The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis?

A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case

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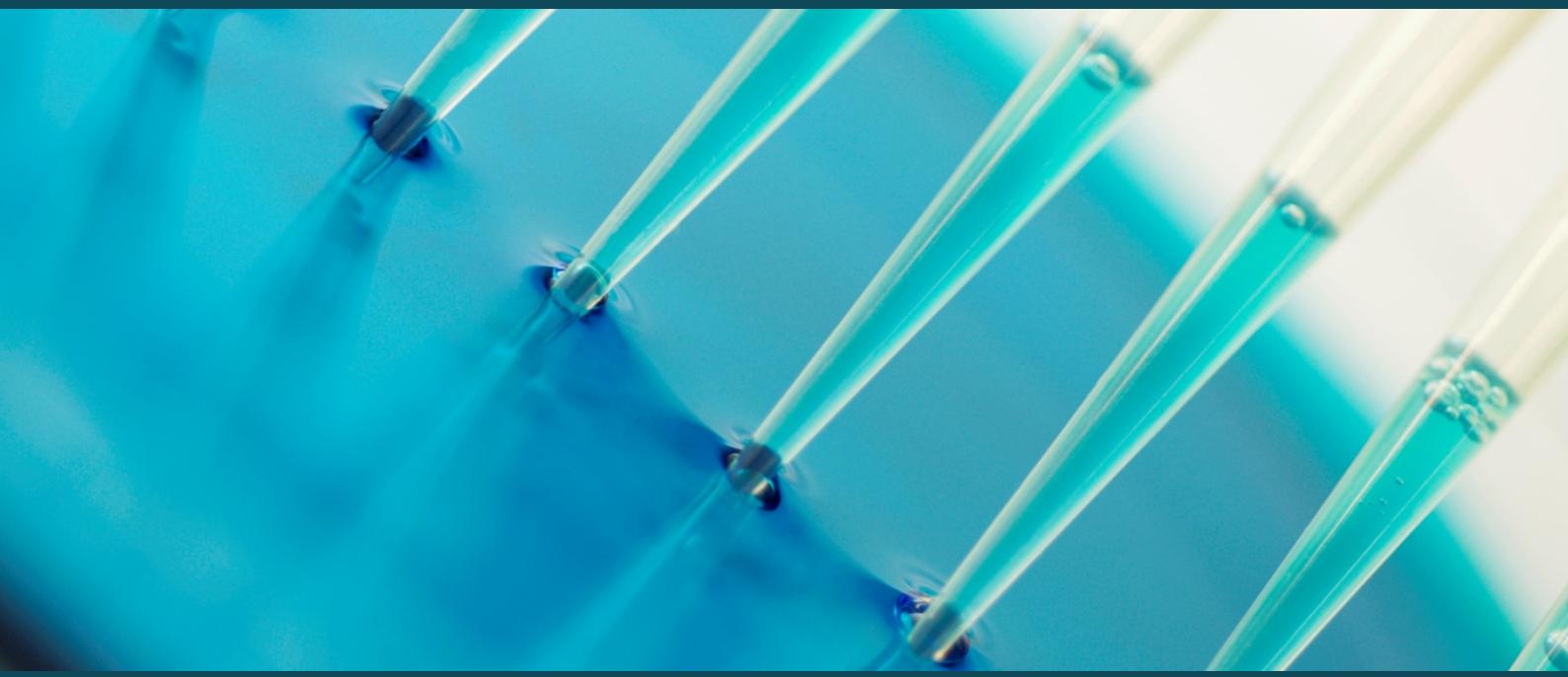

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The purpose of this briefing paper is to synthetise the European Commission ("Commission")'s approach to reverse patent settlement agreements in the pharmaceutical sector, in light of its almost 500-page landmark decision concerning the Lundbeck citalopram case.

Whilst the Commission's Pharmaceutical Sector Inquiry Report ("Report") provided some high level - and often novel - guiding principles in this area, reverse patent settlement agreements remained almost uncharted waters to be navigated by pharmaceutical companies. In this respect, the Lundbeck decision provides a clear and detailed analytical framework for such companies in the European Union ("EU") to assess this type of agreement.

By way of introduction, and before assessing the Commission's Lundbeck decision in detail, a brief overview of the EU regulatory framework and of the Report is provided below.

1. Key Aspects of the EU Framework for Medicines

Originator companies invest significant resources into the development of new medicines. In order to allow them to recoup - and legitimately profit from - their investments in R&D, various protection mechanisms exists for certain periods of time.

Patents guarantee protection of the invention for a period of up to 20 years from the filing date of the patent. The Commission itself reiterates in *Lundbeck* that a patent is "*a legal title protecting an invention, which can be a product or a process, by granting its holder the right to prevent third parties from making, using, offering for sale, selling, importing, distributing or stocking the product (including the product obtained directly by a patented manufacturing process) without the patent holder's consent*".[1]

Even if pharmaceutical companies can opt for a centralised procedure under the European Patent Convention[2], patents are still mainly granted by national authorities in Member States. As a consequence, there may be differences between Member States regarding the expiry of a patent, which will impact the strategies developed by originator companies with regard to their patented medicines.

Originator companies usually tend to file for patent protection at an early stage of the development of their products, in order to protect any invention as early as possible. Accordingly, the protection offered to the company is significantly shortened as the time period between the filing of the patent and the date at which the product ultimately reaches the market is quite long. To partially address this situation, a specific regime was introduced in 1992 - the so-called Supplementary Protection Certificate ("SPC") - which extends the protection of the patent by a maximum of five years and allows originator companies to minimise the loss of revenues caused by their inability to market their patented product until they obtain the required marketing authorisation.[3]

In addition to patents and SPC regimes, originator companies also benefit from a data exclusivity period. Pursuant to this principle, other companies are, for a certain period, prevented from relying on clinical and non-clinical data submitted by the originator company to support its

[1] *COMP/AT. 39226, Commission decision of 19 June 2013,* para. 64 (hereafter *Lundbeck* decision).

