

Survey

The Application of EU Competition Law in the Pharmaceutical Sector

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I. Introduction

This survey article reviews the major EU competition law developments in the pharmaceutical sector from 1 July 2014 through 31 October 2015 as well as decisions that were adopted earlier but only published during the period. The European Commission did not adopt any decisions dealing with the pharmaceutical sector during this period, but published its decisions in *Lundbeck*, *Servier*, and *J&J/Novartis*, which provide a rich source of information on how the Commission approaches IP, regulatory, and commercial strategies that delay generic entry. National competition authorities continue to be active, notably in the area of pricing and distribution/parallel trade.

II. Agreements hindering generic competition

A. Reverse-payment patent settlements

Reverse-payment patent settlements remain a priority for the Commission. In June 2013, it adopted its first decision dealing with these settlements in *Lundbeck*,¹ and, in July 2014, it adopted its second such decision in *Servier*.² Both decisions are now on appeal to the General Court. The various *Lundbeck* cases (Lundbeck and each of the generic companies have appealed, and each appeal is treated as a separate case) were argued in the fall of 2015, so it is likely that the General Court will issue its judgments in the first half of 2016. The Commission has at least one ongoing investigation, which involves a settlement agreement between Cephalon and Teva.³ The UK Competition and Markets Authority (CMA) has an ongoing investigation concerning reverse-payment settlements between GlaxoSmithKline (GSK) and various generic manufacturers for the anti-depressant drug paroxetine.⁴

The *Lundbeck* and *Servier* decisions are voluminous—*Lundbeck* is 466 pages and *Servier* is 805 pages—and

Key Points

- This survey article discusses the major EU competition law developments in the pharmaceutical sector from 1 July 2014 through 31 October 2015.
- During that period, the European Commission did not adopt any new decisions dealing with the pharmaceutical sector, but it published decisions that it had adopted earlier, which provide a rich source of information on its approach to IP, regulatory, and commercial strategies that delay generic entry.
- National competition authorities have been active, notably in the area of pricing and distribution/parallel trade.

contain a wealth of information on how the Commission analyses reverse-payment settlements, on the more general topic of the interplay between competition and IP laws, on the definition of markets for drugs, and on the application of Article 102 to late life cycle management strategies. The length of these decisions is due in large part to the fact that, after discussing issues common to the various agreements between the originator and each generic, the Commission must analyse each settlement agreement separately. The length is also undoubtedly due to the fact that the Commission drafted them with an eye towards the likely appeals to the General Court—each decision sets out the facts and the Commission's reasoning in detail complete with explanatory footnotes, which are at times more interesting than the actual text of the decision.

In *Lundbeck*, the European Commission imposed a fine of €93.8 million on Lundbeck, the Danish pharmaceutical company, and fines totalling €52.2 million on

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1 Case AT.39266, *Lundbeck*, Decision of 19 June 2013.

2 Case AT.39612, *Servier*, Decision of 9 July 2014.

3 'Commission Opens Investigation Against Pharmaceutical Companies Cephalon and Teva', European Commission Press Release IP/11/511 (28 April 2011).

4 'OFT Issues Statement of Objections to Certain Pharmaceutical Companies', OFT Press Release 36/13 (19 April 2013).

generic manufacturers Alpharma, Merck KGaA/Generics UK, Arrow, and Ranbaxy. The agreements at issue involved Lundbeck's blockbuster anti-depressant citalopram. The compound patent on the citalopram molecule had expired, but Lundbeck still had various process patents. Lundbeck entered into settlement agreements with the generic manufacturers in which it made payments to them, and they allegedly agreed not to enter the market for the duration of the agreement and, in some cases, agreed to destroy their stocks of generics.

The Commission's analysis of the various agreements focused on the following key points:

- *Potential competition.* In the Commission's view, a generic is a potential competitor as long as there has not been a final ruling from a court on the patent as it is free to enter the market and challenge the patent.⁵ The Commission rejected the argument raised by Lundbeck and numerous generics that patents must be presumed to be valid and, thus, the generic may not be considered as a potential competitor because, if it entered the market, it would violate the patent.
- *Payment.* According to the Commission, when a settlement is made without a payment or other transfer of value from the originator to the generic, it is unlikely to raise competition concerns as the settlement likely would be the result of the parties' independent assessments of the patent situation.⁶ In contrast, where there is a payment, it may well be that it is the payment rather than the patent that causes the generic to agree not to enter the market for a certain period.⁷ The Commission rejected the argument that the payment may simply reflect an asymmetry of risk as between the originator and the generics in that the originator has much more to lose if the patent is struck down or held not to be infringed.
- *By object infringement.* The Commission found that the settlements constituted restrictions of competition 'by object' so that it was not necessary to establish anticompetitive effects. As there are few issues in the competition law field that have generated more debate in the past few years than how reverse-payment settlements should be analysed, and as the Commission has no experience with such settlements, it would seem at least questionable whether they should be treated as 'by object' restrictions that 'by their very nature' are restrictive of competition, particularly in light of the Court of Justice's ruling in *Cartes Bancaires*,⁸ in which

it seemed to narrow the scope of the 'by object' restriction.

In *Servier*, the Commission imposed a fine of €331 million on Servier, the French pharmaceutical company, and fines totalling €96 million on five generic manufacturers—Unichem, Matrix (now Mylan), Teva, Krka, and Lupin. The agreements involved Servier's best-selling blood pressure medicine, perindopril. Servier's basic molecule patents had expired in 2003, but it still held a number of patents related to the manufacturing process and the product's formulation, which the Commission described as 'secondary' patents. Generic manufacturers were challenging these patents before various courts and, at the same time, preparing to enter the market.

