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Profitability as safe harbour against pay-for-delay claims

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Reverse payment settlements are supposed to violate antitrust law when the drug patent owner is compensating a potential competitor to stay out of the market – but what if the brand-name pharmaceutical company has other business reasons to pay up? **Eric Grannon** and **Rahul Guha** explain.

A year and a half after the US Supreme Court refused to deem reverse payment settlements either *per se* legal or illegal, lower courts are still figuring out what the *FTC v Actavis* decision meant. While much of the focus has been on the patent element, one concern stated in Justice Stephen Breyer's opinion for the majority is that "payment in return for staying out of the market simply keeps prices at patentee-set levels", dividing the monopoly rents between "the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses".

As the Federal Trade Commission noted in its recent report on pharmaceutical companies' patent settlements in fiscal year 2013, many of the agreements the agency considers to potentially involve "pay-for-delay" include compensation in the form of a side business deal between the brand and generic manufacturer. These side deals come in a variety of forms, such as co-promotion, distribution, and cross-licensing agreements.

Partner **Eric Grannon** leads the White & Case team defending two pharmaceutical companies against the commission's and private plaintiffs' antitrust claims of pay-for-delay settlements. He proposes a safe harbour against antitrust lawsuits for pharmaceutical settlements in which the contemporaneous business transaction between the brand-name and generic company is profitable to the brand-name company solely on the terms of that transaction. Grannon and Cornerstone Research economist **Rahul Guha** talk with Pallavi Guniganti about what such a test could mean.

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Grannon: *Actavis* held that the “payment may reflect compensation for other services that the generic has promised to perform”. If the brand pays the generic $1 for co-promote services and makes $1.10 from those services, the conduct is not diseconomic. Actavis’s repeated emphasis on “large, unexplained” payments means that from such diseconomic conduct courts can infer the payment was for delay. Without such diseconomy, there can be no such inference. There’s nothing “unexplained” about entering into a profitable transaction.

In our *FTC v Actavis* case, the FTC does not allege that the brand company lost money on either of the two co-promotes with the generic companies. Instead, the FTC alleges only that the brand company had cheaper co-promotion alternatives. The antitrust laws are not designed to punish firms for taking a less profitable approach, as opposed to another profitable approach. If you look at the predatory pricing context, for example, there is an absolute safe harbour for above-cost pricing. Justice Kennedy’s opinion for the court in *Brooke Group* acknowledges that above-cost pricing can still potentially have some anti-competitive effect, but deems that problem irremediable by antitrust because courts are ill-suited to price setting. The same logic should apply to side deals that are profitable to the brand company.

This safe harbour would still enable the antitrust laws to meet *Actavis’s* objective of policing “large, unexplained” payments that make no sense for the brand company aside from purchasing delay.

The lower courts already are issuing conflicting decisions under *Actavis*, and thus far have not really wrestled with how messy it is for a court to sit as an appraiser of a business deal like a co-promote or manufacturing agreement. Once that starts happening, district judges will be very interested in a potential safe harbour that makes sense under *Actavis*. It’s exactly what the Supreme Court invited the lower courts to do.

Otherwise, it becomes extremely difficult to resolve a case on summary judgment when each side will be able to obtain some expert who will be able to say varying things about whether a transaction was fair market value. If the side transaction is on its own terms profitable – whatever the brand company pays out, it gets back more from the co-promote, for example – that’s not what the Supreme Court was talking about when it said “large, unexplained payments”. If you don’t have that unexplained component, the flavour of providing unwarranted compensation to purchase delay, then it’s not what the Supreme Court was trying to get at.

Guha: I’ve been thinking about this issue in a way closely related to Eric’s, but slightly differently. Appraising the side deals is going to be an important and complicated issue. We should think carefully about the nature of these side deals and whether all these side deals are created alike. In particular, are there certain types of side deals that should not pose any antitrust issues?

Suppose a brand company can make a pill for a dollar. Further suppose that in the course of negotiating a settlement of patent litigation with a generic company the brand company learns that the generic company can make the same pill for 90 cents and enters into a manufacturing agreement with the generic. You can think of this transaction as one in which the brand company has figured out a better manufacturing technology. In this situation, there’s a direct reduction of costs, which leads to lower prices for consumers. There seems to be a clear link between the deal and consumer welfare. Note that a deal that lowers costs for the company is also – by definition – profitable on its own terms.

Under these circumstances, it does not seem that the appropriate analysis is to then ask: "Could the brand company have gotten a *better* deal? That is, is there someone in the world who could have made this pill for 75 cents instead of 90 cents?" There is an analogy with the *Brooke Group* analysis. Under *Brooke Group*, you cannot rule out the possibility that above-cost pricing can be predatory, but to the extent that lowering costs is generally a good thing, you don't want to chill price-cutting more generally by questioning why the company is cutting prices. Similar mechanics are at play here. If the side deal results in lower costs, which in turn leads to lower prices, it seems inappropriate to second guess it.

To the extent you can identify some clear cost reductions or efficiencies that should be a safe harbour.