[2] *Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.*

[3] In addition, the SPC may qualify for a six-month extension under the paediatric rules as a reward for developing data on the use of the medicine in children.

application for a marketing authorisation. Data exclusivity periods were only partially harmonised in the past (and typically lasted for either six or ten years, depending on the approval procedure for the product and the Member State concerned). The 2004 revision of the pharmaceutical legislation imposed a prospective harmonisation, based on eight years of data exclusivity and two (possibly three) years of marketing exclusivity. The protection aims at rewarding the significant investment made by originator companies to generate the costly and complex data necessary to obtain a marketing authorisation.

It should be noted that patent protection and data exclusivity are two separate and distinct mechanisms. Indeed, pursuant to the absence of a "patent linkage" principle, there is no link between the regulatory approval of a medicine and its patent protection. Therefore, the EU regulatory framework allows competitors to develop similar medicines and seek their approval, irrespective of any existing patent protection.[4] On various occasions, the Commission has made it clear that a "patent linkage" principle is not permissible under EU law and can unduly delay the entry of generic medicines on the market.[5]

When the originator company's patent protection and/or data exclusivity comes close to expiry, a company may start to consider strategies to minimise the losses expected as a result of the entry of generic competitors. This was also recognised by the European Court of Justice in *AstraZeneca* where it held that *"the preparation by an undertaking, even in a dominant position, of a strategy whose object is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers".*[6]

Several of these commercial strategies - also known as "life cycle management" strategies - are legitimate and compliant with EU competition and regulatory laws, whilst others may now be considered as problematic under EU competition rules despite being fully compliant with EU regulatory rules.

2. Setting the Scene—the Pharmaceutical Sector Inquiry

Patent settlements have also received increasing attention by competition authorities both inside and outside the EU in the last decade. In 2009, the Commission conducted an in-depth investigation into the pharmaceutical sector which lead to the publication of the Report.

The Report highlighted a number of structural issues in company practices potentially delaying entry of cheaper generic medicines on the EU market. The Commission also emphasised the need for stricter law enforcement and started closely monitoring patent settlements.

[4] See also Article 10(6) of Directive 2001/83, which enables a generic marketing authorisation applicant to run the necessary tests for approval irrespective of any patent protection. See also Article 126 of Directive 2001/83 and Article 81 of Regulation 726/2004, which both provide that marketing authorisations may only be refused on the grounds set respectively in the Directive and the Regulation (on this principle, see the interpretation of the European Court of Justice in *Pierrel SpA and Ministero della Sanita*, Case C-83/92). The existence of patent rights is no such ground and cannot be relied on to refuse the granting of a marketing authorisation.

[5] In January 2012, for instance, the European Commission has issued a formal request to Italy to comply with the European legislation concerning the authorisation procedures of generic medicinal products. See the press release of the European Commission of 26 January 2012: "Pharmaceuticals: Commission calls on Italy to comply with EU rules on marketing authorisation of generic drugs".

[6] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012], para.129.

Figure 1

	Originator Company perspective		Generic Company perspective	
	Consideration	*Mentioned by % of respondents*	*Consideration*	*Mentioned by % of respondents*
1	Strength of own company position in the case (probability of winning or losing)	95%	Expected cost/avoided costs of litigation and impact on personnel cost	75%
2	Market size and revenue of the originator product to be protected	82%	Inherent uncertainty involved in patent litigation	67%
3	Expected cost/avoided costs of litigation and impact on personnel cost	68%	Strength of the company position in the case (probability of winning or losing)	67%
4	Inherent uncertainty involved in patent litigation	68%	The country where litigation takes place	42%
5	The expected duration of litigation	55%	The expected duration of litigation	42%

Source: the Report at pages 266 and 267.

With regard to patent settlement agreements, the Commission for instance noted that "*[p]atent settlement agreements are commercial agreements to settle actual or potential patent-related disputes. Patent settlement agreements are concluded in order to resolve claims in patent disputes, opposition procedures or litigation where no final adjudication has been handed down or there has not yet been a court proceeding. The primary aim of a settlement agreement is to end the dispute, opposition procedure or litigation. Patent settlements are fact-specific, depending on the dispute at issue. As they are commercial agreements, they also reflect the negotiated positions of the parties. Consequently, the specific contents and terms of settlement agreements vary. […] However, certain basic elements and features are found in all EU settlement agreements between originator and generic companies. First, the object of a settlement agreement is to resolve the actual or potential dispute, opposition procedure or litigation concerning the manufacturing and/or marketing of a generic version of a product which is claimed to be protected by a patent. Secondly, the geographic scope of an EU settlement agreement typically covers those Member States in which the dispute, opposition or litigation has occurred and possibly territories in which there is a high probability of it occurring. Finally, patent settlement agreements in the EU are usually intended to be the full and final settlement of the specific claims of the parties*"[7].

Furthermore, the Commission set out the five top considerations on the basis of which originator and generic companies usually assess whether to enter into a patent settlement agreement, as illustrated in the table seen at **Figure 1**.

After having defined the notion and assessed the rationale behind patent settlement agreements, the Commission concluded first of all, and by referring to statistical figures, that the vast majority of settlements reported in the EU are unproblematic and that only a small portion of these agreements are potentially problematic.[8] Generally, the Commission's analysis is not aimed at discouraging companies from entering into settlement agreements, provided that such agreements do not violate competition laws.

[7] Pharmaceutical Sector Inquiry Report, paras. 704-706.

[8] 5th Report on the Monitoring of Patent Settlements, para. 30: "*Thus 45% (66 of 146) of settlements did not limit generic market entry at all (category A), whereas 47% (69) limited generic market entry but did not show a value transfer from originator to generic company (category B.I) and only 8% (11) limited generic market entry showing a value transfer from the originator to the generic company.*"

Figure 2

		Limitation on generic entry	
		No	Yes
Value transfer from the originator company to the generic company	No	Category A	Category B.I.
	Yes		**Category B.II.**

Source: European Commission, 5th Patent Settlement Monitoring Report

The Commission then attempted to provide guidance as to the types of agreements that risk being considered anticompetitive.

