Drug Test: When are Pay-for-Delay Agreements Illegal?

Irene Fraile

Ankur Kapoor

Rosa Morales*

Competition agreements; EU law; Generic medicines; Infringement; Market entry; Patents; Pharmaceutical industry; Settlement; United States

Introduction

In recent years, so-called "pay-for-delay" agreements between originator pharmaceutical companies and generic drug manufacturers have preoccupied antitrust authorities worldwide. Together with shortcomings in patent and regulatory systems and other factors, these sorts of potentially anticompetitive practices have been found to be one of the causes of a progressive decline in the number of novel medicines reaching the market and of significant delays in the market entry of generic drugs.

In 2013 there were two landmark decisions in this area both in the US and in the EU.[1] This article will analyse these decisions and developments since, in particular, regarding the standards that are applied by authorities to decide whether there has been an antitrust infringement.

Pay-for-delay agreements and reverse payment settlements

In a nutshell, pay-for-delay agreements are commercial agreements whereby the company who originally patented the branded drug (the "originator" or "branded" company) pays its actual or potential competitor (the "generic" company) to delay introducing the bioequivalent version of its drug.

Although these agreements may be totally unrelated to any patent dispute or litigation (a "naked pay-for-delay agreement"), they are normally concluded to settle patent-related disputes, opposition procedures or other pending litigation. These particular agreements are also called "reverse payment settlements" because, whereas in a typical patent infringement settlement the alleged infringer pays the patent holder, in a pay-for-delay settlement it is the patent holder who pays the alleged infringer (in return for delaying commercialisation of the generic version).

In a typical reverse payment scenario, the 20-year period of protection afforded by the original drug patent (the "basic patent")[2] would have expired or be close to expiring, leaving the originator with the weaker protection, if any, of so-called "process" patents and/or "secondary" patents on improvements of the basic patent.[3] At this stage, generic companies may decide to enter the market with a generic version either because they have managed to produce the generic drug using a different manufacturing process (avoiding process patents), or because they claim that the originator's patents still in force are invalid. The originator company sues for patent infringement and a settlement is agreed.

Settlements are a generally accepted, legitimate way of ending private disagreements. This is particularly true in pharmaceutical patent litigation, where disputes can be extremely costly and time-consuming, as well as having uncertain outcomes due, among other factors, to the fragmented patent system, even within the EU. Settlements also benefit society by saving time and effort for the litigants and authorities.

However, generic entry that would have occurred but for the agreement which, as a result of the agreement, is unlawfully delayed can cause consumer harm.[4] This is because, once a former monopolist faces effective generic competition, the increased supply of the product meeting the same demand drives prices down dramatically (even up to a 90 per cent decrease). Concerted action by competitors thus deprives consumers and national health systems of dramatically lower prices. As the US Supreme Court described it, "The patentee and the challenger gain; the consumer loses."[5]

The position in the US

Actavis: clarifying the legal standard under US antitrust law…

In *Actavis*,[6] the Federal Trade Commission (FTC) challenged patent infringement settlements between Solvay Pharmaceuticals, the patent holder of the branded low-testosterone drug AndroGel, and various generics including Watson Pharmaceuticals (as Actavis was then known). Per the settlements, the generics would receive monetary payments ($19–$30 million per year for

* Irene Fraile is an Associate at Constantine Cannon in London, Ankur Kapoor is a Partner at Constantine Cannon in New York and Rosa M. Morales is a Litigation Associate at Constantine Cannon in New York. Mr. Kapoor and Ms. Morales recently assisted Lloyd Constantine as a consultant to the court in *In re Modafinil Antitrust Litigation*, a multi-district reverse-payment litigation pending in the US District Court for the Eastern District of Pennsylvania. The views expressed are those of the authors and do not necessarily reflect the views of Constantine Cannon. The authors express their thanks to Richard Pike for his comments on a draft of this article.

[1] Antitrust authorities in other jurisdictions are increasingly showing their interest in pay-for-delay agreements and abusive practices. A recent example is Brazil, where, on August 29, 2014, the antitrust regulator fined Merck for conspiring to prevent distributors from working with generic drug makers.

[2] Namely, the patent on the basic chemical compound or substance of the drug.

