further sales. Upsher-Smith's ANDA was approved in November 1998, but Upsher-Smith did not begin marketing its products, so that its 180-day exclusivity did not begin to run, and no other generic could enter the market.

In December 1995, the ESI Lederle, Incorporated division of American Home Products Corporation filed an ANDA for its generic alternative to K-Dur 20 along with a ¶14 certification. Schering sued ESI in February 1996 for patent infringement, triggering the 30-month stay that would end in August 1998.

In January 1998, Schering, American Home Products and ESI reached an agreement under which AHP and ESI agreed...

1. Not to market their versions of K-Dur 20, infringing or non-infringing, until January 2004;
2. Not to market more than one generic version between January 2004 and September 2006;
3. Not to support any study of the bioequivalence to K-Dur 20 of any product until September 2006 when the K-Dur 20 patent expires;
4. To license to Schering two generic products that ESI was developing.

In return, Schering was to pay ESI up to \$30 million in lump sums and in installments over seven years.

Following the agreement, Schering made no sales of the products it licensed from ESI. ESI received tentative approval of its ANDA in May 1999, but is not eligible for final approval until Upsher-Smith's 180-day exclusivity expires.

The FTC filed an administrative complaint against Schering, Upsher-Smith and American Home Products in April 2001.¹¹ In the meantime, Andrx filed an ANDA for its generic alternative.

ESTABLISHING A LEGAL STANDARD WHERE THE RIGHTS HOLDER PAYS FOR A NON-COMPETE

The FTC staff and some courts have apparently taken the position that these types of agreements to resolve patent disputes are *per se* illegal.¹² FTC staff have commented at ABA programs that they have great skepticism toward such agreements and are unlikely to subject them to full rule of reason analysis. They have apparently concluded that there has been a violation of the antitrust laws if...

1. An intellectual property rights holder who occupies its market position in substantial part because of its rights pays an alleged infringer;
2. The alleged infringer then withholds its product from the market.

Certainly a simple agreement whereby a monopolist offers to share some of its monopoly profits with a potential competitor in return for the competitor's withdrawal

from the market constitutes, at the least, monopolization or the allocation of the market between competitors that offends the antitrust laws. But what if the agreement is more complex, such as one that also settles a dispute over the scope and validity of intellectual property rights? A consideration of the fact patterns in Case 1 and Case 2 indicates that a *per se* approach may be simplistic and does not take full account of the intellectual property policies implicated.

Simplicity and minimizing burden are worthy goals, but they should not be pursued at the cost of the policies underlying intellectual property rights. “Bright-line” tests may also create serious distortions and imbalances in the marketplace and in the incentives to market participants. Fact-specific inquiries cannot always be avoided, and in fact have been at the core of the development of antitrust jurisprudence.

Case 1 Analysis

In Case 1, once the case is fully litigated, the likelihood is that P1’s patent will be upheld, G1 will be found to have infringed the patent, and P1 will be able to enforce the patent for the remainder of its term. In that case, if the final decision is reached in five years (after trial and appeals), then P1 will be able to prevent G1 from selling its generic alternative for 10 years thereafter, until P1’s patent expires. From that perspective, the agreement that was reached does not change the competitive landscape in five years from what it might otherwise be.

The difference is that, under the agreement, for the next five years G1 will not sell in the market, while if there were no agreement, G1 would be in the market while the litigation proceeds to trial and appeals. Consumers lose the benefit of G1’s competition for the five years, or less, that the agreement requires G1 to abstain from the market. However, if the patent were valid and G1 would be infringing it with its generic alternative, then it could be argued that due regard for intellectual property values dictates that G1’s presence during the litigation should be viewed as a windfall to consumers and not something to be protected by the antitrust laws.

It may be argued that G1’s presence is a benefit that the patent laws expressly intend to withhold, by providing the patent holder the right to exclude infringers from the market place. In fact, it might be argued that the agreement was a means by which P1 could fully maintain the value of its patent until it is vindicated. Of course, if P1 ultimate-

ly loses on its patent claim, then consumers have irretrievably lost the benefit of five years of G1’s competition.