In essence, it introduced a distinction between two broad categories, namely (a) patent settlement agreements that do not restrict the generic company's ability to market its own product (so-called "A-type") and (b) patent settlement agreements that limit the generic company's ability to enter on the market (so-called "B-type").[9] Within the B-type category, the Commission further distinguished between (i) patent settlement agreements that do not contain a "value transfer" (so-called "B-type.I") and (ii) those that do contain a "value transfer" (so-called "B-type.II") - **(Figure 2)**.

On the basis of this classification, reverse payment settlement agreements, also referred to as "pay-for-delay" agreements, fall within the B-type.II category. In essence, reverse patent settlement agreements are characterised by the fact that *"generic suppliers seeking to enter the market will often challenge the validity of these patents or may simply launch their products, forcing the originators to bring litigation to enforce their patents and prevent the generics' entry. In the context of the corresponding litigation, the originators and generic suppliers often decide to enter into a settlement. While the settlement terms will vary from case to case, a number of settlements have involved a payment made from the patent holder (the originator) to the accused infringer (the generic supplier) in order to settle the dispute"*.[10]

Normally, the Commission would regard A-type agreements and B-type.I agreements (with certain exceptions) as *prima facie* "unproblematic" from an EU competition law perspective. B-type.II agreements would however be considered *prima facie* "problematic". To use the Commission's own wording *"[…] category B.II settlements are likely to attract the highest degree of antitrust scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. Nonetheless, this is not to suggest that agreements falling into this category would always be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case"*.[11]

B-type.II settlement agreements remain subject to a case-by-case analysis. Thus, one must not conclude that all reverse patent settlement agreements are automatically problematic or illegal. In *Lundbeck,* the Commission emphasises that *"it is not, of course, as such illegal to*

[9] 5th Report on the Monitoring of Patent Settlements, para. 14.

[10] See M. Clancy, D. Gerardin and A. Lazerow, "Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law", *Social Science Research Network,* 10/27/2013.

[11] 5th Report on the Monitoring of Patent Settlements, para. 17.

settle patent disputes. Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies such as patent offices' time and effort and can therefore be in the public interest."[12] The decision, however, also shows that the Commission is inclined to adopt a stringent approach for those agreements that it does consider illegal, as discussed in the following sections.

3. The Lundbeck Case in a Nutshell according to the Commission

In the years 2002 and 2003, the Danish pharmaceutical company *Lundbeck* concluded six agreements with four companies to delay market entry of generic versions of its blockbuster antidepressant citalopram. The product was sold under the brand name Cipramil. *Lundbeck* itself referred to the product as its *"golden egg"*.[13] The agreements referred to citalopram either in the form of an Active Pharmaceutical Ingredient (API) or a medicine.

The agreements concerned by the Commission's decision are:

- Two agreements with Merck KGaA/Generic UK ("Merck"), now part of Mylan, one regarding the United Kingdom ("UK") from 24 January 2002 until 1 November 2003 and one regarding the European Economic Area ("EEA") excluding the UK from 22 October 2002 until 22 October 2003;
- Two agreements with Arrow, now part of Actavis, one regarding the UK from 24 January 2002 until 20 October 2003 and one regarding Denmark from 2 June 2002 until 1 April 2003;
- One agreement with Alpharma, now part of Zoetis, regarding the EEA from 22 February 2002 until 30 June 2003; and
- One agreement with Ranbaxy regarding the EEA, from 16 June 2002 until 31 December 2003.[14]

A crucial aspect of this case is that at the time of entering into these various agreements, the citalopram compound and the two original production processes were no longer protected by patents. *Lundbeck* still had a number of more recent process patents (including in particular a crystallisation patent) that covered several possible ways to produce citalopram. These rights, however, did not allow the company to generally prevent generic companies from marketing citalopram products in the EEA. [15]

Even though there was no actual underlying patent dispute in *Lundbeck* (except for the agreement with Alpharma regarding the EEA, all agreements were in fact concluded before actual litigation had started), each of the agreements was negotiated in the context of at least a potential dispute between *Lundbeck* and the generic companies regarding their intended marketing of generic citalopram API or medicine.

The Commission also holds that *Lundbeck* itself did not believe that its patent was particularly strong or that it could have won a litigation case in court based on the patent. The Commission bases this assessment on internal documents that, for instance, point out:

"It is like a poker game

- *We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards*
- *But we have a large pile of $$$ at our side*
- *We call it – 'the art of playing a losing hand slowly'."*[16]

[12] *Lundbeck* decision, para. 5.
[13] *Lundbeck* decision, para. 120.
[14] *Lundbeck* decision, para. 1.
[15] *Lundbeck* decision, para. 635.
[16] *Lundbeck* decision, para. 187.

Many API producers and generic suppliers argued that the crystallisation process - used to manufacture the API in question - was "*high school chemistry*" and not novel.[17]

By entering into the various agreements, *Lundbeck* was able to avoid litigation and had the certainty that the generic companies would stay out of the market for the duration of the agreements without giving them any guarantee of market entry thereafter. Thus, instead of continuing their efforts to enter the market and compete with *Lundbeck*, the generic companies, in return for substantial payments from *Lundbeck*, refrained from entering the citalopram market.

In the Commission's view, what gave these agreements their truly anticompetitive character was the fact that (i) *Lundbeck* not only paid the generic companies a sum that roughly corresponded to the turnover or the profit they expected to make by successfully entering the citalopram market, but also transferred additional value to each company by purchasing their stock (which it later destroyed) and by offering guaranteed profits in distribution agreements[18] and (ii) the systematic approach adopted by *Lundbeck* as soon as it perceived a concrete and serious threat of market entry by a generic company.

Moreover, by accepting these commitments, the generic companies went, according to the Commission, far beyond what *Lundbeck* could have achieved by enforcing its process patents before national courts. Each agreement indeed prevented the concerned generic company from selling (and to some extent importing) any generic citalopram. A court judgment would at best have prohibited the sale of citalopram manufactured by using the specific crystallisation (and other) processes covered by the *Lundbeck* patents.