[3] e.g., on new therapeutic uses, new formulations, new treatment regimes, etc.

[4] On the economics of reverse payment settlements see, e.g., William Choi, Bruce Den Uyl and Mat Hughes, "Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis and others" (2014) J.E.C.L. & Pract. 5(1).

[5] *FTC v Actavis Inc* 133 S.Ct. 2223 (2013) at 2235.

[6] *Activis* 133 S.Ct. 2223 (2013) at 2229.

Watson) and "delayed licenses" to begin manufacturing generic AndroGel five years before Solvay's patent expired.[7] Solvay also received certain marketing and drug supply services.[8]

The US Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal of the FTC's challenge holding, under what has been called the "scope-of-the-patent" test, that reverse payment settlements were lawful "absent sham litigation or fraud in obtaining the patent" and "so long as [the settlement's] anticompetitive effects fall within the scope of the exclusionary potential of the patent."[9]

The Supreme Court reversed and rejected both the "scope-of-the-patent" test applied by the Eleventh Circuit (as well as the Second and Federal Circuits) and the FTC's proposed "quick-look" or "presumptively-unlawful" test which would have shifted the burden to the defendants to show a pro-competitive justification sufficient to overcome the settlement's presumptive illegality.[10] Instead, the Court acknowledged that some reverse-payment settlements might be reasonable and lawful and, recognising the inherent complexity, the majority held that the rule of reason must apply to reverse-payment settlements.[11]

> "[T]he 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. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases."[12]

Or maybe not…

Beyond the need for a rule-of-reason assessment, the Supreme Court offered little guidance in analysing these settlements. The Court suggested only that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" and that a "large" payment indicates that the patentee possesses some degree of market power.[13] But the Court did not say exactly how to identify "unexplained" or "large" payments. Also, the Court did not foreclose inquiry into the strength of the patent(s), stating only that "it is normally not necessary to litigate patent validity to answer the antitrust question."[14] The first problems that the district courts faced in implementing *Actavis*, however, did not arise in relation to these questions left open by the Supreme Court, but in relation to the preliminary question concerning what is to be understood by a "payment".

In January 2014, the US District Court for the District of New Jersey dismissed an antitrust challenge to a reverse-payment settlement in *In re Lamictal Direct Purchaser Antitrust Litigation*[15] because there was no cash payment flowing from the patent holder to the would-be generic competitor, narrowly interpreting *Actavis* as imposing a "bright-line" requirement of a cash payment. The court therefore held that it was unnecessary to engage in the requisite rule-of-reason analysis to determine the settlement's anticompetitive effects (if any).

Just a few months earlier in September 2013 in the same district, however, a different judge took a less restrictive view of *Actavis* in *In re Lipitor Antitrust Litigation*.[16] In this case no major cash payment was involved from Pfizer (Lipitor's patent-holder) to Ranbaxy (the would-be competitor) for settling the case, but a reciprocal dropping of unrelated patent lawsuits against each other. However, the Court held that "nothing in *Actavis* strictly requires that the payment be in the form of money".

Similarly, in *In re Nexium (Esomeprazole) Antitrust Litigation*, in a summary judgment opinion issued on September 4, 2014,[17] the US District Court for the District of Massachusetts applied *Actavis* broadly, holding that the following deals may constitute a reverse payment:

- profitable side deals, such as manufacturing, distribution, and marketing deals[18];
- an agreement by the brand to refrain from launching its own authorised generic[19]; and
- forgiveness of considerable debt (in the present case $22.1 million in damages owed from an unrelated infringement suit).[20]

The FTC seems to agree that cash is not necessary. In *AbbVie*[21] the FTC filed a complaint[22] against brand manufacturer AbbVie and generic Teva after they settled a patent infringement suit for the testosterone replacement drug, AndroGel (involving a different patent settlement than *Actavis*), which is currently manufactured by

