

Supreme Court could be next up in "pay for delay" saga



[Jonathan Gardner](#)

After years of refusing to judge payments by branded drugmakers to delay generic entry, the US Supreme Court will likely take on the issue following a surprise lower court ruling against a 1997 deal postponing competition for the hypokalaemia drug K-Dur.

A decision by America's highest court would decide for good whether such deals amount to legitimate protection of patent estates or are anticompetitive transactions that unfairly raise healthcare costs. Given that the July decision by the Third Circuit Court of Appeals has gone against previous appellate court rulings, it seems a good bet the top judges will take it on.

Challenged but victorious

For years, payers, pharmacy benefit managers and wholesalers have challenged these "pay for delay" deals on antitrust grounds. The claim is that they create a monopoly past the date of potential generic entry, particularly in the case of weaker formulation patents that can extend the life of an important franchise beyond the expiry of composition-of-matter patents. It is something President Barack Obama, the Federal Trade Commission and some lawmakers have tried unsuccessfully to eradicate ([US health reform passes and market barely pauses](#), March 22, 2010).

In the absence of specific legislation addressing reverse payments, case law had been gravitating toward their legality, with decisions in three of the 13 circuit courts allowing them as long as they apply to the patented product only and do not extend beyond expiry, a standard set in two cases decided in 2006 and 2008 involving the breast cancer drug tamoxifen and the antibacterial ciprofloxacin ([Court gives new hope for bans on pay for delay deals](#), April 30, 2010).

These two cases have led to a "wave" of reverse payment settlements, according to analysts from Bernstein Research, including those concerning AstraZeneca's Nexium, Pfizer's Lipitor and Cephalon's Provigil.

However, in the K-Dur case the Philadelphia-based Third Circuit declared that a reverse payment showed immediate evidence of monopolistic activities, and when they are challenged courts should authorise the agreements only if there is a pro-competitive benefit or if the payment was made for some purpose other than delayed entry.

The Third Circuit's decision has created different legal precedents that apply in different parts of the US, which seems likely to force the Supreme Court to settle by the time its 2012-13 term ends next summer, especially since its jurisdiction includes Delaware, where a large share of US companies are incorporated.

"You shouldn't have the law depend on where you are in the country," said Kevin Noonan, a partner with the Chicago law firm McDonnell Boehnen Hulbert & Berghoff who specialises in biotech intellectual property law.

Immediate impact

Assuming the Supreme Court does agree to hear the case - Merck & Co and Upsher Smith Laboratories, the losers in the K-Dur case, have both filed petitions - the immediate impact will be that innovative drug companies will probably not be settling with generic manufacturers until the justices rule.

A decision allowing reverse payments to continue would strengthen the hand of branded drugmakers, argues Bernstein analyst Ronny Gal, particularly in the speciality pharma world of dermatology and ophthalmological drugs where strategies depend on formulation patents that extend the life of a drug franchise. Clear authorisation will allow them to buy uncontested market exclusivity from generic challengers until the end of those relatively weak patent terms.

It would no doubt lead to intensified calls from the FTC and such interest groups as the American Association for Retired Persons and Public Citizen for clear congressional action that specifically bans the payouts - the

agency has been among the parties challenging them in court. With budget worries on Congress's mind, a ban could be justified thanks to its potential to save billions of dollars in healthcare spending every year.

On the other hand, a decision against reverse payments would not only prohibit future ones, it would put past ones at risk of being declared invalid. Mr Gal cites Teva and Watson as being particularly at risk.

Whether the court decides in favour or against is partly a matter of a philosophical approach to the law, Mr Noonan notes. Because Congress has not specifically acted, the justices might decide that they are not in any place to make law that bans reverse payments. On the other hand, it could take a more activist view and invalidate them because extending patent life unfairly impairs competition and leads to increased costs for society, he said.

Predicting the Supreme Court's action is difficult at best, and of course the justices could decline to hear the case altogether. However, the need for a single national precedent is clear, and it would be a surprise if the court demurred.

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