The Commission's decision in *Servier* differs from the *Lundbeck* decision in two basic respects. First, while the Commission only analysed the settlement agreements under a 'by object' test in *Lundbeck*, it hedged its bets and also applied an 'effects' test in *Servier*. As the Court of Justice's ruling in *Cartes Bancaires*, which came several months after the decision in *Servier*, would not seem to augur well for the Commission's case because it appears to narrow the scope of the 'by object' restriction, this two-pronged strategy may turn out to be prescient.

Second, the Commission found that, in addition to entering into agreements that restricted competition in violation of Article 101, Servier's conduct constituted an abuse of its dominant position in violation of Article 102. This is the first time that the Commission has applied Article 102 to late life cycle management strategies since its decision in *AstraZeneca*, and is therefore useful in understanding its thinking. The Commission began its analysis by emphasising that a strategy designed to protect an originator's market position against generic entry is 'generally legitimate to the extent it resorts to measures representing competition on the merits', which it described as competition on product quality and the strategic use of IPRs and the patent system.⁹ In contrast, a dominant company's use of measures that deviate from competition on the merits and are capable of producing foreclosure effects will be subject to antitrust scrutiny.

Applying these principles to Servier's late life cycle management strategy, the Commission found that Servier had abused its dominant position by engaging in a 'single and continuous exclusionary strategy' that consisted of both acquiring technology that would have allowed generic manufacturers to make a product that did not infringe Servier's process patents and the con-

5 *Lundbeck*, para. 624.

6 *Ibid.*, para. 604.

7 *Ibid.*

8 Case C-67/13P, *Groupement des Cartes Bancaires v European Commission* (11 September 2014) (not yet reported).

9 *Servier*, para. 2766.

clusion of the settlement agreements.¹⁰ In finding that these features of Servier's strategy were abusive, the Commission emphasised that they took place in the context of a broader strategy aimed at curbing generic entry that included the creation of a patent thicket and efforts to convince regulators to adopt stricter product specifications that favoured the Servier's product. While the Commission did not establish that these practices contributed to foreclosure effects, it nevertheless found them to be pertinent to its analysis insofar as they explained why competition from generics was limited to certain avenues that Servier then proceeded to shut off through its acquisition of technology and the settlement agreements.¹¹ This approach seems inconsistent with the Commission's declaration that strategic use of patents is generally not problematic and is disturbing in that it seems to suggest that it will be easier to find that conduct is abusive if it takes place in the context of an entirely legitimate IP and regulatory strategy aimed at combatting generic competition.

The abuse identified in Servier is interesting in that the Commission went out of its way to construct an abuse did not consist of a single action taken in isolation, but rather was a combination of various activities—the acquisition and the settlements. To link these activities, the Commission borrowed the phrase 'single and continuous act' so familiar in the context of its cartel decisions.¹² It underscored that the technology acquisition and the settlements were 'intertwined'¹³ and 'complementary',¹⁴ forming a 'clear pattern'¹⁵ of conduct where Servier targeted potential entrants to remove the competitive threat. In the Commission's view, the technology acquisition and the settlements were necessary complements to a successful exclusionary strategy as they shut off the two principle routes to market for generics—inventing around the patented process or convincing a court to issue a finding of invalidity or non-infringement.¹⁶

In concluding that the technology acquisition contributed to the foreclosure effects of its single and continuous exclusionary strategy, the Commission found that Servier did not acquire the technology to improve its own production processes (as there was evidence that Servier did not use the technology), but rather to reinforce its thicket of blocking patents.¹⁷ The Commission examined the technological landscape in some

detail and found that the technology acquired by Servier was the most advanced in terms of potential to bring a product to market and, thus, represented the most immediate competitive threat to Servier. By acquiring the technology, Servier eliminated this threat.

Turning to the settlements, the Commission found that they fell outside of competition on the merits and also contributed to the foreclosure effects of Servier's strategy. According to the Commission, Servier engaged in unilateral abusive conduct by using the profits it reaped in a market where it was dominant to buy off competitors.¹⁸ The Commission highlighted that the settlements were a 'chain of agreements which were mutually reinforcing'¹⁹ and that they formed part of a pattern pursuant to which Servier 'systematically targeted' close potential competitors.²⁰

The Commission continues to monitor patent settlements in the pharmaceutical sector. Each year, the Commission requests originator and generic companies to submit copies of all patent settlement agreements covering EU/EEA markets concluded during the previous calendar year together with related agreements. The principle aim of this annual monitoring exercise is to identify reverse-payment patent settlements and other settlements that could delay generic entry, such as those that contain restrictions extending beyond the geographic or material scope of the patent.

As in the previous monitoring reports, the Fifth Monitoring Report²¹ first discusses the main categories of settlements and then provides an overview of the replies submitted by companies and an analysis of the main characteristics of the settlements falling within particular categories. The Commission's discussion of the categories of patent settlements in these reports is about the only concrete guidance that companies have as to when a settlement is likely to raise competition law concerns. Perhaps reflecting an awareness that this report is viewed as informal guidance, the Commission tends to use exactly the same language each year. Indeed, the Fifth Monitoring Report repeats the previous year's report verbatim except for the actual figures on the settlements.