[7] *Activis* 133 S.Ct. 2223 (2013) at 2229.
[8] *Activis* 133 S.Ct. 2223 (2013) at 2229.
[9] *FTC v Watson Pharm., Inc* 677 F.3d 1298, 1312 (11th Cir. 2012).
[10] *Actavis* , 133 S.Ct. 2223 (2013) at 2237.
[11] *Activis* 133 S.Ct. 2223 (2013) at 2230–31.
[12] *Activis* 133 S.Ct. 2223 (2013) at 2237.
[13] *Activis* 133 S.Ct. 2223 (2013) at 2235–36.
[14] *Activis* 133 S.Ct. 2223 (2013) at 2235–36.
[15] *In re Lamictal Direct Purchaser Antitrust Litigation* No. 12-cv-995-WHW (D.N.J. Jan. 24, 2014).
[16] *In re Lipitor Antitrust Litigation*No. 3:12-cv-02389 (PGS) (D. N.J. Sept. 9, 2012).
[17] *In re Nexium (Esomeprazole) Antitrust Litigation* No. 12-md-02409-WGY (D. Mass. Sept. 4, 2014).
[18] *Nexium* No. 12-md-02409-WGY (D. Mass. Sept. 4, 2014) at 20.
[19] *Nexium* No. 12-md-02409-WGY (D. Mass. Sept. 4, 2014) at 55–56.
[20] *Nexium* No. 12-md-02409-WGY (D. Mass. Sept. 4, 2014) at 116–17.
[21] *FTC v AbbVie* Inc No. 2:14-cv-05151-RK (E.D. Penn. Sept. 9, 2014).
[22] Interestingly, it is the FTC's first pay-for-delay complaint filed since the Supreme Court's ruling in *Actavis*.

AbbVie. No cash was involved, but AbbVie gave Teva a "highly profitable authorized generic deal for another product"—Tricor (a cholesterol medication) for which no generic was previously available—in exchange for staying out of the market for AndroGel. The commissioners, however, voted 3 to2 to issue the complaint, making it the first time a vote on a pay-for-delay complaint was not unanimous, which makes the legal uncertainty on the appropriate standard to adopt after *Actavis* even more obvious.

As Chief Justice Roberts stated in the dissent in *Actavis*, much if not virtually all of the guidance on the antitrust analysis of reverse-payment settlements is being left to the district courts, who are still struggling even to begin to find their way to a consistent and coherent approach to analyse the competitive effects of reverse-payment settlements within the challenging patent and regulatory environment of this important public health issue.

European Commission's antitrust enforcement in pay-for-delay agreements

In 2008 the European Commission launched the Pharmaceutical Sector Inquiry to investigate the reasons for the apparent lack of competition in the market for human medicines in Europe. The final report,[23] published on July 8, 2009, found that there had been a decline in the number of novel medicines reaching the market and identified significant delays in the market entry of generic drugs. The Commission made several recommendations to address these problems, including the adoption of regulatory measures,[24] and put particular emphasis on stronger enforcement of competition rules and monitoring of pharmaceutical companies.

Since then the Commission has been closely scrutinising practices in this sector which may have infringed EU antitrust rules, particularly, arts 101 and 102 of the Treaty on the Functioning of the European Union (TFEU), which prohibit anticompetitive agreements between companies and anticompetitive abuses by dominant firms. The Commission has so far adopted three infringement decisions on pay-for-delay agreements, and there is another investigation still ongoing.[25]

The Citalopram case[26]

On June 19, 2013 the Commission imposed a fine of €93.8 million on Lundbeck and fines totalling €52.2 million on several producers of generic medicines for delaying generic market entry of the drug Citalopram in breach of art.101 TFEU that prohibits anticompetitive agreements.

In 2002, Citalopram, Lundbeck's best-selling medicine at the time and one of the most widely prescribed antidepressants, was nearing the end of its life cycle. After Lundbeck's basic patent for the Citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection. At that point, several generic companies were all preparing to launch their own versions of the product and, indeed, one of them started to sell generic Citalopram.

However, instead of competing, the generic producers agreed not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros. Lundbeck paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement. However, the agreements gave the generic producers no guarantee of market entry thereafter.

According to the Commission, the companies shared the monopoly rents among themselves: internal documents even spoke of this group of companies as a "club" and referred to "a pile of dollars" to be shared.

The Fentanyl case[27]

On December 10, 2013, the Commission adopted a decision against Johnson & Johnson and Novartis, and imposed fines totalling €16 million, for entering into an anticompetitive agreement to delay the market entry of a generic version of the pain-killer Fentanyl in the Netherlands. The Commission found that such a "naked" pay-for-delay agreement infringes art.101 TFEU.

