Side Effects
The Evolving Law of ‘Reverse Payments’ and Its Impact on Drug Litigation
Few areas of health law have seen as much attention in the last decade as “pay-for-delay” or “reverse payment” antitrust lawsuits. These suits are brought by government agencies and private drug purchasers against branded and generic pharmaceutical drugmakers that enter into settlements over drug patent litigation. These settlement deals have been a focal point of scrutiny by the Federal Trade Commission (FTC), which has attempted to paint the deals that delay entry of generic drug competition as “per se” anti-competitive under the Sherman Act. Drugmakers have countered that settlements of patent infringement litigation are permissible and that the terms of the deals – usually a payment from the branded to the generic drugmaker – are reasonable given litigation uncertainties and the valuable patent exclusivity rights at stake. The battles have been fierce, with both sides of the debate suffering litigation setbacks.

The litigation landscape is complicated by the number of issues and subissues involved and even the positions of the major players: At one point in 2011, the FTC and Department of Justice couldn’t agree on whether these arrangements should be challenged. One thing has, however, remained constant - the extremely high stakes for both plaintiffs and defendants.

In one case, just before trial, the FTC settled reverse payment claims with two drug companies, Cephalon and Teva, for $1.2 billion, which was placed in a settlement fund and made available to other injured parties. The FTC settlement prohibited Teva from entering into pay-for-delay settlements for 10 years. Attorneys general for 47 states and the District of Columbia also settled their related claims for $125 million, which was facilitated at least in part by the FTC settlement fund. Claims asserted by direct purchasers against Cephalon, Teva, and a third drugmaker settled for $512 million, which was also credited against the FTC settlement fund. Two other drug companies named in the case settled direct purchaser claims for $96.5 million.

Some serious money was at stake in this litigation, and this involved allegations over just one prescription drug: modafinil. Numerous other cases involving allegedly anti-competitive dealings between branded and generic drug companies have been litigated for approximately 20 years and there appears to be no end in sight.

Against this backdrop, counsel for drug companies, health insurers, employers who sponsor their own health plans, and other direct and indirect prescription drug purchasers have a monumental task in determining how the law has evolved, and applies, to “reverse payments” and an array of other restraint of trade claims asserted against branded and generic drug companies. In the March 2017 Bloomberg BNA article, Reverse Payments After Actavis, the commentators summed up the challenges facing counsel this way:

The lack of a concrete blueprint for evaluating whether potential reverse payments violate the antitrust laws, coupled with minimal case law addressing causation and damages, makes counseling in this area difficult in the extreme.

Finding the tools needed to keep close tabs on the numerous cases moving through the courts that include antitrust attacks on reverse payment settlements is critical. The need for effective tools is heightened by the fact that the law is still developing - and doing so at a frustratingly slow pace.
Although searching the wealth of Bloomberg BNA content – Insights articles, Portfolios, and weekly and daily news coverage – can be extremely useful in training counsel’s focus in this area, a new Bloomberg Law® tool, Points of Law, can improve the speed, efficiency, and comprehensiveness of your case law research. Powered by state-of-the-art technology, Points of Law can help you quickly find language critical to a court’s reasoning, even when it’s buried deep in the text. Points of Law provides comprehensive, objective, and timely points of law and leading cases in support of those points, so you can more quickly identify essential court reasoning and identify the best language to support your legal arguments.

Attorneys interested in using Points of Law to augment their research related to reverse payment cases can do so in two main ways. First, a practitioner aware of an important decision will want to see the points of law established in that ruling and learn how they have been followed, embraced, or disavowed by other courts over time and in specific jurisdictions. Second, an attorney can use search terms across the Points of Law database to find court decisions that have applied or interpreted a given issue. This provides a way for counsel to determine what courts have said about specific issues and what points of law have been addressed in those decisions.

For attorneys researching the pay-for-delay issue, the U.S. Supreme Court’s decision in FTC v. Actavis, Inc., 133 S. Ct. 2223, 186 L. Ed. 2d 343, 106 U.S.P.Q.2d 1953, 2013 BL 158126 (2013) is a logical starting place because it provides a recent, authoritative look at the legality of “reverse payments.”

The Supreme Court held that reverse payment settlements in patent infringement litigation are not immune from antitrust attack, and that the anticompetitive effects of pay-for-delay agreements may give rise to Sherman Act claims. The court rejected the notion that the agreements are “per se” illegal, but found they may nonetheless be found to violate federal antitrust law under a “rule-of-reason” analytical framework that weighs pro-competitive considerations against anti-competitive ones. The court explained reverse settlements as:

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company A, the patentee, to pay B many millions of dollars.

The court ruled that reverse payment antitrust claims must be evaluated using the fact-intensive rule-of-reason framework partly:

because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payer’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

Cases applying the rule-of-reason analysis to antitrust violations look to whether the restraint imposed is one that merely regulates and perhaps thereby promotes competition or whether it thwarts or destroys competition. As noted by Justice Brandeis in Chicago Board of Trade v. United States, courts are required to consider the:

facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.

To root out these unjustified anti-competitive consequences, the majority opinion in the Actavis ruling noted that:

trial courts can structure antitrust litigation so as to avoid, on one hand, the use of antitrust theories too abbreviated to permit proper analysis, and on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question.

Chief Justice Roberts, writing in dissent about the application of an “unruly” rule-of-reason analytical construct in these cases, offered trial courts left to apply the court’s decision a few words of advice:

Good luck.
While the same advice could be offered to counsel involved in this type of litigation, the Points of Law solution provides a substantial degree of support for those desiring to wade into this complex legal thicket. And although the Supreme Court “moved the ball” considerably concerning how these cases will be litigated and decided, attorneys know well that it is how the decision affects their litigation strategies, and how subsequent court decisions interpret and apply the justices’ reasoning in Actavis that will make or break their clients’ cases.

(SCREEN SHOT AND DATA CAPTURED ON SEPT. 20, 2017)
Within the Actavis case Bloomberg Law identifies 19 points of law (as of Sept. 20, 2017) and makes connections to related points and expressions of each point in other cases. Looking at just one point of law highlighted in research that starts with the Actavis decision shows all of the cases that have built on or tried to interpret the Supreme Court’s reasoning in assessing whether reverse payments are legitimate business strategies or anti-competitive restraints on trade. [See Image 1]

Using the chosen point of law, the most cited cases are set forth in a pop-up, with the ability to click through to uncover a more robust list of cases. [See Image 2]

A Points of Law user can also click into the Citation Map, which details the genesis of the judicial discussions around that point of law over time and denotes the type of court involved. This visualization offers unique perspectives on the application of the Actavis standard for reverse payments in more recent opinions. [See Image 3]

Legal research on complex issues rarely stops evolving. Even a Supreme Court decision, such as Actavis, is subject to review and interpretation as lower courts mold and shape the precedent to unique sets of facts. Whether your task is to attack or defend a past settlement in court, or negotiate a new one that will stand up to future litigation, Points of Law lets you easily follow the evolution of the precedent, across jurisdictions...
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