Practice Point

Patent settlements and competition law: where is the European Commission going?

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One of the clearer messages from the EU Pharmaceutical Sector Inquiry was that the European Commission believes some patent settlement agreements—in particular those involving payments from the patent holder to the challenger (so-called 'reverse payments')—may infringe EU competition law. Indeed, on the day it published the Final Report of the Inquiry, the Commission announced a formal investigation of Les Laboratoires Servier and various generic companies in relation to what are understood to be settlements concerning Servier's perindopril patents.[1]

This is a new development in Europe where patent settlements have not previously been a significant focus of competition law enforcement. In the USA, however, they have been the subject of significant antitrust litigation and debate and, it seems, the Commission is influenced by the US situation.

Based on a review of the Commission's statements and US case law, this article sets out the relevant issues in relation to reverse payment patent settlements, seeking to identify the approach likely to be taken under EU competition law. It also outlines some practical guidance on how to approach patent settlements without engaging competition law concerns.

Key issues

- Patent settlement agreements are a focus of EU competition law enforcement in the wake of the Pharmaceutical Sector Inquiry.
- Settlements involving payments from the patent holder to the challenger are a key concern.
- Some in the USA consider such agreements presumptively unlawful. Will the EU approach follow this model?

The historical approach to patent settlements under EU competition law

Historically, the stated approach to patent settlements under EU competition rules has been simple: they are merely agreements to be treated the same as any other. As the European Court of Justice put it in *Bayer v Süllhöfer*:

> Article [81(1)] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.[2]

This simple approach ignores the value of settlements. A settlement avoids the cost of litigation and creates certainty that allows parties to plan and invest. Both the settling parties and, importantly, society in general benefit. The simple approach also created a problem. Most patent settlements involve a no-challenge obligation. No-challenge clauses are generally regarded as restrictions of competition caught by the prohibition on anti-competitive agreements in Article 81(1) of the EC Treaty.[3] If settlement offered no pro-competitive benefits to set against that restriction, the implication appeared to be that most settlements potentially infringed EU competition law. In its 2004 Guidelines on technology transfer agreements, the Commission addressed (if not perhaps fully resolved) this issue by making it clear that, in the context of settlement and non-assertion agreements, appropriately tailored no-challenge clauses are not in its view caught by Article 81(1).[4] Although arguably this represents an implied recognition of the value of settlements, the Commission does not recognize the point expressly.[5]

Notwithstanding these difficulties, the simple approach at least suggested that patent settlements

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1 Commission Press Release 09/332, 8 July 2009.

2 Case 65/86 *Bayer v Süllhöfer* [1988] ECR 5249.

3 Case 193/83 *Windsurfing International* [1986] ECR 611 and Guidelines on technology transfer agreements, OJ C101, 2004, p. 2, §112.

4 Guidelines on technology transfer agreements, above, §209.

5 At §204, the Guidelines (*supra*) state that 'Licensing in the context of settlement agreements is treated like other licence agreements'.

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raised no specific competition law concerns. But, even that advantage seemed to vanish when the Commission indicated that it would be looking at settlement agreements as part of its Pharmaceuticals Sector Inquiry and included the following statement in the Preliminary Report of the Inquiry:

> as is shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules.[6]

The same language has now also been included in the Final Report of the Inquiry.[7] Though these reports assert that they do not aim to provide legal guidance, the implication seems clear. The Commission now considers that some patent settlements may raise specific competition law issues and this view is inspired by the approach to patent settlements under US antitrust law, in particular that of the Federal Trade Commission ('FTC'). The fact that, in the wake of the Sector Inquiry, the Commission now identifies patent settlements as one focus of increased competition law scrutiny and the opening of the *Servier* investigation, appear to confirm this.

Reverse payment settlements under US antitrust rules

The assessment of patent settlement agreements under US law is the subject of ongoing controversy. The FTC takes the view that reverse payment settlements should in most cases be presumed unlawful. The US courts have strongly disagreed, reversing findings of the FTC and rejecting private claims based on the presumption of illegality proposed by the FTC. The second US enforcement agency, the Department of Justice ('DoJ'), has until recently taken a position somewhere between that of the courts and the FTC.

