

# The Antitrust issues of "Pay for Delay" Deals USA

A recent US Supreme Court ruling has paved the way for drugmakers to be sued for paying rivals to delay the market introduction of generic drugs. With this in mind, *Lawyer Monthly* finds out more by speaking to Chris Stomberg, a Partner at Bates White Economic Consulting and a co-founder of the firm's Health Care and Life Sciences practice.

## Please introduce yourself and your firm.

Our firm provides a full range of litigation support and consulting services to our clients. My practice is focused primarily on pharmaceuticals and devices where a significant amount of our work centres on alleged False Claims Act violations such as off-label promotion and kickbacks. We also have a budding pricing compliance practice.

## What are the key cases you deal with related to anti-trust law?

Some examples of the cases our firm has handled include AMD v. Intel (monopolization), Express Scripts/Medco (merger investigation), and in re: LCDs (cartel).

## What are the main implications of the recent Supreme Court ruling in terms of antitrust issues?

Probably the biggest implications of the Supreme Court's opinion stem from its rejection of the 2nd Circuit's "within the scope of the patent" test. But, the Supreme Court also stopped well short of embracing the FTC's position that these settlement arrangements should be considered either per-se or presumptively illegal.

To me this makes some sense: neither the 2nd Circuit's opinion nor the FTC's position have been wholly satisfying because they ignore the essential strength of the patent as a relevant factor. It is widely recognized that not all patents are created equal. Measures that could be justified as defense of a well-established right for a holder of a strong patent could easily be cast as improper restraint of competition for a holder of a weak patent.

While the Supreme Court's opinion appears to allow potential scope for this type of argument, it suggests that a patent examination might not be necessary. It also offers few specifics about what a rule of reason approach would constitute, so the real impact of this decision is uncertain.

## Is this a positive development for antitrust law in your opinion?

Because the Supreme Court has put it back on the lower courts to work out all the details, I think we will just have to wait and see how these cases are litigated in light of the Supreme Court's decision before passing judgment.

## What are the main contractual agreements that restrict competition?

The central issue in these settlements is the money or "value" that trades hands and the agreed dates of generic entry.

## Can you please give me a brief overview of the "rule of reason" analysis?

I believe there will be many facets to this analysis. One consideration to which I would pay particular attention is the recognition that the dollar value of a settlement in any litigation is potentially a poor indicator of the strength of the underlying claim. This is due to the uncertainty introduced by courts, which is perhaps best illustrated by the rate at which appellate courts reverse lower court opinions. This separate source of uncertainty is not under the control of the litigants in the same way that, for example, the strength of the underlying claim might be. This court risk can be a driving factor in settlement. In the pharmaceutical context, because of the

unusual economics of the Hatch Waxman rules, this can lead to reverse settlement payments even when both sides acknowledge that the underlying patent claim is strong. Other considerations such as risk-aversion and asymmetric beliefs of the litigants can further compound this effect. The bottom line is that one has to be careful about inferring too much about the strength of the underlying patent claim and thus the potential for antitrust harm from the face value of a settlement alone.

## Is there anything else you would like to add?

It was exciting to finally see the Supreme Court weigh in on these issues. It will now be interesting to see what rule of reason analyses are carried out, and whether any consensus emerges. **LM**

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