Fentanyl is a painkiller, which was initially developed by Johnson & Johnson who has commercialised it in different formats since the 1960s. In 2005, Johnson & Johnson's protection on the Fentanyl depot patch had expired in the Netherlands and the Dutch subsidiary of Swiss firm Novartis, Sandoz, was on the verge of launching its generic Fentanyl depot patch. Indeed, it had already produced the necessary packaging material.

However, in July 2005, instead of actually starting to sell the generic version, Sandoz concluded a so-called "co-promotion agreement" with Janssen-Cilag—Johnson & Johnson's Dutch subsidiary—which provided strong incentives for Sandoz not to enter the market. Indeed, the agreed monthly payments exceeded the profits that Sandoz expected to obtain from selling its generic product, for as long as there was no generic entry.

[23] Available at *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html* [Accessed October 24, 2014].
[24] Such as improving pricing and reimbursement procedures for medicines and creating a unified patent system.
[25] Case COMP/AT.39686—*Cephalon*, not discussed further due to involvement in the US litigation related to the same drug.
[26] Case COMP/ AT. 39226—*Lundbeck*, Commission Decision of June 19, 2013, of which there is no public version available yet. See the Commission's press release and related statement by Competition Commissioner Almunia available at *http://europa.eu/rapid/press-release_IP-13-563_en.htm* [Accessed October 24, 2014] and *http://europa.eu/rapid/press-release_SPEECH-13-553_en.htm* [Accessed October 24, 2014].
[27] Case COMP/ AT. 39685—*Fentanyl*, Commission Decision of December 10, 2013, of which there is no public version available yet. See the Commission's press release and related statement by Competition Commissioner Almunia available at *http://europa.eu/rapid/press-release_IP-13-1233_en.htm* [Accessed October 24, 2014] and *http://europa.eu/rapid/press-release_SPEECH-13-1053_en.htm* [Accessed October 24, 2014].

Consequently, Sandoz did not offer its product on the market until December 2006, when a third party was about to launch a generic Fentanyl patch.

According to internal documents there would be no entry into the Dutch market in exchange for "a part of [the] cake". Janssen-Cilag did not consider any other existing potential partners for the so-called "co-promotion agreement" but just focused on its close competitor Sandoz. Sandoz engaged in very limited or no actual co-promotion activities.

The Perindopril case[28]

On July 9, 2014 the Commission imposed fines totalling €427.7 million on the French pharmaceutical company Servier and five producers of generic medicines for breaching EU competition rules. In particular, according to the Commission, Servier committed an abuse of its dominant position in the market for the perindopril molecule by pursuing an anti-competitive strategy to delay the entry of cheaper generic versions in breach of art.102 TFEU. Also, as part of this strategy, Servier entered into anticompetitive agreements with the generic makers in breach of art.101 TFEU.

The basic patent for Perindopril, Servier's bestselling blood pressure medicine and—as described in internal documents—its "dairy cow", had for the most part gradually expired across Europe in 2003. Although Servier still had a number of process and secondary patents, generic companies were intensively preparing their market entry. There were very few sources of patent-free manufacturing technology at the time and in 2004 Servier acquired the most advanced one, forcing a number of generic projects to be abandoned and entry to be delayed. Servier recognised that this acquisition merely sought to "strengthen the defence mechanism" and the technology was never put to use.

With this way to the market cut off, some generic producers continued in their efforts to launch a generic version of Perindopril by challenging Servier's patents in court and preparing their own products. However, between 2005 and 2007, virtually each time a generic company came close to entering the market, Servier and the company in question settled the challenge. This happened at least five times between 2005 and 2007. One generic company acknowledged that it was being "bought out of perindopril". In total, cash payments from Servier to generics amounted to several tens of millions of euros. In one case, the settlement was not based on cash payments but on a market-sharing arrangement with the generic company: Servier offered a generic company a licence for seven national markets; in return, the generic company agreed to "sacrifice" all other EU markets and stop efforts to launch its Perindopril there.

When, after five patent settlements, litigation finally led to a first court judgment, the relevant patent was annulled. But Servier commented that this was still a "great success, as four years were won". Right after the patent was annulled, prices of generic Perindopril dropped by as much as 90 per cent.

