CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle

July 2012 (2)

Pharmaceutical Patents, Settlements, "Reverse Payments," and Exclusion: Update

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"The game's afoot"

William Shakespeare, *King Henry III*
(also, Sir Arthur Conan Doyle, *The Adventure of the Abbey Grange*)

I. INTRODUCTION

In the June issue of this *Chronicle* my fellow contributors and I described a trend in appellate court decisions involving so called "Reverse Payment" settlements. The trend was towards a rule, called the "scope of the patent" rule, which protects settlements from challenge so long as the terms of settlement are confined to the nominal life of the patent.[2] Less than three weeks after those articles were published the Third Circuit Court of Appeals in Philadelphia handed down a decision establishing a rule for the Third Circuit that is diametrically opposed to the trend we described. In the Third Circuit merely showing that a settlement embodies a "reverse payment" will be sufficient to establish *prima facie* evidence of anticompetitive effect, and the burden of proof will shift to the antitrust defendants to defend their agreement.

II. THE THIRD CIRCUIT DECISION IN *IN RE: K-DUR ANTITRUST LITIGATION*

The decision was not only a victory for the plaintiffs in the case, who were appealing a summary judgment decision against them. It was also a victory for the Federal Trade Commission ("FTC"). Indeed, the Court's concluding language:

> Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.[3]

echoes the outcome the FTC advocated in its *amicus* brief, which was:

> Accordingly, the Commission submits that the lessons of economics, the teachings of experience, and an appropriate balancing of important congressional objectives justify a rule that proof of an exclusion-payment agreement [agreements with a payment from the patent holder to the generic entrant and a

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[2] John P. Bigelow, *Pharmaceutical Patents, Settlements, 'Reverse Payments,' and Exclusion*, 6(2) CPI ANTITRUST CHRON. 2-7 (June 2012), (hereafter, "June Essay.") *See also* the papers by Anne Layne-Farrar, C. Kyle Musgrove &Richard Ripley, Kevin E. Noonan, William H. Rooney & Jodi A. Lucena-Pichardo, and Aidan Synnott & William B. Michael in the same issue.

[3] United States Court of Appeals for the Third Circuit, *In Re: K-Dur Antitrust Litigation,* No.s 10-2077, 10-2078, 10-2079, and 10-4571, July 16, 2012, p. 27. (Hereafter, "K-Dur.")

> negotiated entry date] is sufficient to establish a prima facie case of illegality. At that point, the settlement parties should be required to make a showing of how and why their agreement is not anticompetitive.[4]

The case in which this decision came about is the private litigation "version" of the *K-Dur* case that was litigated before the FTC and in the Eleventh Circuit. The original case involved settlements between Schering Plough, which held a patent on a time-release formulation of K-Dur, a potassium chloride supplement, and Upsher Smith and ESI-Lederle. Schering settled patent litigation cases it had filed against both generic manufacturers on terms that the FTC described as including "Reverse Payments," and the FTC challenged the settlements. In 2002 an FTC Administrative Law Judge ("ALJ") dismissed the case. The full commission reversed that decision in 2003, and was, in turn, reversed by the Eleventh Circuit in 2005.

The Eleventh Circuit decision was one of the decisions that made up the seeming trend we described in the June issue of this *Chronicle,* although in that decision the appeals court didn't fully accept that the FTC had demonstrated the *existence* of a reverse payment.[5] Nonetheless, by the time the FTC filed its (ultimately unsuccessful) petition for *certiorari* with the Supreme Court it anticipated that the Eleventh Circuit decision would lead to something like the scope of the patent rule.[6]

In its recent decision the Third Circuit explicitly recognizes that it is taking a position at odds with other circuits:

> [W]e cannot agree with those courts that apply the scope of the patent test. In our view, that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.[7]

Nor is the court apologetic about doing so, noting that:

> Defendants argue in passing that this court should begin its analysis in this case with a strong presumption in favor of following the Eleventh Circuit's decision in *Schering-Plough*. However, none of the cases cited by defendants employs such a presumption; rather, they stand for the unsurprising proposition that this court will follow the decisions of its sister courts where it finds them persuasive. . . . As explained below, we do not find the Eleventh Circuit's decision in *Schering-Plough* persuasive, and thus decline to follow it.[8]