The FTC's position

The FTC takes the view that settlements involving a substantial reverse payment often reflect a concern on the part of the patent holder that its patent rights are not strong and that the patent holder is, in effect, paying the generic challenger to stay out of the market so that it can prolong its patent monopoly. In its 2006 submission to the US Supreme Court in the *Schering-Plough* case, the FTC summarized its position as follows:

> [If] the patent holder makes a substantial payment to the challenger as part of the deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise.[8]

The FTC's position is therefore that a settlement involving a reverse payment should be treated as unlawful if

- the reverse payment is substantial,
- entry by the generic challenger is delayed, and
- there is no proof of any motive for the reverse payment other than the delay to generic entry.

In this context, a reverse payment limited to reasonable litigation costs will not normally be considered substantial. However, any settlement that does not provide for immediate generic entry may be considered to involve delay.

The position of the US courts

The presumption of illegality in relation to reverse payment settlements advocated by the FTC has been the subject of decisions by the Courts of Appeal in three separate US Circuits: *Schering-Plough* in the 11th Circuit, *In re Tamoxifen* in the 2nd Circuit, and *In re Ciprofloxacin* in the Federal Circuit.[9] In all three, the courts have firmly rejected the FTC presumption, and the US Supreme Court has refused to hear an appeal when one was sought.[10]

Instead, the courts have held that reverse payment settlements should be treated as lawful—regardless of the presence of a reverse payment—where the delay to generic entry occurs only within the scope of the relevant patent, ie

- within the period of patent validity and
- in relation to products that can reasonably be considered to infringe the patent.[11]

In contrast, reverse payment settlements that extend beyond the scope of patent protection, eg by preventing

6 Pharmaceutical Sector Inquiry, Preliminary Report, 28 November 2008, §579, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

7 Pharmaceutical Sector Inquiry, Final Report, Technical Annex, 8 July 2009, §708, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

8 FTC Petition for a writ of certiorari, *FTC v Schering-Plough Corp.*, 126 S. Ct. 2929 (2006), available at: http://www.ftc.gov/os/2005/08/050829scheringploughpet.pdf.

9 *Schering-Plough Corp. v FTC*, 402 F.3d 1056 (11th Cir. 2005) cert. denied, 126 S. Ct. 2929 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2nd Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert denied*, 129 S. Ct. 2828 (2009).

10 *Schering-Plough* and *In re Ciprofloxacin*, above.

11 *In re Tamoxifen* and *In re Ciprofloxacin*, above.

the generic from entering the market with products that do not infringe the relevant patent, have been found to constitute per se infringements of antitrust rules.[12]

The reasons given by the various US courts in rejecting the FTC position are interesting.

Deference to settlements

US law recognizes the private and social benefits offered by settlement agreements, including the avoidance of the costly effects of litigation and the resolution of uncertainty. As a result, settlements are not generally considered to infringe antitrust rules even where they may have some adverse effect on competition.[13]

The US position is therefore in contrast to the stated position under EU competition law which, as outlined above, is that settlements are not subject to special treatment. If therefore deference to settlements was the only reason given by the US courts for rejecting the FTC position, the European Commission might, in law, be justified in following the FTC line, although, as mentioned, the stated EU position on settlements ignores their very real benefits and there is arguably some precedent for a more balanced approach.[14]

Counterfactual difficulties

A second reason given by the US courts for rejecting the FTC's presumption of illegality concerns the FTC's counterfactual analysis. Under both US and EU competition rules, for an agreement to be considered anti-competitive, it must be shown that the counterfactual—ie the position but for the agreement—would be more competitive.

In *Schering-Plough*, the FTC argued (as set out in the quote above) that, absent the reverse payment, the parties would have agreed a settlement involving an earlier date for generic entry. The court in *Schering-Plough* rightly rejected this analysis, describing it as 'untenable'.[15] The problem is that, absent the reverse payment, it may be that no settlement would have been possible. First, it is unlikely to be possible to exchange the reverse payment for an earlier entry date without changing the terms of the agreement. Second, there is no reason to believe that a settlement on terms other than those actually agreed would be possible.