After 5 years, the monitoring exercise has become stale. It offers statistics that are of little use in understanding what is actually happening. For example, the Fifth Report shows that the number of settlements has

10 Ibid, para. 2774.

11 Ibid, para. 2772.

12 Ibid, paras 2962, 2963, and footnote 3804.

13 Ibid, para. 2783.

14 Ibid, para. 2777.

15 Ibid, para. 2794.

16 Ibid.

17 Servier, para. 2776.

18 Ibid, para. 2933.

19 Ibid, para. 2942.

20 Ibid, para. 2945.

21 *5th Report on the Monitoring of Patent Settlements (period: January–December 2013)* (5 December 2014).

increased, a meaningless statistic unless it is compared with the number of cases litigated, which the Report fails to do. Other than the figures on how many settlements fall into the various categories used to classify settlements, the Report does not provide any detail concerning the settlements that would be useful in understanding which ones are most likely to raise concerns.

Perhaps the most troubling aspect of the monitoring report is that the categories used to classify settlements in terms of the degree of competition law risk attached to them provide little useful information and arguably have a chilling effect on settlements that could be pro-competitive to the extent that they would allow early generic entry. These categories had their origin in the Commission's Report on the Pharmaceutical Sector Inquiry, which is somewhat ironic given that, in this Report, the Commission explicitly disavowed reaching any conclusions concerning the application of competition law in the pharmaceutical sector.²² Settlements falling in Category A and Category B.I are considered to be generally unproblematic, which is not surprising as Category A settlements are those that allow immediate market entry by the generic and those in Category B.I where there is no value transfer from the originator, ie where the generic agrees to enter after patent expiry. It is questionable whether settlements in these categories are settlements at all in the sense that the one side or the other has capitulated entirely.

Settlements falling in the remaining category—Category B.II—that do not allow immediate entry by the generic and involve a value transfer from the originator to the generic are deemed the most likely to raise competition law concerns. The problem with this category is that it includes almost every form of settlement that would seem to fall within the normal definition of the term and, thus, risks discouraging companies from entering into meaningful settlements at all, including those that would allow early entry. For example, this category includes a common form of settlement that would seem to be benign in most circumstances: early entry by the generic. The Commission itself admits that such settlements are 'not likely to attract the highest degree of anti-trust scrutiny'.²³ Instead of using such vague language, it would be helpful if the Commission clearly stated that such a settlement would be unlikely to raise concerns. More generally, after 5 years of monitoring as well as having adopted decisions in *Lundbeck* and *Servier*, it

would seem that the Commission has enough experience under its belt that it could issue some form of guidance to companies that puts meat on the bones of the sparse guidance found in its monitoring reports.

In light of the strong views held by those on each side of the debate on patent settlements, it would seem likely that any ruling of the General Court would be appealed to the Court of Justice, which means that it could be a number of years before these issues are finally settled. In the meantime, originators and generics enter into reverse-payment settlements at their peril.

B. Co-promotion and co-marketing agreements

While the Commission's enforcement efforts have focussed on reverse-payment patent settlements, it has made it clear that other kinds of agreements that delay generic entry may raise competition law concerns. On 10 December 2013, the Commission adopted a decision imposing fines totalling €16 million on Johnson & Johnson (J&J) and Novartis for entering into a co-promotion agreement that had the object of delaying entry into the Dutch market of a generic version of fentanyl, a painkiller used by cancer patients.²⁴ The Commission published its 147-page decision in this case on 5 March 2015.

J&J had developed fentanyl and had commercialised it in different forms since the 1960s. By 2005, J&J's patent protection on the fentanyl depot patch had expired in the Netherlands, and Novartis's subsidiary Sandoz was on the verge of launching a generic version of that patch. However, Sandoz never launched the generic patch because, in July 2005, it entered into a co-promotion agreement with J&J's subsidiary, Janssen-Cilag. Under this agreement, Sandoz would co-promote a new version of J&J's fentanyl patch in exchange for monthly payments that exceeded the profits that Sandoz expected to make from the sale of generic patches. This agreement stayed in place until December 2006, when a third party was about to launch a generic version of the fentanyl depot patch.

The Commission found that the co-promotion agreement harmed competition because it delayed the entry of a cheaper generic fentanyl patch, leading to the maintenance of higher price levels in the Netherlands. The Commission's decision contains extensive documentary evidence—emails, presentations, and notes—showing the progression of the negotiations leading up to the settle-

22 Communication from Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 6 (8 July 2009). ('It is important to note underline that ... [the report] does not identify individual cases of wrongdoing or provide any guidance on the compatibility of the practices examined with the EC competition rules.')

23 *5th Monitoring Report*, para. 12.

24 Decision in Case AT.39685, *Fentanyl* (10 December 2015).

ment and that the settlement's goal was to prevent Sandoz from entering the market with a generic that would erode price levels. These documents included detailed financial calculations showing that the amount of the payment was intended to match what Sandoz would have lost by not entering the market. The Commission also emphasised that Sandoz engaged in very limited or no co-promotion activities, which supported the Commission's case that the payment was in return for Sandoz's agreement to stay off the market during the period of the agreement.

While the Commission has described *Fentanyl* as a 'pay-for-delay' case, this description is misleading to the extent that this suggests that it is comparable with a reverse-payment settlement case. The payment did not occur in the context of a patent settlement as did the payments in *Lundbeck* and *Servier*. In *Fentanyl*, the relevant patent had already expired, so the case does not involve the complex policy issues raised by the reverse-payment settlement cases. Rather, it appears to be a more straightforward case involving market sharing by competitors.

