COMPETITION LAW

PAYING FOR DELAY AND THE RULE OF REASON – *FEDERAL TRADE COMMISSION V ACTAVIS INC ET AL*[1]

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On 17 June 2013, the Supreme Court of the United States handed down its judgment in FTC v Actavis, Inc., where it considered for the first time the appropriate antitrust analysis of reverse payment patent settlements (so-called "pay for delay" agreements) in the pharmaceutical sector and held that such settlements fall to be analysed under the "rule of reason", that is by reference to their actual effects on competition in all the relevant circumstances. In taking this view, the Supreme Court overturned Eleventh Circuit precedent under which settlements were exempt from anti-trust scrutiny provided that they fell within the scope of the patent.

Notwithstanding the Supreme Court's refusal to condemn reverse payment settlements as *per se* unlawful or even to adopt a presumption of illegality, its judgment is likely to have a chilling effect on such agreements. The decision is relevant to European companies not only because of the extraterritorial reach of US antitrust law, but also because European regulatory enforcement activity in relation to "pay for delay" is increasing and may well take its cues from the US approach.

"Pay for delay" agreements – overview and concerns

"Pay for delay" agreements involve the settlement of patent infringement litigation between the holder of a pharmaceutical patent ("the originator") and a person wishing to manufacture or supply its own version of the patented product ("the generic company") on terms (i) requiring the generic company to delay market entry of its non-branded product, either until the relevant patent expires or for some shorter period of time, in return for (ii) a "reverse payment"[3] from the originator.

Reverse payments have become a relatively common feature of pharmaceutical patent settlement both in the US and in the EU. In the absence of a patent, a payment by one firm

1. As yet unreported. The Slip Opinion is available on-line at: http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf

2. The views expressed in this case note are those of the author, and do not reflect the views of Monckton Chambers or any of its members.

3. "Reverse payments" are so-called because the expected direction of payment in a patent enforcement action is reversed – i.e. flowing from the patent holder (which is typically seeking damages for infringement of his patent) to the alleged infringer.

to a potential competitor in return for a promise from the latter not to enter the relevant market would amount to market allocation, a *per se* breach of US anti-trust law and a object infringement under EU law. However, the existence of a valid patent gives the patent holder a legal right to prevent others from manufacturing and distributing the patented product altogether, making the competitive impact of a reverse payment patent settlement much more difficult to ascertain than that of a straight market allocation arrangement – and logically dependent on the validity of the underlying patent.

European enforcement

European Competition authorities have expressed concern that reverse payments can be used as a means to prolong unmeritorious patent claims and divide resultant monopoly rents between the originator and the generic company at the expense of consumers (who would most benefit from the reduced prices flowing from generic entry). Regulatory enforcement is now intensifying in this area:

- On 19 April 2013, the Office of Fair Trading ("OFT") published its first Statement of Objections in relation to allegations of reverse payment settlements relating to GlaxoSmithKline's patented anti-depressant, paroxetine.[4]
- On 19 June 2013, the European Commission issued a press release indicating that it has imposed fines totaling over €140 million on a number of European pharmaceutical companies in connection with alleged reverse payment settlements involving Lundbeck's blockbuster anti-depressant drug, citalopram.[5]

US enforcement – divergent approaches

Across the Atlantic, the United States Federal District and Circuit Courts have been wrestling with the correct antitrust analysis of reverse payment patent settlements for over ten years and have developed three distinct approaches:

- **The "*per se*" approach:** Reverse payment settlements are subject to a *"conclusive presumption of illegality"*, which the settling parties cannot rebut by pointing to countervailing pro-competitive benefits of the settlement: see, e.g., In *re Cardizem CD Antitrust Litigation* 332 F.3d 896 at 912 (6th Cir. 2003). This approach effectively refuses to recognize any difference between a patent settlement and an ordinary market allocation agreement.

- **The "quick look" approach:** The presence of a reverse payment creates a presumption that the settlement is amounts to an unreasonable restraint of trade, which can be rebutted by evidence that the reverse payment *"(1) was for a purpose other than delayed entry* [of the generic] *or (2) offers some pro-competitive benefit"*: see, e.g., *In re K-Dur Antitrust Litigation* 686 F. 3d 197 at 214-218 (3rd Cir. 2012).