These points are well illustrated by the facts surrounding one of the settlements at issue in *Schering-Plough*, that between Schering-Plough and ESI. The settlement involved delayed entry and a $10 million payment from Schering-Plough to ESI. The settlement had not been easily reached. In fact it had been reached only after 15 months of court supervised mediation, and then only after the presiding judge had intervened and worked with Schering-Plough to develop the offer of a $10 million payment that was ultimately accepted by ESI. There is no good reason to believe that the parties would have settled on terms that were not equivalent to those actually agreed. And any settlement involving an earlier entry date for ESI could not have been on equivalent terms. The problem is that, because prices fall following generic entry, delay is worth more to the patent holder than early entry is to the generic challenger. Here, Schering-Plough would achieve higher prices during the period of delay than ESI would if allowed to enter. As a result, agreeing to an earlier entry date that would allow ESI to make an addition $10 million in profit to replace the payment would almost certainly cost Schering-Plough more than $10 million in lost profit. Conversely, an earlier entry date that cost Schering-Plough only $10 million would almost certainly be worth less than $10 million to ESI. These problems are implicitly recognized by the FTC, which has conceded that, in the absence of a reverse payment, settlement may be impossible in some cases.[16]

In more recent cases, the FTC has developed its counterfactual reasoning, without obviously improving it. It now argues that, if no settlement with an earlier entry date could be reached, continued litigation without settlement would 'yield a greater prospect of competition'.[17] This analysis too is apparently flawed. First, it suggests that, in some circumstances, parties must litigate their disputes to a resolution rather than settling them—notwithstanding the costs and uncertainties involved. Secondly, it ignores the fact that, if the dispute is litigated to a result, the outcome will only be more competitive if the generic challenger wins. Implicitly, therefore, the FTC must be arguing that existence of a reverse payment shows that the patent holder would lose the litigation. This does not follow. At most, the mere existence of a reverse

12 *In re Cardizem CD Antitrust Litig.*, 332 f.3d 896 (6th Cir. 2003), *cert. denied*, 543 US 939 (2004).

13 *In re Tamoxifen*, above, at 202.

14 Guidelines on technology transfer agreements, above, §209 and see also Case 35/83 *BAT v Commission* [1985] ECR 363.

15 *Schering-Plough*, above, at 1066 footnote 15.

16 *In re Schering-Plough Corp.*, No. 9297 (FTC 18 December 2003), at 38, available at http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.

17 *FTC v Cephalon*, FTC pleadings available at: http://www.ftc.gov/os/caselist/ 0610182080213complaint.pdf.

payment shows only that the patent holder believes that there is some risk (which may be substantially less than 50%) that it might lose the litigation.

Limited anticompetitive impact and the presumption of validity

A third concern of the US courts relates to the impact of any one settlement on competition, and is perhaps best explained in terms of the presumption of patent validity. If the disputed patent is presumed valid, a settlement that delays generic entry only within the scope of the patent will have no anticompetitive effect, since the restricted entry is prohibited under the patent even absent the settlement. This applies whether or not the settlement involves a reverse payment.

Moreover, as pointed out by the court in *In re Tamoxifen*, a settlement is also unlikely to have an anticompetitive effect if the presumption is reversed and the patent assumed to be invalid:

> while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.[18]

Thus, whether the patent is assumed to be strong or weak, US courts have concluded that an individual settlement is unlikely to have a significant anticompetitive impact. Further, it is unlikely that the holder of a weak patent could stave off all possible challengers by entering into reverse payment settlements with each of them because the economics simply would not justify it.[19]

The facts in *In re Tamoxifen* are worth considering in this regard. The case concerned a settlement between the patent holder Zeneca and Barr. Barr had succeeded in having the relevant patent set aside at first instance, and the settlement related to the appeal from that decision. Under the settlement, Zeneca agreed to pay Bar $21 million in return for Barr obtaining a vacatur of the first instance judgment holding the patent invalid. There therefore seemed to be good grounds for suspecting that the settlement was intended to shore up a weak patent. However, the facts subsequently suggest otherwise. Following the settlement, there were three further challenges to the Zeneca patent by other generic companies wishing to enter the market. Each of these attempts failed, with the patent being upheld by the courts despite the earlier finding of invalidity.

