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Competition Law

BEWARE OF “PAY-FOR-DELAY” SETTLEMENTS

On 8 September, the General Court of the European Union upheld a €93.8 million fine imposed by the European Commission in 2013 against Danish pharmaceutical provider, Lundbeck, in addition to fines totalling €52.2 million against four generic pharmaceutical companies. The fines were imposed on these companies as a result of so called "pay-for-delay" settlement agreements they entered into, which were found by the court to be anti-competitive.

What is a pay for delay settlement?

Pay-for-delay settlements operate in the pharmaceutical space in the following way: In settling a patent dispute between a patent holder (also known as the patent originator) and a generic producer, the patent originator agrees to transfer some form of value to the generic producer in exchange for which the generic producer agrees not to enter the market for a certain length of time.

Settlements such as these have become known as pay-for-delay settlements, or reverse payments, because the patent originator pays the entity accused of infringement to settle the dispute, the opposite of what normally happens in patent litigation settlements.

There is an argument that pay-for-delay settlement agreements are, like any settlement agreement, socially and economically efficient as they avoid the cost of litigation. Patent litigation can be hugely risky and full of uncertainty as the patent must be assessed for novelty and inventiveness, the latter concept being somewhat subjective.

However, competition watchdogs, such as the Federal Trade Commission (FTC) in the United States (US) and the European Commission, argue that pay-for-delay settlement agreements are potentially anti-competitive as they can result in an artificial maintenance of the patent originator's monopoly where there would otherwise have been competition in the market. This allows the patent originator to keep its prices high.

How do they fit into the Patent landscape?

A valid patent grants the owner 20-years of market exclusivity, during which time the patent owner and its licensees are the only entities that may make and sell the patented invention. This creates a competition vacuum, which allows the patent owner to charge high prices for its product. Bringing a single drug to market is an expensive exercise, although how expensive remains a debate as these figures are not in the public domain. As a result, it is the *modus operandi* of all pharmaceutical companies to make significant profits out of their successful drugs before their patent expires and

competitors enter the market.

After a patent expires, or is challenged in court and found to be invalid, anyone may take that invention and exploit it, including making a generic version of a patented pharmaceutical product. Once generics enter the market, competition is stimulated and the drug becomes much more affordable.

This is all within the parameters of the not uncontroversial bargain which legislatures have struck on behalf of the public, in order to incentivise the invention of new medicines.

However, some pay-for-delay settlements appear to reach beyond this agreed upon social contract, allowing the patent originator to continue to exploit a monopoly to which they are not entitled.

The US and the EU have taken different approaches in dealing with these settlements.

European Union

The European Commission has, since 2009, been keeping a watchful eye on pay-for-delay settlement agreements, looking out for those that may be problematic. Specifically, it is on the lookout for settlements that delay the entry of generics into the market, in exchange for a value transfer from the patent holder.

The *Lundbeck* case (Case T-472/13 *Lundbeck v Commission)*

In 2010 the European Commission began investigating Lundbeck, the patent originator of the blockbuster anti-depressant molecule, citalopram. Lundbeck's basic patent on the citalopram molecule had expired; it held various process patents which provided only weak protection. This meant that it was possible for generic companies to challenge these patents and possibly enter the citalopram market. Various generics companies, including Generics UK, Arrow, Alpharma, and Ranbaxy, were preparing to do so. However, instead of bringing their generics onto the market, these companies entered into settlement agreements with Lundbeck in terms of which they agreed to stay out of the market for a certain period of time, in return for a substantial "value transfer" from Lundbeck. The value transfer included not only a lump sum payment but also an agreement to purchase stock of the generic products for the sole purpose of destroying it, and offering guaranteed profits in a distribution agreement. This allowed Lundbeck to retain its monopoly in the citalopram market, as its weak process patents remained unchallenged. The amount Lundbeck paid to the generic companies was approximately the same amount those companies would have made had they successfully entered the market.

The Commission found that these agreements intended to delay the entry of generic versions of the citalopram molecule into the market, thereby negatively affecting consumers, and the national health system.

The General Court confirmed the Commission's findings, including that these settlements constituted *"buying off of competition".*

The court agreed that the agreements eliminated competition and were a restriction of competition *"by object".* In 2013 the Commission found that where a settlement agreement has restriction of competition as its object, there is no need to establish the concrete effects of such an agreement, as it is *"by object"* anti-competitive. Furthermore, the court found that Lundbeck was unable to show that the agreements were necessary to protect its intellectual property.

After the court's decision was announced, Lundbeck issued a statement in which it maintained that the settlements *"did not restrict competition and did not go beyond the protection already offered by society via Lundbeck's patent rights".*

United States

The position is even more intriguing in the United States where the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, incentivises generic producers to enter the market by giving 180-days of market exclusivity to the first generic company to have its Abbreviated New Drug Application (ANDA) passed by the Food and Drug Administration (FDA). To be successful, the applicant must also certify that any patent covering the drug has expired, that it is invalid, or that it will not be infringed by the sale of the generic. The patent originator often sues the generic company at this point. It is usually once litigation proceedings have been initiated that pay-for-delay settlements are reached.

One of the Federal Trade Commissions' top priorities in recent years has been to oppose pay-for-delay settlement agreements, which they argue stifle competition for lower cost medicines.

An FTC study published in 2010 estimates that pay-for-delay settlements cost American consumers and taxpayers approximately $3.5 billion annually. The patent holders, on the other hand, argue that the settlements are legal and bring generics to market sooner than if patent litigation continued.

***Federal Trade Commission v Actavis (FTC v. Actavis, Inc.,* 133 S. Ct. 2223 (2013)).**

The United States Supreme Court in the *Actavis* case said that these types of settlement cannot be said to be either always legal or always illegal. Rather, it held that each settlement agreement would need to be assessed on a case- by-case basis to determine if it is reasonable, taking into account any anti-competitive effects it may have, as well as its legitimate objectives. This is known as the *"rule of reason".*

However, the court did not set out the factors to be considered under the rule of reason, except to say that *"the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."*

South Africa

South African courts have not yet dealt with pay-for-delay settlements; it will be interesting to see if it they will follow the stricter EU approach, or the more nuanced US approach.

Section 4(1)(a) of the Competition Act (89 of 1998) says that an agreement between competitors is prohibited if it has the effect of substantially preventing or lessening competition in a market, unless a party to the agreement can prove that any technological, efficiency, or other pro-competitive gain resulting from the agreement outweighs that effect.

This wording appears to be more aligned with the US rule of reason approach, presumably requiring the anti-competitive effect of an agreement to be proved, rather than assumed.

Until the position is clarified, however, litigants may be left with a somewhat uneasy feeling that their carefully negotiated settlement agreements could fall foul of the competition laws if they involve pay-for-delay.

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