Grannon: You wouldn't necessarily have cost savings from a co-promote deal. It might just be that the additional efforts made money for the brand company. It could be that the brand reduces costs through the deal, but it might just be profitable through higher revenue.

Rahul and I are making complementary points. To me, a profitable side transaction is enough for a safe harbour. Rahul is showing how the brand company can make money by lowering its costs, with a resulting benefit to consumer welfare. But a benefit to consumer welfare is not necessary to what I'm saying.

Guha: I agree. I'm framing the issue slightly more narrowly than Eric is, but conceptually you could think of various examples of side deals that are profit-enhancing for the settling party and can also be framed in terms of cost lowering.

Grannon: In a co-promote situation, what would the brand's costs be if it had to come up with this product promotion on its own? I don't think the cost lowering is necessary. The transaction could still be profitable even if somehow the brand could have done it cheaper on its own.

I think this kind of safe harbour will resonate with a lot of judges. A number of the decisions have granted motions to dismiss in favour of defendants. There is already an appetite among judges to get rid of these cases that don't have plausible allegations. The facts that went before the Supreme Court were the facts as alleged by the FTC, which alleged the side deals were "worth very little", or basically worthless. Once we're beyond bare allegations, the evidence will be unquestionable that the co-promotes were profitable for the brand. That's not a large and unexplained payment. More broadly, should a case be going to a jury based on the post hoc analysis of some expert to see whether the manufacturing could have been done for 75 cents per unit instead of 90 cents when the brand's prior cost was $1?

Guha: If you have to prove that whatever you did to lower costs or enhance profits was the best you could have done, that seems like an impossible standard to meet. For example, in Eric's example, the distinction would be between proving that the co-promotion deal was profitable versus proving that there wasn't another deal out there that was even better. How would you prove that?

Grannon: When the Supreme Court refers to a fair market transaction contemporaneous with the settlement, the inquiry is not whether the transaction is lowering costs or separately beneficial for consumers. If it's fair market value, it's not a large, unexplained payment. When the Supreme Court says district courts should develop tests to implement this rule, should courts hold a trial every time a third-party plaintiff says the brand company could have gotten that co-promote or manufacturing agreement cheaper elsewhere? How would you ever resolve that without a trial? If you read *Actavis* and think of the settlements that led up to the reverse payment controversy, they're about payments that made no sense whatsoever. They're about companies making naked payments or paying gross amounts more than something is worth. If it's the gross overpayment that's the concern, how could you make a profit on the transaction on its own terms if there's a gross overpayment?

Guha: The only way you might say that, is if it is linked to maintaining the franchise.

Grannon: I'm glad Rahul raised that because in discussing this safe harbour at the ABA fall forum someone said that the maintenance of market power has to be accounted for in assessing a side deal, and I disagree. A co-promote, for example, doesn't have to be on the same product whose patent is being challenged. Suppose the patent litigation is about Drug X, and the co-promote is on Drug Y. If the brand company pays a dollar for the co-promote of Drug Y, and gets back a $1.10 in revenue, that is profit. Market power has nothing to do with the valuation of a side deal. The question has always been, "Did the brand pay too much?" If they bought services from the generic, and they made money or saved money by doing it, then they didn't pay too much.

That takes us right back to *Brooke Group*, which says some above-cost pricing can cause consumer harm, but courts are not equipped to make those fine-tuned pricing decisions, so we're going to create a safe harbour.

Look at the allegations in *Cephalon* or another case in which the side deals are alleged to be gross overpayments for the services by the generics. If the plaintiff can plausibly allege, and then prove, that the side deal was unprofitable, the case would not qualify for the safe harbour. Whereas the side deals in our case, there's no way anyone could plausibly say they weren't profitable to the brand.

Guha: Not every side deal can easily be evaluated under this proposed safe harbour. For example, if the generic company owns a patent and the brand company acquires a licence to that patent, there could be considerable subjectivity in evaluating the value of such a licensing deal on an ex-ante basis. That's the kind of situation where you may need to conduct a more elaborate valuation exercise to determine if the deal constitutes fair market value. It's possible that certain licencing side deals are ultimately profitable for the company and also beneficial for consumers. But that may not be clear on an ex ante basis. There's a distinction to be made between deals whose effects are unclear ex ante, versus deals – such as the co-promote or manufacturing cost reduction examples that we were discussing earlier – whose effects are clear on an ex ante basis.

Grannon: To be clear, a consumer welfare element is not necessary to the safe harbour because the Supreme Court didn't discuss valuation on a consumer welfare basis.

Guha: I think that's an important distinction, because you are interpreting from a legal perspective, and I am trying to draw an analogy to *Brooke Group* from an economic perspective.

Grannon: That's an important clarification. If you're juxtaposing our views to reflect what we're saying, we're talking about different things. Rahul is talking about what makes economic sense to him. I'm trying to come up with a way to apply practically the Supreme Court's rule that a patent holder cannot make "large and unexplained" payments to avoid a risk of loss. The safe harbour for profitable contemporaneous transactions effectively screens out those settlements where the patent holder has not made an "unexplained" payment to avoid the risk of loss.