The DoJ position

The position of the DoJ is also worth-considering. Until recently, it took a position somewhere between that of the US courts and the FTC. The *amicus curiae* brief to the Supreme Court in *Schering-Plough*, drafted by the DoJ, argued that FTC's position was contrary to the public policy favouring settlements and would potentially frustrate the statutory rights of patentees.[20] In particular, the DoJ was concerned that, even if a reverse payment could be seen as evidence that the parties (particularly the patent holder) believed the patent was weak, it was only evidence of their *subjective* assessment. The DoJ argued that an appropriate legal standard should take account of an *objective* assessment of the patent holder's likelihood of success in the litigation (judged *ex ante*). To this end, the DoJ suggested that the assessment should be based on:

> a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties' negotiations.[21]

This proposal was, in turn, dismissed by the FTC, not least because of concerns about the ability of competition authorities (or courts) to make such an assessment absent a full trial on the merits.[22] It has not been adopted by the US courts.

Following his election, President Obama appointed Christine Varney, a known supporter of the FTC's position on reverse payment settlements, as head of the DoJ's antitrust division. The DoJ has subsequently fallen into line with the FTC and endorsed the presumption of illegality in relation to reverse payment settlements.[23]

Ongoing developments in the USA

Debate and developments in the USA on this issue continue. Both the FTC and private parties continue to bring cases to the US courts in relation to settlements within patent scope, despite their lack of success to

18 *In re Tamoxifen*, above, at 211. See also *In re Ciprofloxacin*, above, at 534.

19 *In re Tamoxifen*, above, at 212. See also *In re Ciprofloxacin*, above, at 535.

20 Brief for United States as Amicus Curiae, *FTC v Schering-Plough Corp.*, 126 S. CT 2929 (2006) (No. 05-273), available at: http://www.usdoj.gov/atr/cases/f216300/216358.pdf.

21 Brief for United States as Amicus Curiae, *FTC v Schering-Plough Corp.*, above.

22 *In re Schering-Plough Corp.*, No. 9297 (FTC 18 December 2003), above, at 34.

23 Brief for United States in response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund et al v Bayer et al*, available at http://www.usdoj.gov/atr/cases/f247700/2477008.pdf.

date.[24] The most interesting of these cases is *Arkansas Carpenters* which is currently before the 2nd Circuit Court of Appeal.[25] This is the court that rejected the FTC presumption of illegality in *In re Tamoxifen* and, all other things being equal, it would be expected to follow that precedent. However, the Court of Appeal has taken the unusual step of requesting a submission from the DoJ before reaching a decision. Since it was known at the time of the request that the DoJ had changed its view and now supported the FTC position, one possibility is that the Court of Appeal requested the submission because it too is considering changing its position and supporting the FTC line.

At the same time, legislation which would prohibit reverse payment settlements is currently before both Houses of Congress. So, the law may change even if the US courts maintain their current line.

The final report of the sector inquiry

In addition to the passage cited above, the Final Report of the Sector Inquiry contains a reasonably detailed summary of the FTC's position in relation to reverse payment settlements and a much briefer summary of the US court's rejection of it. It also includes a factual assessment of the patent settlements identified by the Commission in the course of the Sector Inquiry. The class of settlement agreements on which the Commission focuses goes beyond simple reverse payment agreements in two respects.

First, the Commission extends its assessment beyond settlements involving a simple monetary reverse payment to all settlement agreements involving a 'value transfer' from the patent holder to the generic challenger.[26] A value transfer is defined, in this context, to include the grant of a licence, appointment of the challenger as a distributor, supply agreements for active substances, and other side deals.

Second, the Commission's focus extends beyond agreements that involve a delayed date for generic entry to all settlements that involve a 'limitation' on generic entry.[27] Examples of limitations on generic entry include agreements in which the patent holder grants a licence of the disputed patent to the generic challenger, in which the challenger is appointed a distributor of the patent holder's product, or in which the patent holder supplies the challenger with the relevant active substance. In the Commission's view, under all of these arrangements, the generic company's entry onto the market is to some extent 'controlled' by the patent holder.[28]