The case highlights the need for pharmaceutical companies to exercise caution when entering into agreements with competitors or potential competitors, particularly when such agreements enter into force around the time that a product is going off patent so that a generic could enter the market. While *Novartis/J&J* dealt with a co-promotion agreement, a similar analysis could apply in the case of, for instance, an 'authorised generic' agreement where the originator grants the generic a license to sell the original product rather than entering with its own generic version.

C. Denigration

On 18 December 2014, the Paris Court of Appeal issued a judgment upholding a May 2013 decision of the French competition authority (FCA), which found that Sanofi-Aventis had abused its dominant position by denigrating generic versions of its blockbuster Plavix, and imposed a fine of €40.6 million.²⁵ The FCA found that Sanofi-Aventis had engaged in a marketing campaign that systematically discouraged the use of generic versions of Plavix by highlighting that they used different salts from the original version and that they were not indicated for use in combination with aspirin for acute coronary syndrome.

On appeal, Sanofi-Aventis argued that, as a drug manufacturer, it has a duty to provide information and counselling to doctors and pharmacists, and that it fulfilled this obligation by providing complete and precise information about the objective characteristics of the

products. The Court rejected this argument, holding that the problem was not the information communicated, but how Sanofi-Aventis communicated it. The Court noted that the differences highlighted between the Sanofi-Aventis product and the generic versions did not affect their therapeutic substitutability, and were simply the result of Sanofi-Aventis's patents over certain salts. While Sanofi-Aventis did not claim that the use of different salts could affect the efficacy or safety of a generic, the Court held that Sanofi-Aventis implied as much, which created doubts concerning generics. Further, Sanofi's representatives encouraged doctors to write '*non-substitutable*' on prescriptions and advised pharmacists to only substitute with Sanofi's own generic clopidogrel.

In assessing the FCA's decision that such practices constituted an abuse, the Court of Appeal recalled that the language of Article 102 is broad, which means that a wide range of practices, including denigrating actual or potential competitors, may constitute an abuse of a dominant position. It then looked at the pharmaceutical sector, noting that doctors and pharmacists are reluctant to change their prescribing habits and are risk averse. Thus, any dissemination of negative information or insinuation that a generic product may present risk will be sufficient to convince doctors not to prescribe it and pharmacists not to provide it to the patient when given a choice. The Court thus agreed with the FCA's conclusion that diffusing information that is incomplete, ambiguous, or presented in such a way as to suggest that generics substitution could create a therapeutic risk constitutes an abuse in violation of Article 102.

The Court of Appeal's judgment confirms that originators need to be careful in raising concerns about generics, as marketing campaign may be held to be abusive if it creates unsubstantiated doubt in the minds of doctors and pharmacists about the quality of the generic.

Sanofi-Aventis has appealed this judgment to the French Supreme Court, and the judgment is pending. The FCA is investigating similar allegations against Janssen-Cilag for denigrating a generic producer for competing against its Durogesic painkiller, as well as granting discounts to hospitals.²⁶

III. Pricing

Competition authorities have continued to investigate pricing strategies of innovative pharmaceutical companies, leading to important developments on discount/rebate strategies, special hospital discounts, and allegations of excessive pricing.

25 Paris Court of Appeal, Case No. 2013/12370 (18 December 2014).

26 'French Antitrust Authority to Rule on Janssen Cilag Generic Defamation Case in 2014', MLex (23 January 2014).

A. Pricing/rebate strategies

In June 2015, the UK CMA announced that it had issued a warning letter to an unnamed pharmaceutical company concerning a suspected loyalty-inducing discount scheme, though it closed the case on administrative priority grounds.²⁷ While the CMA's announcement does not provide details of the scheme or reach any decision on whether the scheme infringed competition law, it nevertheless provides guidance on the types of rebates and discounts that may cause competition concerns. The CMA indicated that schemes are more likely to give rise to competition concerns where the rebates or discounts:

- are conditional on the customer obtaining all or most of its requirements from the dominant company;
- are retroactive (ie only apply if the customer reaches a volume threshold, and trigger lower prices on units above *and below* the threshold), especially if the customer may wish to source some (but not all) of its demand from a competitor;
- result in below-cost prices for contestable sales (ie the sales for which another supplier could compete); or
- result in negative incremental pricing (ie if the customer purchases more from the dominant company, then the total price paid by the customer goes down).

While the CMA identified the above types of rebates as increasing the competition law risks, it noted that it will consider 'all of the circumstances', and thus any assessment of whether discounts or rebates violate competition law will necessarily be fact specific.

This announcement by the CMA is broadly in line with the recent case law of the EU Courts, including *Intel*²⁸ and *Post Danmark II*,²⁹ pursuant to which exclusivity and retroactive rebates or discounts will give rise to a high risk of violating EU competition law. For other forms of rebates and discounts, the CMA's guidance indicates, in line with the European Commission's Article 102 Guidance, that they will give rise to less risk if the dominant supplier's net effective price for the contestable sales is above the supplier's long-run average incremental costs.

In light of the CMA's guidance, dominant pharmaceutical suppliers would be well advised to avoid exclusivity and retroactive rebates, absent special circumstances, and should also ensure that any volume discounts or rebates

do not decrease the net effective prices of its products to a level that is below cost.