The Commission eventually concludes that these agreements were anticompetitive in that they restricted competition 'by object' in violation of article 101(1) of the Treaty on the Functioning of the European Union (TFEU). Accordingly, the Commission imposes a fine of €93.8 million on *Lundbeck* and fines totalling €52.2 million on the generic companies. The parties have appealed the Commission's decision to the General Court.

4. The Commission's Assessment in Lundbeck from a Competition Law Perspective

The Commission's assessment in *Lundbeck* is based on a couple of general pillars with a competition law angle.

The analysis below provides an overview of the most important aspects of this assessment.

1. The interplay between patent and competition law

Before beginning its in-depth competition law analysis, the Commission sets the scene by illustrating the interplay between patent and competition law.

The Commission reiterates that *"the conclusion of an agreement settling a patent dispute does not provide immunity from competition law simply because the agreement relates to patent law. A patent holder only has the right under patent law to enforce its patent rights unilaterally, if necessary through infringement action before the court. Patent settlement agreements are, just like any other civil law contracts, voluntarily concluded by a meeting of the free will of two or more parties. Such agreements are fully subject to the discipline of competition law."*[19]

The Commission also refers to the General Court's *Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer* case, stating that: *"[i]n its prohibition of certain "agreements"*

[17] *Lundbeck* decision, para. 669.
[18] *Lundbeck* decision, para. 6.
[19] *Lundbeck* decision, para. 600.

between undertakings, Article 85(1) [now 101(1) of the Treaty] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind."[20]

The above principle applies to agreements whose purpose is to "*put an end to or otherwise deal with patent litigation or, more broadly, patent disputes*".[21] While companies in principle have the right to reach an agreement on their patent disputes, *"just as they have the right in principle to conclude other kinds of agreements, even if they are actual or potential competitors, in doing so they must respect Union competition law*."[22]

2. The context: *Lundbeck*'s overall commercial strategy

According to the Commission, *Lundbeck* pursued several goals as part of an overall strategy against generic entry of citalopram. The strategy was defined as early as 1997 and aimed at restricting competition by:

- Patenting processes to manufacture citalopram;
- Intervening in marketing authorisation procedures for generic citalopram medicines;
- Eliminating the competitive threat of upcoming citalopram API producers;
- Persuading generic companies to stop their efforts to enter the citalopram market. [23]

The overall purpose of the strategy was to allow effective market entry of escitalopram (Cipralex), *Lundbeck*'s single enantiomer version of citalopram, before generic companies would enter the citalopram market.

The competition law analysis of the Commission focuses on the company's efforts to persuade generic companies to delay their entry into the citalopram market. The other elements of the commercial strategy are, however, also relevant as a general context for the assessment.

Lundbeck's internal documents allegedly show that the company conducted thorough market research and analysis to assess to what extent entry of generic citalopram will impact the price and sales of their products. *Lundbeck* assumed that "*Citalopram generic will gain 40-70% of total substance volume in year five after introduction (at a 40% price discount to the original) (emphasis in the original)*".[24]

The Commission considers that *Lundbeck*'s objective was clearly to "*create a window of opportunity for the Cipralex switch*"[25] and their strategy was to:

- *"Focus on EU and particularly the northern European markets – the generic markets*
- *Three main tactics:*
  - *Influencing the authorities*
  - *Patent defence, mainly process patents*
  - *Deal making".*[26]

According to the Commission, *Lundbeck* wanted to delay generic market entry to allow good market penetration of Cipralex at an interesting price. This would have allowed *Lundbeck* to compensate for its loss of revenues on Cipramil. The development of escitalopram was accelerated so as to transfer sales of Cipramil to Cipralex.

The Commission explains that this commercial strategy was pursued in conjunction with other steps. One should recall that citalopram was first patented in 1976, therefore patent protection of the

[20] *Lundbeck* decision, para. 600 referring to Case 65/86 *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer* [1988], para. 15, see also Case 193/83 *Windsurfing International v Commission* [1986], para. 52.
[21] *Lundbeck* decision, para. 600.
[22] *Lundbeck* decision, para. 81.
[23] *Lundbeck* decision, para. 134.
[24] *Lundbeck* decision, para 124.
[25] *Lundbeck* decision, para 131.
[26] *Lundbeck* decision, para. 131.

citalopram compound started to expire in the mid-90s. In reaction to this situation, *Lundbeck* filed for patent protection for all manufacturing processes for citalopram. *Lundbeck* covered each aspect of the manufacturing and production methods by patents. This "process patent defence"[27] was revealed after the examination of *Lundbeck*'s internal documents. In total, more than 30 different citalopram processes were patented.[28] This course of action allegedly put generic companies in a situation of uncertainty as they could not really assess their legal exposure regarding *Lundbeck*'s array of patents. At that time, it was not clear whether all of these patents were valid and to what extent generic companies could start producing generic citalopram without infringing one of the numerous *Lundbeck* process patents.

This "process patent defence" also aimed at deterring API manufacturers from starting to produce generic citalopram. Conscious of the threat posed by *Lundbeck*'s manufacturing process patents, they would refrain from entering the citalopram market despite the expiry of the patent covering the citalopram compound. In this respect, *Lundbeck's* main argument was that it was almost impossible for API manufacturers to produce generic citalopram without infringing *Lundbeck*'s crystallisation patent of the free base. Although *Lundbeck* recognised that generic manufacturers could develop other crystallisation processes, and some did, it considered that its process was the most effective from a commercial point of view as it allowed to produce significant volumes of API in a very short timeframe. *Lundbeck* therefore concluded that generic companies would opt for this process as it is the most efficient one. In line with this, *Lundbeck* for instance sent a warning letter to the API suppliers of generic citalopram and to generic companies to stress that "*the creation of highly pure crystalline base of citalopram*"[29] amounted in itself to a patent infringement.