The legal standard under EU antitrust law

Despite Competition Commissioner Almunia's statement in the *Perindopril* case that "[t]oday's decision draws a clear line on the ground, which will give the entire sector even more guidance on what antitrust rules do not allow",[29] the legal standard on pay-for-delay agreements under EU antitrust law is far from certain. This legal uncertainty will not disappear at least until the Commission publishes non-confidential versions of the decision adopted so far and, arguably, not until there are European Court rulings on the same.

There are, however, certain principles and preliminary conclusions on the legal standard to apply under EU antitrust law that can be inferred from the public information available,[30] which will be analysed in the following sections.

Classification of patent settlements

The Sector Inquiry final report[31] provided for a classification of patent settlements in the pharmaceutical sector and offered invaluable guidance on the Commission's approach to patent settlements and related concepts, distinguishing the following:

1) **Category A:**

   agreements that do not restrict the generic company's ability to market its own product. Typically, these settlements should be unproblematic from a competition law perspective, as they allow immediate market entry by the generic company with its own product.

2) **Category B:**

   agreements that do limit generic entry, e.g., (a) when the settlement agreement contains a clause explicitly stating that the generic company will refrain from challenging the validity of the originator company's

[28] Case COMP/AT.39612—*Perindopril (Servier)*, Commission Decision of July 9, 2014, of which there is no public version available yet. See the Commission's press release and related statement by Competition Commissioner Almunia available at *http://europa.eu/rapid/press-release_IP-14-799_en.htm* [Accessed October 24, 2014] and *http://europa.eu/rapid/press-release_SPEECH-14-541_en.htm?locale=FR* [Accessed October 24, 2014].

[29] See Competition Commissioner Almunia's statement on the *Perindopril* case available at *http://europa.eu/rapid/press-release_SPEECH-14-541_en.htm?locale=FR* [Accessed November 12, 2014].

[30] i.e., press releases, speeches, reports issued in the context of the Pharmaceutical Sector Inquiry, case-law and soft-law instruments such as guidelines or communications on general antitrust matters.

[31] See the relevant summary in the 4th Report on the Monitoring of Patent Settlements, published on December 9, 2013, section 2. Available at *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf* [Accessed October 24, 2014].

patent(s) (non-challenge clause) and/or refrains from entering the market until the patent(s) have expired (non-compete clause); (b) when the branded company grants a licence to the generic company when the generic company cannot enter the market with its own product or cannot set the conditions for the commercialisation of its product freely; (c) when the parties agree that the generic company will be a distributor of the originator product concerned or that the generic company will source its supplies of the active pharmaceutical ingredient (API) from the originator company; or (d), when the agreement provides for an early entry of a generic medicine but such entry is not immediate. These agreements are further categorised in two groups:

a) B.I settlements, which comprise those settlements where no value transfer from the originator to the generic company took place. These settlements are normally unproblematic, although some of them may attract competition law scrutiny, for instance, (a) when concluded outside the exclusionary zone of the patent; and/or (b) when the settlement agreement is in relation to a patent which the patent holder knows does not meet the patentability criteria (e.g. where the patent was granted following the provision of incorrect, misleading or incomplete information); and

b) B.II settlements, which foresee a value transfer from the originator to the generic company. These settlements are likely to attract the highest degree of antitrust scrutiny.

The Commission's guidance and practice[32] makes it clear that, for the purposes of the antitrust assessment, a value transfer can take several forms, e.g., (a) a direct monetary transfer regardless of its alleged purpose (e.g., purchasing an asset such as the generic company's stock of own products); (b) distribution agreements or a "side-deal" in which the originator company grants a commercial benefit to the generic company (e.g., by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company); or (c) a licence granted to the generic company enabling it to enter the market.[33]

Restrictions by object or by effect

Through the abovementioned B.II classification the Commission applies its first filter and selects the general type of agreements that may require a closer look. Nonetheless, this is not to suggest that agreements falling into this category will always be incompatible with EU competition law. Category B.II agreements need to be assessed under art.101.1 TFEU on the basis of the circumstances of each individual case.