B. Hospital discounts

In December 2014, the Dutch Consumers and Markets Authority announced the closure of its investigation into AstraZeneca, concerning allegations that AstraZeneca was selling its product Nexium below cost to hospitals in order to increase prescriptions and sales in the community (eg in pharmacies) at higher prices.³⁰ Such allegations bear strong similarities to the activities sanctioned by the UK competition authority in its 2001 decision in *Napp Pharmaceuticals*. In public statements, a member of the Dutch Authority has indicated that it considers such a strategy of discounting to hospitals to be problematic, as it allegedly reduces the substitution by cheaper generic equivalents.³¹

However, the Dutch Authority closed the case without reaching any conclusion, as it did not find that AstraZeneca was dominant either on the hospital market or in the community market. Initially, the view of the Authority was that the relevant community market should be defined very narrowly to only include Nexium, and exclude generics, as patients were thought to be bound to use Nexium due to the initial prescription in the hospital. However, AstraZeneca was able to refute this theory by presenting evidence of substitution, so there was no dominant position on which to base a case.

C. Excessive pricing

Despite the often strong public and governmental pressure to pursue pharmaceutical suppliers for excessive pricing, competition authorities are generally reluctant to launch such cases because they raise very difficult questions (eg what is the correct price), they may chill innovation, and they are generally unnecessary in light of the strong buyer power exercised by national health authorities and other payors.

For example, in December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Hepatitis C drugs, despite pressure from members of the European Parliament. In response to two parliamentary questions, the Commission noted that Member States have both economic

27 See Competition and Markets Authority, *Statement regarding the CMA's decision to close an investigation into a suspected breach of competition law in the pharmaceutical sector on the grounds of administrative priority* (26 June 2015).

28 Judgment of the General Court, Case T-286/09, *Intel v Commission* (12 June 2014).

29 Judgment of the Court of Justice, Case C-23/14, *Post Danmark v Konkurrencerådet* (6 October 2015).

30 See 'ACM closes investigation into AstraZeneca', ACM Press Release (2 December 2014).

31 Speech, Anita Vegter, Member of the Board of the Netherlands Consumers and Markets Authority, UNCTAD, Geneva (8 July 2015), available at <<https://www.acm.nl/nl/publicaties/publicatie/14483/Speech-Anita-Vegter-UNCTAD-8-juli-2015-Pharmaceutical-markets-and-consumers/>>, last accessed 15 November 2015.

bargaining power and regulatory powers to control the prices of pharmaceutical products, and that such powers were being used to limit the prices of the Hepatitis C drugs.³² The Commission appeared to acknowledge the market dynamics that typify the pharmaceutical sector in which national health authorities and insurance funds exercise significant buyer power that limits the scope for pharmaceutical suppliers to charge excessive prices.

Where such buyer power does not exist, however, and pharmaceutical suppliers attempt to significantly increase the prices of their medicines above the established prices, the competition authorities may step in to investigate, as illustrated by ongoing cases in the UK and Italy. On 6 August 2015, the UK CMA issued a statement of objections to Pfizer and Flynn Pharma concerning allegations of excessive pricing for an anti-epilepsy drug.³³ According to the CMA, prior to 2012, Pfizer manufactured and marketed the drug under the brand name Epanutin. Pfizer then transferred the UK marketing rights to Flynn Pharma, which 'genericised' the drug and started selling it in September 2012 at prices alleged to be 25–27 times higher than Pfizer's historical prices. The statement of objections covers both Pfizer's supply prices to Flynn Pharma and Flynn Pharma's prices to the market. This case is ongoing.

In a similar case, on 27 November 2014, the Italian competition authority (ICA) launched an investigation into allegations that Aspen Pharma abused its dominant market position by increasing the price of its cancer medications from 250 to 1,500 per cent.³⁴ According to the authority, Aspen had made efforts to increase the prices in Italy up to the levels in other EU countries, in order to limit the levels of parallel trade of the product out of Italy. The authority also alleges that Aspen threatened to withdraw the marketing authorisation of the product if the health authority did not agree to the price increases. This case is also ongoing.

IV. Licensing agreements between competitors

The alleged attempt by Roche and Novartis to limit competition between two products by preventing the off-label use of one of them has led to fines in Italy and is under investigation in other Member States. On 27 February 2014, the ICA imposed a fine of €92 million

on the Novartis group and €90.6 million on the Roche group,³⁵ and the Italian health authority is seeking damages of around €1.2 billion for the increased prices that it had to pay due to the agreement. The parties appealed the ICA's decision, which the Regional Court of Lazio upheld in a judgment issued on 5 November 2014 that is discussed below.³⁶ This judgment is on appeal to the Italian Council of State.

Shortly after the ICA announced its decision, the FCA opened an investigation into the same practices by Novartis and Roche on the French market.³⁷ It is reported that consumer organisations have filed complaints in other Member States, including Belgium, Spain, and Portugal.³⁸ The Commission has not opened a case at the EU level, but says that it is 'gathering more information and is in close contact with NCAs, notably with the French NCA, which has conducted inspections at the premises of some of the companies involved'.³⁹

The case involved two drugs developed by Genentech that came out of a research programme aimed at finding ways to stop the process of blood vessel formation called angiogenesis, which feeds tumour growth in cancer patients and also causes certain eye diseases. The first drug to be developed was Avastin, which was designed to treat cancer. A couple of years later, a derivative of the main compound in Avastin was developed into Lucentis, a drug to treat eye disease. Before Lucentis came onto the market, doctors used Avastin on an 'off-label' basis to treat eye disease as well. In other words, even though Avastin was only approved for the treatment of cancer, doctors also prescribed it for treating the eye disease, an unregistered or 'off-label' use.