In 2002, after it started marketing generic citalopram on the UK market, Lagap was the first company sued for patent infringement by *Lundbeck*. Lagap had obtained a marketing authorisation for generic citalopram on 1 August 2002. It was sourcing its generic citalopram API from Matrix, an API producer based in India. After inspections of the Matrix facilities, Lagap was convinced that the generic citalopram API was manufactured without infringing *Lundbeck*'s crystallisation process patent. *Lundbeck* started patent infringement proceedings in October 2002 and in response Lagap challenged *Lundbeck*'s patent. About a year later, the parties entered into a settlement agreement, before a judgment on the merits was rendered. In this settlement, Sandoz (Lagap's parent company) agreed to drop all legal challenges against *Lundbeck's* patent in exchange for *Lundbeck's* promise to drop all pending claims and to grant "*an irrevocable, non-exclusive royalty-free licence to Lundbeck's crystallisation patent covering the EEA*"[30] to Sandoz.

The generic company Neolab Ltd also entered into a settlement agreement with *Lundbeck* in December 2003 to put an end to the infringement proceedings started by *Lundbeck* a year before. Neolab was marketing in the UK generic citalopram medicines containing API supplied by the Indian producer Cipla.

Besides these settlement agreements, the UK Patent Court moreover granted a declaration of non-infringement to the generic company Niche Generics which was marketing a generic citalopram medicine, containing API supplied by the Indian manufacturer Sekhsaria.

As a consequence, the validity of *Lundbeck's* crystallisation patent was

[27] *Lundbeck* decision, para. 145.
[28] *Lundbeck* decision, para. 145.
[29] *Lundbeck* decision, para 151.
[30] *Lundbeck* decision, para 159.

never properly assessed by the UK courts. The scope of the patent was however later significantly reduced at the EPO level.

Faced with the uncertainty regarding the effective protection provided by its crystallisation patent, *Lundbeck* apparently also took steps aimed at preventing or delaying marketing authorisations for generic citalopram medicines. It sent instructions to its subsidiaries regarding actions to be taken in each jurisdiction against generic citalopram approvals. These instructions suggested that generic citalopram posed "*serious public health concerns*"[31]. The strategy was, according the Commission, *inter alia* used in the Netherlands to defeat the approval of a generic citalopram medicine that was to be distributed by Tiefenbacher and sourced from Cipla and Matrix. Even if *Lundbeck* ultimately lost its proceedings in front of the highest Dutch court, the "Hoge Raad", against the Tiefenbacher approval, it managed to nevertheless delay "*by more than half a year […] the issuing of marketing authorisations by the United Kingdom Medicines Control Agency to generic companies whose application in the United Kingdom was based on Tiefenbacher's registration file, including Arrow, Alpharma and Lagap.*"[32]

Lundbeck's documents revealed that this strategy was a success for the company given that according to a contemporaneous *Lundbeck* document of 4 September 2002, the UK Medicines Control Agency normally issued national licenses within fourteen days and here the license took more than seven months. In questioning the quality of generic citalopram, *Lundbeck* managed to "*delay the issuing of the national licenses in all European countries from few to many months*."[33]

Lundbeck's strategy not only focused on generic companies, but also on citalopram API producers. Internal documents allegedly show that *Lundbeck* was debating on the position to adopt in its relation with such companies. *Lundbeck* hesitated between two strategies. The first one was a "litigation approach", according to which it would use patents covering manufacturing processes to stop API producers. The second approach was more collaborative and consisted in entering into partnership agreements with these producers to make them *Lundbeck*'s exclusive producers and thus prevent them from supplying generic citalopram to any generic companies.

Initially, *Lundbeck* decided to go for a more collaborative approach referred to as the "deal making strategy". In October 1999, *Lundbeck* purchased three patent applications filed a year before by the Italian generic citalopram producer Norpharma. These manufacturing processes of citalopram differed from the *Lundbeck* ones. *Lundbeck,* however, never used the processes and the purchase was only aimed at preventing generic companies from using processes that did not infringe the company's main process patents.

VIS Farmaceutici S.p.A (VIS), an Italian generic citalopram API producer, was the second partner under *Lundbeck*'s "deal making strategy". VIS worked closely with Tiefenbacher to produce generic citalopram medicines. Records show that Tiefenbacher filed an application at the end of 1999 for a marketing authorisation for a generic citalopram medicine in the Netherlands, based on VIS API. The marketing authorisation was expected to be granted by the end of 2000. In October 2000, *Lundbeck* purchased VIS and *"[i]mmediately following the purchase, VIS/Lundbeck withdrew the VIS Drug Master File from Tiefenbacher's marketing authorisation application in the Netherlands, claiming impurities in the VIS product.*"[34] Tiefenbacher was ultimately able to identify Cipla and Matrix as alternative suppliers in its marketing

[31] *Lundbeck* decision, para. 167.
[32] *Lundbeck* decision, para. 168.
[33] *Lundbeck* decision, para. 171.
[34] *Lundbeck* decision, para. 176.

authorisation application. However, this change caused the Dutch marketing authorisation for generic citalopram to be delayed by at least nine months, market authorisation that was finally granted in September 2001. In October 2001 *Lundbeck* appealed to the Objections Committee of the Dutch Medicines Evaluation Board ("Objections Committee") against this decision to grant marketing authorisations to Tiefenbacher. This objection was rejected in January 2002. In October 2001, *Lundbeck* had simultaneously lodged a request with the court of Amsterdam for the issuance of an injunction against these marketing authorisations, a request that was eventually denied on 21 December 2001. In January 2002, *Lundbeck* lodged an appeal against the decision of the Objections Committee's confirmation of Tiefenbacher's marketing authorisation in the Netherlands which led to the court proceedings in front of the Dutch "Hoge Raad" previously described.

The same strategy was used towards Merck (GUK) which also initially selected VIS as API supplier in its application for a marketing authorisation in the UK. Merck (GUK) incurred nine months of delay from its switch from VIS to Natco.