Under art.101.1 TFEU agreements between companies which have as their object or effect an appreciable restriction of competition are prohibited. Given the either/or nature of the "object or effect" requirement, the first step is to consider the precise object of the agreement and whether, it can be regarded "by its very nature, as being injurious to the proper functioning of normal competition".[34] When this is the case, it is not necessary to prove actual anti-competitive effects[35]. Rather, it is sufficient to show that the agreement is inherently liable to negatively affect competition, that is to say, that the restraint is capable of resulting in a distortion of competition. It is only when a contextual analysis reveals that the agreement in question is not sufficiently injurious to the proper functioning of normal competition[36] that actual or potential anti-competitive effects need to be established and compared with the relevant counterfactual, i.e., with the situation which could have realistically occurred in the absence of the restraint.

Identifying the anti-competitive object of a restraint does not take place in a vacuum. According to settled case-law,[37] in order to assess the anti-competitive nature of an agreement, regard must be had inter alia to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part. In this context, therefore, the word object does not mean subjective intention of the parties, but the objective meaning and purpose of the agreement considered in the economic and legal context in which it is to be applied. Intention, however, although not essential, can be taken into account to establish an object restriction.[38]

[32] See, e.g., in the *Perindopril* case.
[33] 4th Report on the Monitoring of Patent Settlements (9 December 2013), para 12.
[34] *Competition Authority v Beef Industry Development Society Ltd (BIDS)* (C-209/07) [2008] E.C.R. I-8637 at [17]; [2009] 4 C.M.L.R. 6; [2009] All E.R. (EC) 367.
[35] *Etablissements Constern SaRL v Commission of the European Economic Community* (Joined Cases 56/64 and 58/64) [1966] E.C.R. 299; [1966] C.M.L.R. 418.
[36] *Allianz Hungária Biztosító Zrt v Gazdasági Versenyhivatal* (C-31/11) [2013] R.T.R. 19; [2013] 4 C.M.L.R. 25.
[37] *GlaxoSmithKline Services Unlimited v Commission of the European Communities* (Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P) [2009] E.C.R. I-9291 at[58]; [2010] 4 C.M.L.R. 2; [2010] C.E.C. 885. See also *BIDS* [2008] E.C.R. I-8637 (note 34) at [16] and [21]; [2009] 4 C.M.L.R. 6.
[38] *IAZ International Belgium SA v Commission of European Communities* (Joined Cases 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82) [1983] E.C.R. 3369 at [23]–[25]; [1984] 3 C.M.L.R. 276.

With all this in mind, when assessing a pay-for-delay agreement in its context, the Commission has taken into account[39] several factors, including, inter alia:

- whether there (realistically) exists actual or potential competition[40] to the branded company, i.e., whether generic producers have envisaged viable routes to market by challenging the branded company's patent or using an alternative patent-free manufacturing process. This will be assessed as things stand at the time the agreement is signed, i.e., regardless of whether, in the end, what was considered a viable route to market failed;
- the nature of the mutual commitments, i.e., whether the generic company has committed to limit its independent efforts to enter the market in return for a value transfer from the branded company;
- the likely effects of the value transfer on the generic company's future behaviour, i.e., whether it substantially reduces incentives on the generic company to independently pursue its efforts to enter the EU market, especially where the branded company has taken into account the value that the generic would have made on the market and offered more than that. The size of the payment is therefore only relevant in relative and not absolute terms;
- whether the branded company could have obtained the said limitations on entry through enforcement of its patent(s) still in force;
- whether there is agreement on a specific date of entry or not; and
- the parties' subjective intentions, as evidenced by the facts of the case.

However, even "by object" restrictions are never "per se" unlawful and may theoretically be defended by demonstrating efficiencies under art.101.3 TFEU. It is, however, the parties, and not the Commission, who carry the burden of proof that each of the conditions set out in art.101.3 TFEU are met, providing sufficient and verifiable evidence that a restraint is ultimately pro-competitive and beneficial for consumers.[41] In practice, an object restriction is unlikely to meet these conditions, as they rarely enhance efficiencies or benefit consumers and are rarely indispensable.[42] Indeed, in the cases dealt with by the Commission so far, the parties have reportedly alleged efficiencies but the Commission has not been convinced.