As Genentech did not have a sales network in Europe, it licensed the products out—Avastin to Roche, its parent company, and Lucentis to Novartis. Avastin was sold at a maximum price of €81 per injection in Italy, while Lucentis was much more expensive—it started at a price €1,700 per injection, which was later lowered to €900. Before Lucentis was launched on the Italian market, Avastin was widely prescribed by doctors on an 'off-label' basis to treat eye disease. The Italian regulatory regime allowed such off-label use of a drug if there was no registered treatment available. Once Lucentis was launched on the Italian market, the off-label use of Avastin for eye disease was no longer reimbursed

32 European Commission, Response to Parliamentary Question P-008636/2014, 22 December 2014, and Response to Parliamentary Question E-000261-15 (31 March 2015).

33 'CMA Issues statement of objections to Pfizer and Flynn Pharma in anti-epilepsy drug investigation', CMA Press Release (6 August 2015).

34 See 'Antitrust's Investigation on the Price Increase for Aspen's Anticancer Drugs', ICA Press Release (27 November 2014).

35 Decision No. 24823 of 27 February 2014.

36 Regional Administrative Court (TAR) of Lazio, Judgment No. 6122 of 2014 (2 December 2014).

37 'Roche, Novartis Face French Antitrust Probe Over Eye Drugs', *Law 360*, 10 April 2014.

38 See *Test Achats*, Press Release (26 November 2014).

39 Answer given by Commissioner Vestager to Parliamentary Question No. P-000937-15 (20 February 2015).

because there was now a drug available that was registered for the treatment of eye disease. The switch from Avastin to Lucentis for the treatment of eye disease led to a dramatic increase in the cost of treating the eye disease, which generated the complaints by private healthcare clinics and the Italian Ophthalmological Society that led the ICA to open its investigation.

After a year-long investigation, the ICA concluded that Roche and Novartis had colluded to prevent Avastin from being used for the treatment of eye disease. More specifically, they had carried out a campaign aimed at artificially differentiating Avastin and Lucentis by raising safety concerns about the off-label use of Avastin to treat eye disease. The ICA found numerous communications between the two groups to this effect, particularly between the managers of their respective Italian subsidiaries, as well as internal documents discussing this strategy. It also pointed out that Roche had sought a change to the label of Avastin highlighting the risks of using Avastin to treat eye disease. The two companies also sought to downplay independent studies showing that the two drugs were equivalent. The ICA emphasised that Roche had an economic incentive to prevent Avastin from being used off label to treat eye disease because, as Genentech's parent company, it stood to gain more from the royalties paid to Genentech by Novartis for sales of Lucentis than from sales of Avastin.

In their appeal against the ICA's decision, Roche and Novartis argued that the restrictions on the off-label use of Avastin were the result of the decision of the Italian regulatory authority and were not caused by an illegal agreement. The evaluations carried out by the Italian and EU regulatory authorities indicated that Lucentis and Avastin are not equivalent for the purpose of treating eye disease. Roche and Novartis also emphasised that the systematic off-label use of drugs is unlawful, particularly in a situation where a drug has been approved for the same therapeutic indication. In short, it would have been unlawful to sell Avastin for the eye treatment under the relevant regulatory rules.

The Lazio Regional Court rejected these arguments and upheld the ICA's decision. It easily—perhaps too easily—brushed aside the regulatory arguments raised by Roche and Novartis by finding that they were outside the scope of its competence and, thus, not relevant to its review of the decision. It then proceeded to find that Avastin and Lucentis were competing products as Avastin was used off-label to treat eye disease in competition with Lucentis. Finally, it found that Roche and

Novartis had entered into an illegal agreement to prevent Avastin from being used in competition with Lucentis, pointing to evidence in the file of communications to this effect between the parties.

This judgment is troubling in that the court failed to deal with one of the key issues raised by this case: how to reconcile the tension between the regulatory and competition law regimes. If it is illegal to systematically promote the off-label use of a product, it seems difficult to argue that an agreement that is aimed at preventing such off-label use is restrictive of competition.

The parties do not appear to have raised the argument that the ICA's decision is arguably at odds with the competition law regime governing the licensing of intellectual property rights in that it raises doubts about the ability of pharmaceutical companies to license out their rights for specific fields of use. In this case, Roche's subsidiary, Genentech developed Avastin and Lucentis. Roche decided to license Lucentis out to Novartis for the treatment of eye disease and to commercialise Avastin itself for the treatment of cancer. Under the Technology Transfer Guidelines, the restriction on the sale of Lucentis and Avastin outside of their intended therapeutic areas could have been achieved by placing field-of-use restrictions in the licence agreement.⁴⁰ Indeed, field-of-use restrictions are pro-competitive to the extent that they encourage the dissemination of technology by allowing a licensor to use its technology for one use and to license it out for another.