III. NOW WHAT?

And, what did the Third Circuit find persuasive? What it termed "common sense:"

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[4] In The United States Court Of Appeals For The Third Circuit, *In Re: K-Dur Antitrust Litigation,* No.s 10-2077, 10-2078, and 10-2079, On Appeal From A Final Order Of The United States District Court For The District Of New Jersey Granting Defendants' Motions For Summary Judgment, Brief Of The Federal Trade Commission As *Amicus Curiae* Supporting Appellants And Urging Reversal, May 18, 2011, p. 28.

[5] 402 F.3d 1056.

[6] Federal Trade Commission, Petition for a Writ of Certiorari, *Federal Trade Commission, v. Schering-Plough Corporation et. al.* (August 2005); Available at http://www.ftc.gov/os/2005/08/ 050829scheringploughpet.pdf, pp. 14-15.

[7] K-Dur, p. 27.

[8] *Id.* note 8, p. 22.

> In holding that a reverse payment is prima facie evidence of an unreasonable restraint of trade, we follow the approach suggested by the DC Circuit in *Andrx* and embrace that court's common sense conclusion that "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement . . ."[9]

While "common sense" is rhetorically appealing and intuitive, it's also somewhat imprecise. Intuition, however, isn't always reliable. As I described in June, economics doesn't support the contention, implicit in the presumption against reverse payments, that a reverse payment settlement *must* represent an extension of exclusion. There can be obstacles to bargaining that could keep a patent holder and a generic entrant from ever reaching a settlement if payments to the generic entrant are prohibited. In some cases those obstacles can be overcome through the use of such payments in settlements that advance the date of entry relative to what could be expected under litigation.[10]

One way of interpreting the rule advocated by the FTC and articulated by the Third Circuit is that defendants would have the opportunity to explain how their settlement overcame such obstacles to bargaining in the phase of litigation where the burden shifts to them to demonstrate that the settlement is pro-competitive. The difficulty with this approach is that it puts the defendants in a position reminiscent of Joseph Heller's *Catch-22.* As a matter of economics, a settlement is pro-competitive if it calls for entry on or before the expected entry date determined by the probabilities of the parties' prevailing in the underlying patent litigation. The one thing the Eleventh Circuit (in *Androgel*) and the Third Circuit (in *K-Dur*) agree on is that antitrust courts shouldn't have to take on the merits of the patent case. So, how are the defendants to demonstrate that their agreement is pro-competitive when the standard of reference against which it is to be judged in making that determination is considered unknowable?

All of which brings me back to the theme with which I ended my essay in June. The rule the FTC advocates is one in which the competitive significance of a settlement is inferred from its terms. It does not rely on a specific comparison of the agreed upon entry date with the expected entry date that would be realized if the litigation were not settled. The particular rule the FTC advocates is to look for a payment to the generic and, if that is present, to regard the settlement as anticompetitive. That rule is, for reasons I've explained, not supported by economic theory. But that does not mean that no such rule is possible. A rule that worked well would likely need to be more nuanced (and probably more complex) than the FTC's rule, but if it is out of the question to assess the patent litigation, the development of such a rule is the apparent alternative.

The ball is squarely in the court of the economics profession and that segment of the legal profession that studies law, economics, and competition. What is needed is a deeper understanding of how the effects of settlements on competition are reflected in the design and terms of settlements. Guidance is needed in how to distinguish pro-competitive from anticompetitive settlements by inspecting their terms and conditions.

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[9] K-Dur, p. 33.

[10] *See* June Essay, and Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, ANTITRUST BULL. 655 – 98 (Fall 2004).

With the split between the various circuit courts of appeals becoming more clearly drawn, the likelihood that either the Supreme Court or Congress (or both) will take up the issue grows. It would be too bad if when they do economic science is not yet able to provide them solid guidance. The game is, indeed, afoot, but time is short.