It is worth mentioning that, in its infringement decisions on pay-for-delay agreements, the Commission has so far always found "by object" infringements, therefore not strictly having to show any actual or potential anti-competitive effects. Nevertheless, "for the sake of completeness",[43] in what has been referred to as a "dual object-effect approach", the Commission has also analysed effects to some, limited extent. In particular, in both the *Citalopram* and the *Perindopril* cases, the Commission found that once the restrictive agreements had come to an end, generic entry did take place and prices of the relevant drugs dropped on average by 90 per cent.

It may be that the emphasis will shift further towards an effects analysis in the future, bringing the European approach closer to the US rule of reason required by *Actavis*. The recent judgement of the Court of Justice of the European Union in *Cartes Bancaires*[44] (not a pay-for-delay case) suggests the Court feels the Commission may have gone too far in its identification of "by object" infringements. The judgement does not strictly go any further than previous rulings on the meaning of "by object" restrictions but it is clear in its statement that the category should be defined restrictively, reserved for the most obviously anticompetitive arrangements.

Open questions and conclusions

Despite the guidance available on how the Commission will analyse pay-for-delay agreements under EU competition law, there is still significant legal uncertainty. The questions that remain open include the following:

- What is the relevance of the validity/strength of the patent and its scope? In *Perindopril*, the patent was notoriously weak, but in *Citalopram* there was reportedly[45] no question about the validity of Lundbeck's process patents and, furthermore, in many concurrent documents the generic companies acknowledged that their products violated Lundbeck's patents. The Commission seems to have given significantly more importance to the fact that the basic patent on the molecule had expired and there were, allegedly, alternative ways to enter the market. Additionally, though, the Commission did

[39] See Alexander Italianer "Competitor agreements under EU competition law" (40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute, September 26, 2013, New York), available at *http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf* [Accessed October 1, 2014].
[40] On the concept of actual or potential competitor, see, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements 2014/C 89/03, paras 32 and 33; and, in more general terms, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements 2011/C 11/01, paras 10 et seq.
[41] See, e.g., Case COMP/AT.39595, *Continental/United/Lufthansa/Air Canada (Star Alliance) Commission decision of May 23, 2013*.
[42] Indeed, many commentators have reported on reports of the death of art.101.3 for object restrictions.
[43] See Italianer, "Competitor agreements under EU competition law" (September 26, 2013, New York).
[44] Judgment of September 11, 2014, *Groupement des Cartes Bancaires (CB) v European Commission* (C-67/13 P) (2014) n.y.r
[45] Lundbeck's press release issued after the Commission decision was adopted.

find that the agreement imposed obligations on the generic producer that went beyond the rights of the patent-holder, and took that into consideration in identifying a "by object" restriction. This could suggest that where a settlement remains within the so-called "scope of the patent", even though antitrust scrutiny is not prevented, it is something that will be taken into account.

- What is the relevance of the time at which entry is permitted (if at all) by the settlement? In *Citalopram* the Commission took into account the fact that the agreement did not guarantee entry after expiration. Would a commitment from Lundbeck to refrain from suing the generics for patent infringement once the agreement had expired have changed the Commission's assessment?
- What is the relevance of the relationship in time of patent settlement agreements with different generic companies? In *Citalopram* Lundbeck allegedly paid off all its potential competitors at the same time while in *Perindopril* the agreements were concluded over several years. How does that affect the assessment of potential competition in the contextualised analysis required to identify "by object" restrictions?
- Why did the Commission act both under arts 101 and 102 TFEU in the *Perindopril* case? The well-known complexities and difficulties involved in proving an abuse of a dominant position, may give Servier further ammunition on appeal. Servier will most likely challenge not only the existence of a dominant position and the existence of an abuse, but also the Commission's market definition (limited to the Perindopril molecule).

One conclusion that should not be drawn from the European decisions is that pay-for-delay deals will inevitably be treated as "by object" infringements. The cases to date have involved allegations of subjective intent to foreclose competition as well as other evidence tending to show inherent harm to competition. It is perhaps not surprising that the Commission has aggressively pursued such cases and no doubt it will do so in the future as well. Most cases, though, will require a more nuanced "effects-based" analysis and now more so than ever given the judgment in *Cartes Bancaires*.