The ICA treated the relationship between Roche and Novartis as a horizontal relationship between competitors, but there was no evidence whatsoever that, absent the license, Novartis would have competed with Roche. Thus, it is only because of the license that Novartis was a competitor. In these circumstances, the ICA's treatment of communications between the parties as illegal collusion would seem misplaced as they were in a vertical relationship of licensor and licensee. However, the ICA gave short shrift to the parties' arguments that the relationship was vertical, pointing to an e-mail from Novartis in which it stated that there was no contractual basis for preventing the off-label use of Avastin, which suggested that there was no field-of-use restriction in the license agreement. However, even if the agreement had contained such a restriction, it remains an open question whether the ICA would have taken a different approach. The case serves as a warning to companies to be careful in structuring licensing arrangements and to include field-of-use restrictions where a drug can have different

40 Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ (2014) C89/3 ('Guidelines'), para. 212.

indications. It also highlights that, even where a license agreement exists, competition law may still limit the extent to which a licensor and a licensee may collaborate.

V. Licensing: royalties on an invalid patent

In the context of ongoing litigation between Genentech and Hoechst, on 9 December 2014, the Paris Court of Appeal referred a question to the EU Court of Justice concerning whether EU competition law prohibits the enforcement of a royalty provision in a license agreement where the licensed patent has been held to be invalid.⁴¹ The question arose in the midst of a long-running dispute relating to a 1992 licensing agreement covering two US patents and one European patent, the latter having been revoked in 1999. The license agreement allowed Genentech to use the licensed technology for research purposes for an annual licensing fee and a royalty on the manufacture, use, and sale of the licensed products.

According to Hoechst, Genentech never paid the required royalties. On 27 October 2008, Hoechst notified Genentech that it believed that Genentech was selling products that infringed the licensed patents. Shortly thereafter, Genentech terminated the agreement. Hoechst initiated arbitration proceedings in Europe, seeking the payment of royalties relating to the sale of the drug Rituxan. The arbitral tribunal found in favour of Hoechst and ordered Genentech to pay more than €100 million in damages. The arbitral award emphasised that the parties had foreseen that, as long the agreement was in force, royalties would be due for the manufacture of Rituxan, even if the patent were later to be held invalid.

On appeal, Genentech argued that, according to EU case law, it is contrary to European competition law to pay royalties on an invalid patent, as it imposes unjustified expenses on the licensee for a technology that is unpatented, thus placing the licensee at a competitive disadvantage. The Paris Court of Appeal referred a question to the EU Court of Justice, asking whether ‘the provisions of Article 101 of the TFEU must be interpreted as precluding effect being given, where patents are revoked, to a licence agreement which requires the licensee to pay royalties for the sole use of the rights attached to the licensed patent?’

At present, the European Commission takes the position in its Technology Transfer Guidelines that the parties can normally agree to extend royalty payments beyond the period of the licensed patent.⁴² While this may mean that the licensee will be subject to higher costs after patent

expiry than others who are using the technology, it also gives the parties more freedom in structuring the license, which could foster the dissemination of the technology.

VI. Agreements relating to public tenders

The ICA investigated a co-marketing agreement between Novartis and Italfarmco after various regional health authorities filed complaints concerning alleged collusive behaviour between them in the context of various tenders for cancer drugs. It was alleged that they abstained from participating in tenders in which the other was also participating or else they only participated via a joint bid. The investigation eventually focussed on the co-marketing agreement between Novartis and Italfarmco pursuant to which Italfarmco sold the product supplied by Novartis under a different brand. The ICA found that certain features of the agreement were problematic: it called for the exchange of information between the parties on matters such as quantities sold, promotional expenditures, and medical information; it gave Novartis control over Italfarmco’s promotional strategy; it imposed a non-compete obligation on Italfarmco; and Italfarmco committed to achieve a minimum market share.

In its decision of 30 June 2015,⁴³ the ICA closed the investigation on the basis of commitments offered by the parties that addressed these concerns. The parties agreed to limit the exchange of information to data strictly necessary for the co-marketing, Novartis relinquished control over Italfarmco’s promotional strategy and the obligation on Italfarmco to achieve a minimum market share was removed. Interestingly, the commitments did not cover the non-compete clause, which presumably was considered integral to the co-marketing arrangement.

This decision highlights the somewhat schizophrenic treatment of co-marketing agreements under competition law. On the one hand, they are recognised as bringing more competition to the market than would otherwise be the case. On the other hand, the parties must be careful to ensure that they operate independently on the market.

VII. Distribution and parallel trade

While there have not been any significant developments at the EU level, ongoing cases, investigations, and legislative initiatives at the national level illustrate that the legality of measures to limit parallel trade remain an unresolved issue in the pharmaceuticals industry.

⁴¹ *Genentech, Inc. v Hoechst GmbH, formerly Hoechst AG, Sanofi-Aventis Deutschland GmbH*, Case C-567/14 (9 December 2014).

⁴² Guidelines, para. 187.

⁴³ *ARCA/Novartis-Italfarmco*, Decision No. 24770.

This seemingly never-ending line of parallel trade cases in the industry is due in large part to the fact that parallel trade has differing effects on different EU Member States, with higher-priced countries receiving benefits from the parallel trade of lower-priced medicines, but with lower-priced countries facing disadvantages such as shortages,⁴⁴ higher prices,⁴⁵ and decreased intra-brand competition.⁴⁶

The conflicting effects of parallel trade were the basis for the compromise position adopted by the Court of Justice in the *GSK Greece* case.⁴⁷ In that case, the Court noted that parallel trade increases competition in higher-income Member States, where parallel trade represents an alternate source of supply at lower prices.⁴⁸ But the Court also found that unrestricted parallel trade could have harmful effects on lower-income countries, as pharmaceutical companies might be forced to cease supplying medicines to such countries at lower prices that undermine their profits in higher-income countries.⁴⁹ In light of these conflicting effects, the Court adopted a compromise, whereby pharmaceuticals companies may not block all parallel trade, but may take reasonable and proportionate measures in relation to the threat that parallel exports represent to their legitimate commercial interests.⁵⁰

In the wake of the Court of Justice's judgment, many open questions remain, including issues such as the legality of dual pricing systems in countries such as Spain, as well as how pharmaceutical suppliers may implement supply quotas to limit parallel trade without also hindering competition on the local market.