- **The "scope of the patent" approach:** Provided that the litigation being settled

4. The OFT's press release is available here: http://www.oft.gov.uk/news-and-updates/press/2013/36-13.

5. The Commission's Press Release is available here: http://europa.eu/rapid/press-release_IP-13-563_en.htm

is not a sham and the underlying patent was not procured by fraud, reverse payment settlements are lawful so long as they do not go beyond the scope of the exclusionary potential conferred by the patent: see, e.g., *Valley Drug Co. Inc., v Geneva Pharmaceuticals, Inc.,* 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v FTC* 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187, 213 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation* 544 F.3d 1323 at 1336 (Fed. Cir. 2008).

The scope of the patent approach appeared to be the most popular approach to antitrust analysis prior to the Supreme Court's judgment in *Actavis;* it has now been rejected in favour of a full rule of reason analysis.

FTC v Actavis

Facts

In 2003, Solvay Pharmaceuticals ("Solvay") obtained a US patent for a topical testosterone hormone gel, which it began to market under the brand name Androgel. In that same year, Actavis Inc, Paddock Laboratories and Par Pharmaceutical ("the generic companies") challenged the validity of Solvay's patent and sought authorization from the US Food and Drug Administration ("FDA") to market their own generic (non-branded) versions of Androgel.[6] The resultant patent litigation was settled in 2006 on terms requiring the generic companies not to bring their versions of Androgel to market until 31 August 2015 (some 65 months before Solvay's patent expired) unless a third party marketed a generic version sooner, and to promote Androgel to urologists. In return, Solvay agreed to make substantial payments to each generic company totaling up to USD 352 million over nine years. The validity of Solvay's patent for Androgel has never been determined.

In 2009, the US Federal Trade Commission ("FTC") filed a civil law suit against Solvay and the generic companies claiming that the Androgel settlement agreements were anti-competitive because Solvay's reverse payments to the generic companies involved a sharing of monopoly profits designed to prevent market entry by potential competitors, and, therefore, breached § 5 of the Federal Trade Commission Act and § 1 of the Sherman Act which prohibit agreements in restraint of trade (i.e. anti-competitive agreements).

Supreme Court's approach – Rule of Reason

In the *Actavis* case, the lower courts had analysed the reverse payment settlement under a "scope of the patent" approach[7] and, on that basis, had dismissed the FTC's complaint. Before the Supreme Court, Solvay and the generic companies sought to uphold the judgments of the lower courts, while the FTC argued for a "quick look" antitrust approach.

The Supreme Court (by a majority of 5 to 3)[8] rejected the scope of the patent approach

6. The patent challenge was brought under §355(j)(2)(A)(vii)(IV) of the Drug Price Competition and Patent Restoration Act ("the Hatch-Waxman Act"). The relevant provisions of the Hatch-Waxman Act are described in detail in Section I(A) of the Opinion of the Court.

7. Slip Opinion, Opinion of the Supreme Court, page 6-7.

8. The Opinion of the Court was delivered by Breyer J, and joined by Kennedy, Ginsburg, Sotomayor and Kagan JJ. Roberts CJ delivered a dissent in which

holding that a reverse payment settlement *"can sometimes violate the antitrust laws"*[9] even where the *"agreement's anti-competitive effects fall within the scope of the patent"*[10]. The majority cited some of its older antitrust judgments in which it had held that patent settlements involving the cross-licensing of related patents and an agreement amongst patent holders as to the prices to be charged for sub-licences for those patents were unlawful.[11] The majority went on to reject the FTC's proposed quick look approach[12] in favour of a full "rule of reason" analysis, under which the lower courts are required to determine, in light of all relevant facts and circumstances, whether a particular settlement agreement has overall pro-competitive or anti-competitive effects on the relevant market.[13]

<u>The dissent – Rule of Reason undermines settlement</u>

The dissent of Roberts CJ advocates the "scope of the patent" approach and attacks the majority's holding primarily on the ground that a proper "rule of reason" approach would effectively require the parties to litigate issues of patent validity and infringement in the context of the antitrust claim (and to incur the significant costs of doing so), thereby undermining the very purpose of patent settlement and the public policy favouring such settlement.[14] The need to litigate the validity of the patent flows from the fact that a valid patent confers upon the patent holder a time-limited right to prevent would-be competitors from manufacturing and marketing the patented product or using the patented process to manufacture a product. Thus, logically, patent settlement involving a reverse payment in return for delayed generic entry can only have an anti-competitive effect if the underlying patent is invalid and/or the generic version in question does not infringe - in which case the generic would have been free to enter the market absent the settlement. Where the patent is valid and the generic version does infringe, the generic manufacturer could not lawfully have entered the market in any event, and the reverse payment settlement has, at worst, a neutral competitive effect, and possibly even a pro-competitive one.