Lundbeck also entered into arrangements with CF Pharma, a Hungarian API producer: "*Lundbeck increased its investment and shareholding in CF Pharma. […], CF Pharma became a supplier to Lundbeck of intermediates. The result of these actions was that CF Pharma was prevented from selling generic citalopram to the EEA markets*".[35]

Lundbeck also tried to conclude contracts with Indian API producers. The first of them was Natco, which rejected the proposals made by *Lundbeck*. However, *Lundbeck* managed to prevent Natco from selling citalopram API to the UK and other EEA countries respectively from 24 January 2002 to 1 November 2003 and from 22 October 2002 to 22 October 2003. Indeed, *Lundbeck* entered into two agreements with Merck (GUK), which had a 'preferred' right to purchase the Natco API for distribution in Europe. *Lundbeck* further entered into an agreement with Ranbaxy, preventing sales of citalopram API or medicines to the EEA between 16 June 2002 and 31 December 2003. Finally, *Lundbeck* approached Matrix but could not conclude an agreement.

Overall, this strategy was only partially successful to avoid supplies of API for generic citalopram medicines in the EEA. *Lundbeck* was not able to prevent API supplies by Cipla, Sekhsaria and Matrix and only managed to do so for a limited period of time with respect to Natco. It thus decided to develop a commercial strategy targeting the generic companies directly. As discussed, these strategies where aimed at convincing generic companies to refrain from entering into the citalopram market. This is how and why the saga of the "citalopram clan" started.

The Commission's competition law analysis outlined below focuses solely on the *Lundbeck's* patent settlement agreements. It is, however, important to stress that all the strategies described in this section could also be, if assess on their own merits, even absent a reverse patent settlement agreement, and depending on the circumstances be problematic from a competition law perspective. This may in particular apply to the "process patent defence" strategy, which consisted of patenting various processes to deter API manufacturers from producing generic citalopram.[36]

3. The Commission's analysis

Before looking into the Commission's detailed analysis, it is important to recall that traditionally, article 101(1) TFEU prohibits agreements that have as their 'object *or* effect' the prevention, restriction

[35] *Lundbeck* decision, para. 178.

[36] See in this context e.g., the *Pfizer/Xalatan* case (Italian Competition Authority Decision, 11 January 2012; Judgment TAR Lazio, 3 September 2012; Judgment Consiglio di Stato, 12 February 2013).

or distortion of competition. Some agreements are considered as infringing competition 'by object' which essentially means that they are 'by their very nature' anticompetitive, irrespective of the effects they may have on the market.

In the recent *Cartes Bancaires* judgment[37], adopted after the *Lundbeck* decision, the European Court of Justice clarified that, to amount to an infringement of competition law 'by object', such agreements have to "*be sufficiently harmful to the proper functioning of normal competition*".[38] The assessment of an agreement therefore has to be based *inter alia* on the content of its provisions, its objectives and the economic and legal context of which it forms part. The nature of the goods and services affected can also be taken into account.

Where an agreement does not have the object of restricting competition, the Commission has to demonstrate the restrictive effects of the agreement at hand. Such an analysis has to take into account the whole economic context in which the agreement operates.

It should also be noted that the subjective intention of the parties when entering into the agreement is not as such a necessary condition to characterise an agreement as restrictive by object. It can however be - and usually is - taken into consideration when analysing the overall context of an agreement.

3.1. The Commission's test

In *Lundbeck,* the Commission considers that the agreements between the parties restricted competition 'by object'. In its legal assessment, in order to show that in the present case the parties had infringed Article 101(1) TFEU, the Commission first looks at the precise economic and legal context leading to each agreement. In a second step, it looks at the actual content and objectives of each agreement. In a third step, each party's subjective intentions are considered, in order to examine whether they match the analysis of the objective elements of the first two steps.[39]

In order to identify whether each agreement had the potential of restricting competition by its very nature, the Commission's analysis takes into account in particular whether:

- the generic company and *Lundbeck* were at least potential competitors;
- the generic company committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets with generic citalopram medicines; and
- the agreement involved a transfer of value from *Lundbeck*, which substantially reduced the incentives of the generic company to independently pursue its efforts to enter one or more EEA markets with generic citalopram products.[40]

Based on this analysis, the Commission concludes that the agreements were indeed anticompetitive 'by object'. In addition, the Commission also takes into account the following factors:

- the sum paid by *Lundbeck* to the generic companies was based upon the generic company's expected turnover or profit, had it successfully entered the market;
- *Lundbeck* could not have prevented or delayed entry through the enforcement of its process patents;
- the obligations on the generic companies went beyond the rights usually granted to holders/ licensors of process patents; and
- the agreements did not contain any commitment from *Lundbeck* to refrain from infringement

[37] Case C-67/13 P *Groupement des cartes bancaires v European Commission* [2014].
[38] See para. 82 of the *Cartes Bancaires* judgment.
[39] *Lundbeck* decision, para. 735.
[40] *Lundbeck* decision, para. 662.

proceedings if the generic company entered the market with generic citalopram products after expiry of the agreement.[41]

The Commission's analysis discussed below is more stringent than the "rule of reason" approach adopted by the US Supreme Court in *Actavis*.[42]

3.2. 'At least potential competitors'

Based on the concept of potential competition as developed by the EU Courts[43], the Commission also describes some of the specific characteristics of the pharmaceutical sector. It considers that, given in particular the significant price reductions that normally result from widespread generic entry, "*the mere ability of suppliers of generic medicines to enter a market following expiry of the compound patent in itself poses a significant competitive threat to the incumbent originator undertaking, irrespective of the precise intentions of specific generic undertakings and irrespective of whether one or more of them are more likely to infringe any remaining process patents than others.*"[44]

The Commission further considers that potential competition starts (1) when generic producers that want to launch a generic medicine upon expiry of the exclusivity of the compound patent (or underlying API producers) begin developing a "*commercially viable production process leading to a product that meets regulatory requirements*" and (2) when "*suppliers of generic medicines to the targeted markets (…) will prepare for actual generic entry by applying for marketing authorisations, by ordering supplies, and by developing strategies for commercial market entry in one or more markets in the EEA, by obtaining price levels (where required by the national authorities) and reimbursement levels in the target markets, by creating a sales force and, as a last step before actual entry, by issuing price lists.*"[45]

In *Lundbeck*, "*given that the compound patent on citalopram had expired, legal challenges to the originator undertaking's remaining process patents, whether in the form of a defence against claims of infringement, actions to clear the way or actions to invalidate such patents, were, along with other routes to the market open to the generic undertaking*".[46] The fact that legal challenges were possible and that both *Lundbeck* and the generic companies were in fact assessing the option of challenging the process patents, is for the Commission *"an expression of potential competition from generic undertakings intending to enter the market with a generic version of the compound in question."*[47]