From the parties’ perspective, the agreement in Case 1 might make excellent economic sense, involving a weighing of litigation risks and costs and the value of the patent. For P1, the agreement enables it to retain \$5 million in monthly profits that it might otherwise lose during the five years that it may take to vindicate its patent. Without G1 in the market, P1 makes \$10 million in monthly profits; with G1’s competition, P1 expects only \$3 million in monthly profits, perhaps augmented by \$1 million in royalties from G1. A monthly payment to G1 of \$2 million enables P1 to retain \$5 million of the \$7 million in monthly profits that might otherwise be lost.

P1 would still incur the \$10 million legal fees and three or more years of uncertainty and disruption, but those costs are likely to result in P1 retaining the full benefits of the significant number of years remaining on its patent. For G1, the agreement enables it to receive pure profits of \$2 million monthly, more than the \$1.5 million G1 is estimated to receive if it enters the market.

Case 2 Analysis

In contrast, in Case 2, the likelihood is that P2’s patent claims will *not* withstand scrutiny. The effect of the agreement is to enable P2 to receive the full benefits of its patent for the remaining five years of the life of the patent, without incurring \$10 million in legal fees and at least three years of uncertainty and disruption. If the patent were ultimately found enforceable against G2, then the agreement not only made excellent economic sense for both parties, but also did not change the competitive landscape from what it would have been.

On the other hand, if there were no agreement and the patent were found not to be enforceable against G2 three years later at the end of the trial, then consumers would have had the benefit of G2’s competition during that time. In that case, it could be argued that the agreement made excellent economic sense for the parties, but at the same time, and in contrast to Case 1, enabled P2 to enjoy a patent that it was not entitled to and deprived consumers of the benefits of G2’s competition that would otherwise be available and not precluded by the patent law.

Cases 1 and 2 may be extreme examples. However, they demonstrate that a full analysis would consider the nature of the intellectual property claims involved and the specific terms of the agreement between the par-

ties, beyond provisions for payments and abstention from the marketplace, before reaching any conclusions as to whether the conduct was, on balance, anticompetitive. Failure to conduct such a full analysis may mean giving short shrift to the policies embodied in the intellectual property law. But would a complete competition analysis of that sort be impossibly subjective or unwieldy?

Reviewing the Three FTC Actions

More realistically, a review of the publicly known facts of the three FTC actions also highlights these issues.

In the *Abbott-Geneva* case, if Abbott's patent were not ruled invalid on summary judgment but were sustained and Geneva were found to have infringed the patent, then the agreement Abbott and Geneva reached might not have any anticompetitive effect beyond that contemplated by the patent law. In that scenario, a monthly payment of \$4.5 million by Abbott to protect over \$30 million of monthly sales while the patent issues are litigated is not an act against economic self-interest that necessarily arouses suspicions of cartel behavior. Abbott had estimated that it would lose about \$185 million of sales in the first six months of the introduction of a generic alternative.

Similarly, if Aventis were eventually found to have a valid patent that was infringed by Andrx, then the agreement might not result in a competitive situation that is different from what it should be. Moreover, in that event, an agreement to pay Andrx over \$3 million monthly to protect about \$30 million of monthly sales while the patent issues are being litigated may make excellent economic sense without affecting competition in any way not contemplated by the patent law. Hoechst had apparently projected that it would lose about 40 percent of its \$700 million in annual sales in the first year of sales of a generic alternative. From that perspective, the 150 percent increase in the payments to Andrx after July 1998 is arguably also appropriate, as an incentive to Hoechst to prosecute the litigation to conclusion.

Schering-Plough's calculus was somewhat more complex. There were agreements with both the first and the second filers of ANDAs. Moreover, unlike the Abbott and Hoechst agreements, Schering-Plough's agreements with Upsher-Smith and ESI settled the lawsuits and therefore spared its patent from scrutiny, possibly until the patent expired in September 2006. Under the two agreements, until September 2001, Schering would have no generic competition. Between September 2001

and January 2004, Schering would face competition only from Upsher-Smith. After January 2004, it would face competition from both Upsher-Smith and ESI.

