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After Lundbeck: Is the "pay for delay" debate over?

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The wheels of justice may turn slowly, but their grind is relentless. In 2013, the European Commission fined Lundbeck and several generic pharma companies EUR 146 million in respect of anti-competitive agreements inked in 2002. That marked the Commission's first enforcement action against pharma patent settlements. Nearly two decades after those agreements were concluded, the EU's Court of Justice recently rejected the companies' appeals against the Commission's prohibition decision. A clean and clear vindication of the Commission's approach.

Depression is a leading cause of disability worldwide. Studies show that, at some point in our lives, between 8% and 18% of all humans suffer from depression. A variety of methods have been used to manage the condition, ever since Hippocrates' days of early medicine. Today, patients experiencing "major depressive disorder" are frequently recommended treatment with antidepressant medication classed as selective serotonin reuptake inhibitors ("SSRI"). *Citalopram* is one such SSRI agent, which was discovered by scientists at the Danish pharmaceutical company Lundbeck in the 1970s.

Lundbeck was granted patents covering the *citalopram* molecule and also the process by which it manufactured the agent. By 2002, the substance patents had expired but some process patents remained in force. At the time, other pharma companies were looking to launch generic *citalopram* versions and they disputed the validity of Lundbeck's process patents. Several such disputes were resolved by settlement agreements: the generics – Merck KGaA, Alpharma, Arrow and Ranbaxy – dropped their patent challenges and, in return, received financial compensation from Lundbeck.

The European Commission found in 2013 that these settlements were *"very different from other settlements of patent disputes where generic companies are not simply paid off to stay out of the market"*. It concluded the agreements were anti-competitive *"pay for delay"* agreements and fined the companies EUR 146 million in total. The Commission was not merely concerned that the settlements could give rise to anti-competitive effects, but found that the agreements had the "object" of restricting competition, because:

> Lundbeck and the generic firms were potential competitors (at the very least) when the agreements were concluded;

> Lundbeck had agreed to transfer lump sums of money to the generics, reflecting the profits the generics might generate from their *citalopram* products; and

> those payments were linked to the generics' commitments to delay launch of their generic *citalopram* products.

The Commission had in a sector inquiry some years earlier identified competitive concerns around pay for delay agreements, but the *Lundbeck* matter was a first-of-its-kind enforcement action. The companies appealed against the Commission's decision and the EU's General Court rejected those appeals. The Court of Justice's ruling on the final appeals followed a preliminary ruling requested by a UK Court on a set of pay for delay arrangements involving GSK (incidentally, GSK's agreements involved another SSRI agent: *paroxetine*), and, as expected, the Court maintained a consistent approach to the core issues raised. The *Lundbeck* ruling answers two fundamental questions.

Who is a potential competitor?

This question concerns the companies' main objection to the Commission's decision. In essence, they argued that: Lundbeck held patents that barred the generics' launch of rival *citalopram* products; those patents must be presumed valid (and effective), and; such patents therefore prevented entry before their expiry.

After *Lundbeck* (and the previous *GSK* judgment) that argument does not wash: a valid patent does not preclude that the patent holder and a prospective entrant are potential competitors; not all patents are "blocking" patents. It is not necessary to analyse whether the patent is in fact valid or the strength of the patent claims. But it is important to understand what the patent relates to (for instance, a molecule or a process to manufacture that molecule) and whether an entrant might "work around" the patent and find a way to launch its competing product.

The court clarified that firms are potential competitors when there are real and concrete possibilities for competition between them. A prospective entrant need not inevitably launch its rival product and the success of launch does not necessarily determine competitive potential. It is, however, necessary to consider these two questions:

> Does the generic company have the firm intention and an inherent ability to enter with a competing product? In particular, did that company already take preparatory steps which enable entry in a timeframe that imposes competitive pressure on the originator? Such steps may include investments to support entry, attempts to secure marketing authorisation, or the negotiation of supply contracts.

> Does the generic company face insurmountable barriers to entry? This was the key question in *Lundbeck*. Process patents do not as such constitute insurmountable barriers: if patent protection of a molecule has expired, but patent protection of the manufacturing process has not, generics may well be able to work around the process patents.

These questions need to be assessed when the relevant agreement is concluded. It is irrelevant whether it emerges, at some later stage, that the patent was invalid, or that the generic firm did not enter the market, because the parties were not aware of those events when they concluded the agreement.

When does a patent settlement restrict competition "by object"?