The Commission moreover considers that *Lundbeck*'s argument that its remaining process patents were blocking all possible routes for market entry was invalid. Generic companies wanting to enter the citalopram market in the near future indeed had "*several alternatives open to them that could lead to market entry even in the presence of Lundbeck's process patents, each of which represented potential competition if the option was available not just in theory, but as a real concrete possibility, as an economically viable strategy.*"[48]

Lundbeck apparently itself acknowledged this fact when it stated that "*it would be naïve to think that it is not possible for producers of generic copies to produce Cipramil without breaking our patent.*"[49]

[41] *Lundbeck* decision, para. 662.
[42] *FTC v. Actavis*, 570 U.S. 756 (2013); see also e.g., Covington e-alert "FTC brings its first post-*Actavis* suit", 9 September 2014.
[43] See references in the *Lundbeck* decision, footnotes 1096 and 1099 to Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission* [2011] and Case T-112/07, *Hitachi Ltd, Hitachi Europe Ltd and Japan AE Power Systems Corp. v European Commission* [2011].
[44] *Lundbeck* decision, para. 615.
[45] *Lundbeck* decision, para. 616.
[46] *Lundbeck* decision, para. 633.
[47] *Lundbeck* decision, para. 633.
[48] *Lundbeck* decision, para. 635.
[49] *Lundbeck* decision, para. 150.

The fact that *Lundbeck* and the generic companies were at least potential competitors is all the more true because the generic companies had an actual business plan in place "*to sell generic citalopram in markets in the EEA and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other*".[50]

That such entry was not just purely theoretical is also shown by numerous references to terms such as generic companies competing for the *"pole position"*[51] or the "*race against Tiefenbacher",* in the documents seized and analysed by the Commission.[52] This dynamic race with changing positions of "*front runner[s]*" ended according to the Commission, "*or was in any case significantly slowed down, particularly in the United Kingdom, because of the agreements that Lundbeck concluded with Merck (GUK), Arrow, Alpharma and Ranbaxy.*" [53]

3.3. The generic companies' commitments

Contrary to the situation in *Actavis* in the US, the generic companies' commitments in *Lundbeck* went beyond the scope of the contested process patents (in *Actavis* generic entry was allowed before patent expiry) and thus beyond what *Lundbeck* could have obtained by successfully litigating.

The Commission explains the problematic nature of the generic companies' commitments by stating that "*any commitment from a generic undertaking in an agreement not to sell "citalopram" (here with reference to the compound, whether API or medicine) for a certain period cannot be justified by patent law, simply because a process patent does not give the patent holder rights outside the patent's scope, which for process patents is limited to the particular process covered by that patent and products directly obtained by the patented process.*"[54]

In *Lundbeck*, the generic companies agreed, in exchange for the value transferred, not to sell *any* citalopram even citalopram not manufactured based on a patented process. Accordingly, the Commission confirms that "*even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they are likely to breach Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself, but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market*."[55]

3.4. The concept of 'value transfer'

Each agreement was related to a transfer of (significant) value from the originator to the generic company. This substantially reduced the incentives of the generic companies to independently pursue their efforts to enter one or more EEA markets with generic citalopram.

The Commission does not provide detailed criteria for assessing value transfers between originator and generic companies, but it does explain why it considered value transfers problematic in this context: "*By paying the generic undertaking to give up its competitive challenge, the originator undertaking obtains certainty that the generic undertaking will not enter the market for the period of the agreement, and, because the generic undertaking will no longer have the incentive to try to enter or litigate given that it cannot sell, there is a high probability that the generic undertaking will not seek a ruling of non-infringement or a ruling of invalidity of the invoked patent, even without any non-challenge*

[50] *Lundbeck* decision, para. 621.
[51] *Lundbeck* decision , para. 622.
[52] *Idem.*
[53] *Idem.*
[54] *Lundbeck* decision, para. 642.
[55] *Lundbeck* decision, para 641.

clause in the agreement. From the perspective of the originator undertaking, it is the uncertainty of possible generic market entry, including through patent litigation, which reflects potential competition. This potential competition is eliminated through the transfer of value and transformed into the certainty of no competition. This is in particular the case when the amount of the value transfer matches the profit that the generic producer would have made if it had entered the market."[56]

The Commission concludes that the transfer of value was directly linked to the acceptance by each generic company of the limitations on entry in the respective agreements. The transferred value moreover corresponded roughly to the profits each generic company expected to have made, had it successfully entered the market.[57]

It is thus precisely the fact that *Lundbeck* paid the generic companies to stay out of the market, together with the above criteria, that led the Commission to conclude that each of the agreements constituted a restriction by object.

3.5. The parties' intentions

For each agreement, the Commission also looks into the intentions of the parties regarding the aim of the respective agreements.[58] The Commission concludes that the agreements were all part of *Lundbeck*'s overall strategy to delay generic entry for citalopram and that each of the parties involved knew, or should have known, that their agreement was anticompetitive.[59]

3.6. Additional key factors assessed by the Commission

The Commission takes into consideration two additional key factors to reach its overall conclusion that the agreements were anticompetitive.

First, *Lundbeck* could not have obtained the limitations on entry which it obtained under the agreements through enforcement of its process patents. The obligations of each generic company under the agreements clearly went beyond the scope of the patents in question.[60]

Second, none of the agreements contained a commitment by *Lundbeck* to refrain from infringement proceedings against any of the generic companies after the agreements had expired.[61] This made market entry by the generic companies post-expiry rather uncertain as they had no guarantee that *Lundbeck* would not sue them after all for infringement of the process patents.

4. Efficiency defence under Article 101(3) TFEU

For the sake of completeness, the Commission also assesses the parties' efficiency defence arguments. The parties claimed that they avoided litigation costs, improved distribution of *Lundbeck* citalopram in the UK and claimed efficiency gains from the earlier launch of generic citalopram. [62]

The Commission however concludes that no party submitted the required evidence to justify that one or more of the competitive restrictions could be exempted under Article 101 (3) TFEU.