Schering might be viewed as having paid Upsher-Smith \$60 million to protect the majority of the almost \$900 million in sales it expected to make over four years. The June 1997 agreement with Upsher-Smith provided that Upsher-Smith would not enter the market until September 2001. Schering's annual sales of K-Dur 20 exceeded \$220 million. Schering might also be viewed as having agreed to pay ESI \$30 million to protect some significant percentage of its annual sales over eight years. The January 1998 agreement with ESI provided that ESI will not market any generic alternative until January 2004, and will market only one alternative between January 2004 and September 2006, when the patent expires.

Again, if the litigations had proceeded, Schering-Plough's patent was upheld, and Upsher-Smith and ESI were both found to have infringed the patent, then the payments by Schering may have made good economic sense and the agreements might arguably not have changed the competitive landscape beyond that contemplated by the patent law. In fact, it might be argued that the agreements enabled more competition than might have otherwise existed by permitting the entry of Upsher-Smith's and ESI's products in the face of Schering's patent claims. On the other hand, the facts that the agreements settled the lawsuits and that Schering agreed not to contest the eventual entry into the market by both Upsher-Smith and ESI might reflect a lack of confidence in the patent.

Evaluation of the Results

In short, it could be argued that the agreements in all five cases reviewed may have benefited consumers, injured them, or had no effect at all, depending on the validity of the patent claims involved and the specific terms of the agreements. In all the cases, if the patents were valid and the generic competition had infringed the patents, then the agreements might not have put consumers in any worse a position than they would have been without the agreements. In fact, in the case of Schering-Plough, if the patent were valid and were infringed by Upsher-Smith and ESI, the agreements permitted generic competition before the expiration of the patent, sooner than otherwise would have been the case, and thus may have benefited consumers. On the

other hand, if the patents were invalid or were not infringed, then the agreements may have deprived consumers of the benefits of generic alternatives that they might otherwise have been entitled to during the terms of the agreements.

Noerr-Pennington Analogy

An evaluation of the interplay between the exclusionary policies embodied in the patent law and the competitive playing field sought by the antitrust law suggests that some analog of the test established by the Supreme Court in the *Noerr-Pennington* area in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus.*¹³ may be appropriate in this context. In *Professional Real Estate Investors*, the Supreme Court held that even after all the other elements of a violation of Section 2 of the Sherman Act have been established, a lawsuit for copyright infringement is protected by *Noerr-Pennington* and is not an antitrust violation unless it can also be shown that...

1. The claim was objectively baseless, that no reasonable litigant could have expected success on the merits;
2. The party making the meritless infringement claim had the intent to use the litigation to handicap the other party competitively regardless of the outcome of the lawsuit.

Once these two elements are shown, the lawsuit is no longer protected against antitrust claims, but must still be shown to be an antitrust violation.

To label a settlement agreement in which the intellectual property rights holder pays the alleged infringer a *per se* offense would be to ignore important *Noerr-Pennington* and intellectual property policies. If an infringement claim is protected under *Professional Real Estate Investors* and thus under *Noerr-Pennington*, then without greater experience with such settlements and without fuller consideration of the terms of the settlement, the ability to settle the claim should not be restricted by a *per se* rule. Otherwise, such a *per se* rule may unduly chill the exercise of the right protected under *Noerr-Pennington* to bring the infringement claim. This is especially the case where the agreement may not have changed the competitive landscape significantly from what it would be if the patent or other

intellectual property were found enforceable and were enforced.

There may very well be situations when such agreements violate the antitrust laws. For example, there may be more skepticism about an agreement resolving an infringement claim that has a reasonable but not substantial likelihood of success. Thus, to the extent there may be greater doubt about Schering-Plough's patent, there may be greater skepticism about the propriety of the agreements it reached with Upsher-Smith and ESI. However, acceptability under the antitrust laws should not be determined by nothing more than the existence of payments by the rights holder to the alleged infringer and the delayed entry into the market by the alleged infringer. The underlying infringement claim must also be considered. In fact, Commissioner Leary recognized that "the problem is that the ultimate impact of a pharmaceutical patent settlement is really dependent on the merits of the underlying patent litigation."¹⁴

A PROPOSED TEST

The appropriate test of the legality under the antitrust laws of such arrangements settling intellectual property disputes should not be a *per se* test. The test should take into consideration the following objective factors:

1. The validity of the intellectual property claims;
2. The specific terms of the agreement.

In particular,

- (a) if before the litigation commenced an objective view of the intellectual property infringement claim indicated that there was an objectively reasonable probability that the claim would be upheld and that there was infringement so that
- (b) the infringement claim is protected under *Professional Real Estate Investors* (tracking the Supreme Court's reasoning that, "[i]f an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail"¹⁵),

then an agreement involving a payment by the rights holder to the alleged infringer that . . .