<u>Avoiding the patent law issues</u>

The majority seeks to avoid the practical difficulty associated with the rule of reason approach by stating that *"it is not normally necessary to litigate patent validity to answer the antitrust question"* because *"an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival"*[15] and *"the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness"*[16]. It appears that by

Scalia and Thomas JJ joined. Alito J took no part in the consideration or decision of the case.

9. Slip Opinion, Opinion of the Court, page 2.

10. Slip Opinion, Opinion of the Court, page 8.

11. Slip Opinion, Opinion of the Court, page 8-12. See *United States v Line Material Co* 333 US 287 (1948); *United States v New Wrinkle, Inc.,* 342 US 371 (1952). Also citing *Standard Oil Co (Indiana) v United States* 283 US 163, (patent cross-licensing and agreement on royalties, but no agreement as to price for sub-licences; no anti-trust violation) and *United States v Singer Manufacturing Co* 374 US 174 (1963) (purchase and grantback of patent rights amounts to antitrust violation when done with the purpose of restricting Japanese competition on US market).

12. Slip Opinion, Opinion of the Court, page 20.

13. Slip Opinion, Opinion of the Court, page 21.

14. Slip Opinion, Dissenting Opinion, page 12-13.

15. Slip Opinion, Opinion of the Court, page 18.

16. Slip Opinion, Opinion of the Court, page 19.

"large unexplained" reverse payment, the majority means a payment that cannot be justified by the reference to (i) the costs of litigation saved by the patent holder, (ii) fair value for services rendered by the generic company or (iii) *"other* [unspecified] *justifications"*[17]. The majority does not, however, go so far as to establish a presumption of anti-competitive effects based on a *"large unexplained"* reverse payment, instead leaving to the lower courts *"the structuring of the present rule-of-reason antitrust litigation"*.[18]

The dissent does not consider that the size of the reverse payment is an appropriate short cut for determining the validity of the patent or its infringement, because the size of the payment only measures *"the parties' subjective uncertainty about that legal conclusion",* rather than indicating the correct underlying patent law position.[19] Further, the dissent challenges the majority's assumption that the size of the reverse payment is a good indicator even of the level of the patent holder's doubt as to the validity of its own patent given that *"a patent holder may be 95% sure about the validity of its patent, but particularly risk averse or litigation averse, and willing to pay a good deal of money to rid itself of the 5% chance of a finding of liability"*.[20]

Comment

Both the majority and the dissenters in the US Supreme Court recognize the high transaction costs associated with the determination of patent validity and infringement – and agree that it is desirable to avoid the need for such a determination in the context of an anti-trust assessment.

Further, although the majority and the dissent propose very different antitrust approaches to reverse payment settlements, both approaches are aimed at truncating or abbreviating the full rule of reason analysis of competitive effects in such a way as to avoid the patent law question: the dissent does this by presuming the validity and infringement of the disputed patent; the majority does this by positing a presumption of weakness or invalidity of the patent based on the size of the payment. Neither approach provides an entirely satisfactory outcome. The majority's approach will discourage reverse payments (because parties are likely to be nervous as to whether any payment might be considered *"large and unexplained"*) and reduce the scope for settlement altogether (because the parties are less likely to settle when they have fewer things to exchange); thereby pushing the transaction costs associated with the determination of patent validity and infringement back from the antitrust to the patent law field – rather than actually helping to avoid these transaction costs. While, the dissent's proposed "scope of the patent" approach has the advantage of actually avoiding the transaction costs associated with the determination of validity/infringement and genuinely encouraging settlement, it might be felt that the dissent allows for insufficient regulatory oversight in a socially significant area of economic activity.

17. Slip Opinion, Opinion of the Court, page 17.

18. Slip Opinion, Opinion of the Court, page 21. The majority also points out that it is open to parties to patent litigation to avoid the uncertainty created by the application of the rule of reason to reverse payments by settling their disputes in other ways – for example, by providing for the generic manufacturer to enter the patent holder's market prior to the expiry of the contested patent: Slip Opinion, Opinion of the Court, page 19.

19. Slip Opinion, Dissenting Opinion, page 13.

20. Ibid.

Thus, there is a sense throughout both the Opinion of the Court and the Dissenting Opinion that an anti-trust solution is being fashioned to fix a patent law problem: namely, the fact that litigation is desirable from a whole economy perspective in order to weed out unmeritorious patents, but can be prohibitively expensive and time consuming for the parties actually engaged in litigation who will have a substantial interest in settling as best they can. It seems that patent law (litigation) reform is likely to provide a far better solution to this problem than constraining parties' ability to settle through anti-trust laws: that would, of course, require legislation both in Europe and in the US.

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