5. Calculation of the fines

One final important aspect of the Commission's analysis is its method to calculate the fine and in particular its refusal to accept a reduction of the fine based on the novelty of the case.

Lundbeck and the generic companies raised similar arguments. They considered that they could not have been aware that they were violating applicable competition law principles as "*the relevant facts raise*

[56] *Lundbeck* decision, para. 604.
[57] See e.g., the Commission's conclusion in the Merck/Lundbeck UK agreement, *Lundbeck* decision, para. 824.
[58] *Lundbeck* decision, e.g., paras. 803 – 816.
[59] *Idem.*
[60] *Idem*.
[61] *Idem.*
[62] *Lundbeck* decision, para. 1231.

complex and novel legal issues and no guidance can be derived from existing legal precedent."[63] The Commission rejects the argument and, like in *AstraZeneca*,[64] considers that *Lundbeck* and the generic companies were perfectly aware that the agreements were aimed at excluding competition in the market of citalopram.

As a consequence, the Commission considers that even though there may not be any established precedents specifically in relation to reverse payment agreements, "*the notion that such agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is well established and cannot be seen as novel.*"[65]

The Commission first states that it was well established at the time of the events that excluding actual or potential competitors from the market was likely to constitute an infringement of competition law. Subsequently, it deemed it appropriate to impose fines that would meet the need for appropriate sanctioning and deterrence.

Regarding the actual calculation of fines, the Commission uses the 2006 Guidelines taking into account (i) the gravity and (ii) duration of each infringement. The length of the investigation was taken into account as a mitigating factor.

Ranbaxy eventually applied for a reduction of the fine, claiming inability to pay,[66] but the Commission concludes that the conditions for a reduction are not met.

5. Key 'Takeaways'

The *Lundbeck* case provides a number of key takeaways. This briefing paper will address three of them in further detail.

First, this decision confirms that the overall strategic and commercial approach adopted by a dominant pharmaceutical company is of the essence in assessing the specific conduct that may be deemed abusive, since the former determines the underlying analytical framework on which the detailed assessment is going to be based.

Second, *Lundbeck* confirms the importance of how internal documents are drafted by pharmaceutical companies and the language used therein since such documentation allows the Commission to meet the required standard of proof for its case. Indeed, what allowed the Commission to build its case, was to a large extent the content of the internal documents seized during dawn raids conducted at the premises of several of the companies involved.

The documents analysed not only consisted of the actual agreements concluded between the parties, the content of which the Commission carefully assessed, but also included internal emails and strategic reports. These provided the basis for the Commission's thorough legal analysis.

This clearly shows that the language used in - and content of - companies' internal documentation remain of the essence. The internal documentation of companies continues to serve as the foundation for the Commission's legal assessment, in particular because it allows the Commission to meet the required standard of proof in such cases.

Third, it is crucial to flag that the particularity of this case, that led to the Commission's assessment that the agreements concluded between the parties were anticompetitive 'by their very nature' and had to be put in the 'by object' box, was *Lundbeck's* systematic approach when concluding each of the agreements.

[63] *Lundbeck* decision, para. 1299.
[64] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012], para. 164.
[65] *Lundbeck* decision, para. 1300.
[66] Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003, *OJ* C 210, 1.09.2006, p. 2-5, point 35.

That a company's overall strategy can be of significant importance from a competition law perspective is confirmed by the Commission's press release in the *Servier* case, stating that "*it is of course entirely legitimate to apply for patents, enforce them, transfer technologies and settle litigation. But patent settlements should not be misused. Engaging in an exclusionary strategy to foreclose important competing technologies and buying one close competitor after another is blatantly abusive*".[67]

The fact that, contrary to *Servier*, there was no actual underlying dispute between the parties as to the strength of *Lundbeck*'s process patents, which does not make this an actual settlement linked to a patent, does not alter that assessment. Thus, would there have been a dispute as in a classic "pay-for-delay"/reverse payment settlement scenario, the Commission's conclusion would still have been the same.

In the end, it was the fact that *Lundbeck* systematically entered into reverse patent settlement agreements - usually absent actual litigation - and transferred considerable value to more than just one generic company and potential competitor – that made the agreements under review anticompetitive 'by object'.

This said, and although the Commission threw all the agreements into the same 'by object' box, it is nevertheless important to remember that not all patent settlements, and not even all patent settlements that contain a value transfer, are necessarily problematic under competition law. The Commission itself considers that payments may, in specific legal and commercial circumstances, "*be instrumental to the finding of an acceptable and legitimate solution for both parties.*"[68]

One of the examples the Commission gives in this context is a situation "*where, for example, the generic undertaking had already entered the market and if each party in the course of litigation comes to consider that the likelihood of patent validity and infringement is high, a patent settlement may legitimately include not only a withdrawal from the market of the generic product but also a payment from the generic undertaking to the originator undertaking to settle the damage suffered by the latter.*"[69]

In conclusion, based on the Commission's analysis, a single reverse patent settlement agreement between an originator and a generic company, within the context of actual ligation, even if falling within the Commission's 'problematic' B-type.II category, remains to be assessed on a case-by-case basis, such assessment being based upon both 'by object' and 'by effect' considerations.

Systematic reverse patent settlements on the other hand, that include the transfer of a large sum and are characterised by a "*coherent overall strategy*"[70] to delay generic entry, are however, after *Lundbeck*, much more likely to be considered as a 'by object' infringement of competition law and potential efficiencies of such agreements will be very difficult to prove.

[67] http://europa.eu/rapid/press-release_IP-14-799_en.htm.
[68] *Lundbeck* decision, para. 639.
[69] *Lundbeck* decision, para. 639.
[70] *Lundbeck* decision, e.g., para. 806.

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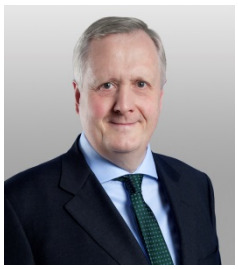

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