- makes economic sense in light of the revenues, costs, and profits involved and
- may facilitate the resolution of the litigation (analogous to the Supreme Court's view that a plaintiff "must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed [it]"¹⁶), should not be considered a *per se* violation of the antitrust law but should be considered more likely to be reasonable than not.

Such a test does not consider amorphous subjective issues such as the parties' intent in entering the agreement. It will require scrutiny of the infringement claims involved, but under an "objectively baseless" test analogous to that established by the Supreme Court in *Professional Real Estate Investors*. The Court explained "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."¹⁷ This test is more complex than a simple *per se* bar of all agreements where the intellectual property rights owner pays the alleged infringer to abstain from the market. However, a simple test would not give proper due to the substantial policy of intellectual property rights. The proposed test provides a balance between the policies embodied in the intel-

lectual property and antitrust laws by setting forth two objective factors to be considered, while avoiding the morass of determining subjective intent.

SOME CONSIDERATIONS

In advising clients, counsel may do well to keep in mind the following factors:

- The strength and remaining term of the intellectual property rights involved. The more questionable an intellectual property right or infringement claim is, the more cautious a client should be in considering an agreement in which the rights holder pays the alleged infringer and the alleged infringer abstains from the market. The remaining term of the intellectual property rights also should be considered in determining the duration of any agreement.
- The time and resources that will need to be diverted if the claims are fully litigated. If the client is considering such an agreement, then the litigation risks and costs should be carefully analyzed.
- The amount of revenues and profits that may be lost under various litigation and market scenarios. The economics of any agreements should be analyzed in the context of these scenarios.

1. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 2001 U.S. Dist. Lexis 15386 (E.D. N.Y. 2001) (Cipro); Report on Form 10-Q for period ended September 30, 2000 of Barr Laboratories Inc. (Tamoxifen); *American Bioscience, Inc. v. Bristol-Myers Squibb Company*, 2000 U.S. Dist. Lexis 21067 (C.D. Cal. 2000) (Taxol); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (Cardizem); *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001) (Cardizem).

2. See, e.g., *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682, 685 (E.D. Mich. 2000).

3. See prepared remarks of Thomas B. Leary, Commissioner, "Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II," Remarks before the American Bar Association Antitrust Healthcare Program, Washington, D.C., (May 17, 2001), www.ftc.gov/speeches/leary.htm.

4. See, e.g., Leary, May 17, 2001, Part I.B.

5. Leary, May 17, 2001, at IV.

6. See, e.g., Leary, May 17, 2001, at I.B.

7. Pub. L. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. §355.

8. *In re Abbott Laboratories*, FTC, Dkt. No. 9273 (March 16, 2000), CCH Trade Reg. Rep. [1997-2001 Transfer Binder] ¶24,715.

9. *In re Hoechst Marion Roussel, Inc.*, FTC, File No. 981-0368 (filed March 16, 2000), CCH Trade Reg. Rep. [1997-2001 Transfer Binder] ¶24,715.

10. *In re Hoechst Marion Roussel, Inc.*, FTC, Dkt. No. 9293 (April 2, 2001).

11. *In the matter of Schering-Plough Corp.*, FTC, Dkt. No. 9297 (filed April 2, 2001).

12. See, e.g., Complaint in *In the matter of Schering-Plough Corp.*; *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682. See also, Leary, May 17, 2001, at IV.

13. 508 U.S. 49, 60-61 (1993).

14. Leary, May 17, 2001.

15. 508 U.S. at 60 (footnote omitted).

16. *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

17. 508 U.S. at 60.