The extension of potential illegality to these more complex settlements would raise further concerns. In particular, in the context of settlements involving side deals—eg cross-licensing or distribution arrangements—it would need to be established that the reverse payment (or value transfer) cannot be explained by the side deal. This issue arose in a second settlement considered in *Schering-Plough*. The only upfront payment in the deal, between Schering-Plough and Upsher, was an initial $60 million royalty paid by Schering-Plough for the right to market five Upsher products. Having extensively analysed the facts surrounding the deal, including the records of negotiations, the FTC concluded that the licence could not explain the scale of the payment. Among others, Schering-Plough did not ultimately commercialize any of the Upsher products. The FTC therefore found that the licence fee was in fact a reverse payment. The difficulty of such analyses is underlined by the strength with which the Court of Appeal in *Schering-Plough* dismissed the FTC's conclusion, stating:

> [the] conclusion that [the licence] was not worth $60 million, and that settlement payment was to keep Upsher off the market is not supported by law or logic.[29]

If the Commission ultimately decides to pursue these issues, it will have to overcome these substantial difficulties. It is not unlikely that, initially at least, it will confine itself to cases involving either only a monetary payment or a side deal that is difficult to explain as a commercial arrangement and can therefore easily be characterized as a disguised reverse payment, eg deals in which the challenger is offered a royalty-free license of unrelated IP.

Predictions and precautions

Until the Commission takes its first decision in an individual case, there will be no certainty as to the status of reverse payment settlements under EU competition rules. Though *Servier* has been formally announced, a decision seems likely to be at least 18 months away. And even then appeals to the European Courts can be

24 *FTC v Watson*, press release available at: http://www.ftc.gov/opa/2009/02/androgel.shtm and *FTC v Cephalon*, above.

25 *Arkansas Carpenters Health and Welfare Fund et al v Bayer et al*, FTC Watch report available at: http://www.nyls.edu/user_files/1/2/100/Peritz%20Op-Ed%2006.15.09%20FTC-Edited.doc.

26 Pharmaceutical Sector Inquiry, Final Report, Technical Annex, above, p. 269.

27 id.

28 id.

29 *Schering-Plough*, above, at 1070.

expected. In the mean time, predictions are difficult, particularly given the ongoing uncertainty in the USA.

Nonetheless, predictions must be made and some can be made with confidence. First, reverse payment settlements which restrict generic entry outside the scope of the relevant patent—ie in relation to non-infringing products or periods after patent expiry—are very likely to be found to infringe EU competition law.

Second, the Commission is not unlikely to take the view that at least some reverse payment settlements that restrict generic entry only within the scope of the patent are unlawful. Whether the Commission will adopt the FTC's presumption of illegality is more difficult to predict. However, the following passage from the Final Report of the Sector Inquiry perhaps offers a hint:

> During the public consultation, some stakeholders expressed concern that all [reverse payment] settlement agreements . . . were *deemed* anticompetitive. In this regard, it is important to underline that . . . any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis (emphasis added).[30]

This passage did not appear in the Preliminary Report and its inclusion may suggest that the Commission does not intend to adopt the FTC's presumption. Given the problems with that presumption identified by the US courts and outlined above, this would seem appropriate. However, even if this reflects the Commission's current view, that view may change. Particularly if the 2nd Circuit Court of Appeal in *Arkansas Farmers* reverses its position and falls in behind the FTC. Such a change of heart by the 2nd Circuit Court would make it politically easier for the Commission to adopt the FTC's line. And the presumption of illegality would make the Commission's enforcement task easier.

If the Commission chooses not to follow the FTC, an alternative might be to follow the approach suggested by the DoJ in *Schering-Plough* and assess 'the merits of the patent claims and other relevant factors'.[31] If the Commission can identify cases where the internal documents of the parties suggest that the motive for the reverse payment was a belief that the patent holder would not prevail in the litigation, they would be tempting candidates for enforcement action.

What does all this mean in practice? For those involved in negotiating patent settlements in the pharmaceutical sector, the following precautions would seem sensible. First, avoid settlements that restrict generic entry in relation to products or periods outside the scope of the relevant patents. Second, to the extent practicable, avoid settlements that include naked reverse payments or arrangements such as royalty-free licences which might be seen as equivalent to a naked payment. Finally, any settlement involving a value transfer from the patent holder to the generic challenger and delayed generic entry is a potential concern if the internal assessment is that the patent holder is unlikely to prevail in the underlying litigation—particularly where that internal assessment is well documented.

30 Pharmaceutical Sector Inquiry, Final Report, Technical Annex, above, §763.

31 Brief for United States as Amicus Curiae, *FTC v Schering-Plough Corp.*, above.