This question is critically important to EU law enforcement against pay for delay agreements. If the Commission (or a national competition authority) demonstrates that an agreement has an anti-competitive "object", it is irrelevant whether the agreement actually produces anti-competitive "effects" – the agreement may be illegal, null and void, and attract risk of fines and damages awards. In *Lundbeck*, the Commission had indeed concluded that the settlement agreements were such serious infringements of EU law that they restricted competition by object.

The Court agreed that the *Lundbeck* agreements restricted competition by object; but it also held that a patent settlement agreement that includes a value transfer does not automatically have that object. The rationale for the value transfer and its net gain to the recipient is key: the patent settlement is a "hardcore restriction" if the payment is important enough to give the recipient incentive to refrain from competing on the merits by launching its rival product. Importantly, that net gain does not necessarily have to exceed the profits that the generic expects to gain after entry.

EU state of play after *Lundbeck*

Originator and generic pharma companies contemplating patent challenges or settlements should consider the EU competition law implications of their objectives. In particular, the following are relevant:

> Settlements between originator and generic firms may be horizontal agreements between competitors, even if the generic has not yet launched a rival product.

> Settlements that involve value transfers from the originator to the generic are more prone to scrutiny. That said, any agreement that includes a restriction on generic entry may potentially attract regulatory scrutiny.

> Value transfers to generic companies must have objective justification, e.g. reimbursement of litigation costs. A payment to refrain from entry is illegal, regardless of whether an entry restriction fits within the scope of the originator's patent.

> Not only *monetary* value transfers are relevant to the assessment whether a settlement is anti-competitive. Value can be transferred by different means – for instance, license agreements, supply agreements, etc. – which may potentially be relevant to the generic's incentive to enter.

So, what's left to debate?

Restrictive patent settlements may be a less important market feature today than they were when the *Lundbeck* agreements were concluded. Each year between 2008 and 2016, the European Commission conducted a survey of pharmaceutical patent settlements in the EU and also published the results of these surveys. The survey data suggests that *"settlements which restrict generic entry and show a value transfer from the originator to the generic company and which might attract competition law scrutiny, have stabilized at a low level"* (22% of recorded settlements in 2008, compared to 11% in 2016).

In that period, the Commission did also adopt enforcement action in three cases relating to practices that delayed generic entry involving citalopram (discussed in this note), *fentanyl* (imposing fines of EUR 16 million) and *perindopril* (fines: EUR 428 million); it also initiated proceedings concerning *modafinil* and adopted a decision in that case in 2020 (fines: EUR 60 million). More than a decade of regulatory attention and Commission enforcement action starkly remind us that patent settlement agreements may attract EU antitrust scrutiny.

But several important questions remain unresolved. Indeed, multiple appeals are pending before the EU courts against the Commission's decisions concerning *perindopril* (see here) and *modafinil* (see here). Three fundamental questions that arise are:

> When value is transferred to the generic by non-monetary means, can the settlement steer clear of antitrust risk? In practice, this is a very important question that the Court of Justice will consider in an appeal by the Commission. The General Court ruled that one settlement between Servier and Krka concerning *perindopril* patents was not illegal, since the Commission had not demonstrated that the value transfer in question had induced Krka to refrain from entry. This was because a licence agreement between those firms was deemed to have been concluded on market terms. Similar questions arise also in the context of Teva's appeal concerning the *modafinil* decision.

> When is a settlement agreement that restricts competition by object legal, because it is exempted from the prohibition against anti-competitive agreements? The fact that an

agreement has the object of restricting competition does not mean that the agreement is illegal *per se*. The agreement is valid and enforceable if it meets strictly defined criteria for individual exemption. Appellants in the *perindopril* and *modafinil* cases argue that the Commission was wrong to find liability in those cases, because the relevant agreements are individually exempted. The case-law on individual exemptions is sparse and additional guidance from the Court of Justice would be valuable.

> When does a pay for delay agreement give rise to abuse of dominance concerns? The Court of Justice is called upon to consider this question in another appeal by the Commission. The reason for that appeal is the General Court's ruling that the Commission failed to support its contention that, in addition to infringing the prohibition against anti-competitive agreements, Servier abused its dominant position by concluding patent settlement agreements and other practices concerning *perindopril*. The Court's assessment of this issue will be hugely important, especially to originators.

In other words: the pay for delay debate is far from over. Even after the Court has ruled on the questions mentioned here, it is important to remember that market circumstances and commercial practices have changed a great deal over the past decade. But tensions between originators and generics have not abated. In many respects, tension has shifted from traditional small molecule therapies to biologics and more advanced therapies. In that respect, the Commission announced recently that it opened proceedings concerning patenting and commercial practices that Teva allegedly employed concerning its best-selling drug Copaxone *(glatiramer acetate)*. Watch this space.