CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
September 2013 (2)

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The EC's 2009 Sector Inquiry Report on certain practices in the European pharmaceutical sector[2] described in considerable detail the practice and nature of settlement agreements between originator companies and generic companies in the European Union in the period 2000-2008. The Report did not intend to lay down guidance on the compatibility of these agreements with EU competition law. However, it does refer to the FTC having found some of these agreements (the so-called "reverse payment settlement agreements") to be an infringement of antitrust rules, adds a brief overview of the U.S. settlement practice, and also discusses the similarities and differences between the EU and U.S. systems. In addition, the EC followed the FTC's example and started monitoring settlement agreements in the wake of the Sector Inquiry.

In June of this year, the U.S. Supreme Court—in *FTC v Actavis*—for the first time ruled on the compatibility of reverse payment settlement agreements with antitrust rules. In the same month, the European Commission ("EC") issued its first decision finding that Lundbeck and a number of generic companies had infringed EC competition rules by entering into reverse payment settlement agreements.

Although the EC is, of course, not bound by U.S. precedent, it has on more than one occasion taken inspiration from the United States when applying its competition rules to the pharmaceutical sector. More generally, it is keen to underline the similarities in approach between the EC and the U.S. on IP/antitrust interface cases.

So how close is the EC's current approach to the majority ruling in *FTC v Actavis*? In particular, the Supreme Court rejected the FTC's "quick look" approach in favor of a "rule-of-reason" approach. Where does that leave the EC's "by object" approach that it seems so far to have been pursuing in these settlement cases?

The U.S. case concerned Solvay's brand-name drug AndroGel. In 2003, Actavis filed an Abbreviated New Drug Application seeking FDA approval to launch a generic drug, claiming that Solvay's patent was invalid and that its drug did not infringe it (a so-called "Paragraph IV certification"). Filing a Paragraph IV certification is an act of infringement under U.S. patent law, and Solvay filed suit against Actavis, which triggered an automatic 30-month delay of the FDA approval process. In 2006, the patent-litigation parties settled. Actavis agreed that it would not bring its generic to market until August 2015, some 5.5 years before Solvay's patent expired, unless someone else marketed a generic sooner. Actavis also agreed to promote AndroGel to urologists. Solvay agreed to pay Actavis an estimated $19–$30 million annually, for nine years. Two other generic manufacturers made roughly similar promises and were paid $12 million and $60 million in total, respectively.

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[2] *Available at* (http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html).

The Supreme Court overruled the Eleventh Circuit's decision that a reverse payment settlement agreement generally is "immune" from antitrust attack as long as its anticompetitive effects fall within the exclusionary scope of the patent. Rather, in the words of Justice Breyer, the antitrust question must be answered "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."

At the other end of the spectrum, the FTC had urged the Supreme Court to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach. The Supreme Court rejected this because, in the words of Justice Breyer:

> the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

In other words, the burden of proof is on the plaintiff (here, the FTC) to show the necessary anticompetitive harm for a finding of infringement. This is in contrast with the "quick look" approach, where there is a presumption of anticompetitive effect and the burden is on the defendant to rebut the presumption.

An analysis "by object" under EC rules differs from the above in at least two important respects. For an agreement to infringe the EC's Article 101, two conditions need to be fulfilled: first, the agreement must have the object or effect of restricting competition in the European Union (as set out in Article 101.1 TFEU) and, second, any pro-competitive effects deriving from the restriction must not outweigh the anticompetitive effects that have been identified (as set out in Article 101.3 TFEU).

In general terms, the practical effect of a "by object" analysis is two-fold. First, the burden of proof for all intents and purposes shifts from the EC (who will be able to limit itself to a rather summary analysis under the first prong of Article 101) to the defendant (who will have to make its case under the third prong of Article 101). Second, the threshold for the defendant to show redeeming virtues of the alleged restriction is considerably higher where the restriction is alleged to be "by object."

The *Lundbeck* decision has not yet been published and, as such, we know little about how the EC has gone about making its case. However, public statements by senior DG COMP officials suggest that the EC remains in favor of a "by object" approach in reverse payment settlement cases.

This approach is ill-suited to an analysis that requires careful weighing of possible anticompetitive effects as described in *FTC v Actavis* (see above), bearing in mind also the interplay with the regulatory framework. Even leaving aside the weighty issue of the burden of proof shift, the "by object" approach risks pushing the investigation into a line of reasoning that fails to do justice to the complexities of the issue. Granted, in past EC cases, including in the pharmaceutical sector, the distinction between Article 101.1 and 101.3 has on occasion—

helpfully or not—been blurred. Still, it does not assist the development of sound case law nor legal certainty if reverse payment settlement agreements continue to be labeled as "by object" restrictions.

Finally, to the extent that in the EC's own view there is no conflict between *FTC v Actavis* and where the EC comes out, dropping the "object" qualification would avoid further confusion and assist in getting both jurisdictions aligned on an important and challenging area of law.