A. Spain: Pfizer

The uncertainty concerning what restrictions are allowable is well illustrated by the ongoing case against Pfizer in Spain, which, after 10 years, is now largely back where it started, with the Spanish competition authority investigating allegations that Pfizer's wholesale distribution agreements restricted parallel trade.

This case began back in 2005, when a Spanish wholesaler complained to the European Commission, alleging that Pfizer's wholesale agreements sought to limit parallel trade. The complaint alleged that Pfizer implemented a system of dual pricing, whereby it charged lower prices for products destined for use in the Spanish health system, and higher prices for other sales, including those destined for export to other countries.

The Commission referred the case to the Spanish competition authority, noting that the complaint against Pfizer bore similarities to the ongoing case against GSK before the EU courts.⁵¹ In that case, the Commission had decided that GSK's dual pricing had the object and effect of restricting competition in violation of Article 101(1),⁵² and these findings were ultimately upheld in the October 2009 judgment of the Court of Justice.⁵³

Following the referral by the Commission, the Spanish competition authority came to the opposite conclusion in its 2009 decision, in which it dismissed the complaint and decided that Pfizer's agreements did not violate Article 101(1)⁵⁴ because Pfizer did not actually set two prices, but rather only charged one (higher) price, and the lower price was charged only because of the applicable Spanish pricing laws. The authority explained that Spanish pricing laws establish a specific price only for those medicines funded by the State and intended to be marketed within Spain. In contrast, the price of medicines, whether or not funded by the State, that are intended to be marketed outside Spain, were freely set by Pfizer.

This decision by the Spanish competition authority was surprising, as the authority departed from the reasoning of the EU Courts in the case against GSK, and came to the opposite result. These opposite results in very similar cases may be explained by the differing effects of parallel trade, and the reluctance of national authorities in lower-income Member States to prohibit restrictions on parallel trade that are likely to have beneficial effects for their local healthcare system.

44 Ibid at para. 68.

45 Pharmaceutical suppliers may refuse to agree to offer lower prices if significant volumes of the products will be resold into higher-price markets. The net effect of this is that the lower-income countries may not be able to afford as many treatments for their citizens.

46 Consistent with the judgment in *GSK Greece*, pharmaceutical suppliers implement supply quotas in order to limit parallel trade into higher-priced countries. However, these supply quotas also have the effect of limiting competition among wholesalers in the local market, because wholesalers will have little incentive to compete for new customers if they are not able to increase their level of supplies.

47 Case C 468/06, *Sot. Lélos kai Sia and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton*, EU:C:2008:504.

48 Ibid at paras 52–57.

49 Ibid at para. 68.

50 Ibid at paras 69–71.

51 Case T-168/01, *GlaxoSmithKline Services v Commission*, EU:T:2006:265 and Case C-515/06 P, *EAEPC v GlaxoSmithKline*, EU:C:2008:738.

52 Commission Decision of 8 May 2001 relating to a proceeding pursuant to Article 81 of the EC Treaty Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), and IV/37.380/F3 EAEPC (complaint).

53 The EU Court of Justice did, however, hold that the Commission failed to adequately consider GSK's arguments for an exemption under Article 101(3), with the result that the. Following the judgment, the Decision of the Commission was annulled and GSK withdrew the application for an individual exemption. The Commission confirmed in 2014 that GSK has never reinstated its dual-pricing scheme in Spain. See Glaxo Wellcome, Case 36957, Rejection Decision (23 September 2014).

54 Decision of the Spanish Competition Authority of 21 May 2009 on Case 2623/05, Spain Pharma.

In light of the conflict between the decision of the Spanish competition authority in *Pfizer* and the judgment of the EU Courts in *GSK*, it is not surprising that the complaining wholesaler appealed the decision to the Spanish courts. The Spanish courts agreed with its claims, first in a 2011 judgment by the national court,⁵⁵ and then in a December 2014 judgment of the Spanish Supreme Court. In the judgments, the Spanish courts held, consistent with the EU Courts, that Pfizer's agreements were subject to Article 101(1), despite the national price regulations, and that the provisions contained therein implementing dual pricing could potentially have the object or effect of harming competition. Thus, the Supreme Court annulled the decision and referred the case back to the Spanish competition authority to assess whether Pfizer's agreements had the object or effect of restricting competition, in line with the case law of the EU Courts.

Following the judgments, in March 2015, the Spanish competition authority opened a formal investigation of Pfizer's distribution practices in Spain. This investigation is ongoing. The difficulty that will be faced by the Spanish competition authority in this case will be to arrive at a compromise position that addresses the differing effects of parallel trade, as ultimately achieved by the Court of Justice in the *GSK Greece* case. As in that case, there is a need to balance any possible negative effects of restrictions on parallel trade, with the benefits of the restrictions, such as protecting the Spanish healthcare system against medicine shortages and higher prices, and ensuring that pharmaceutical suppliers are able to invest in the research and development of new medicines. However, unlike the quotas at issue in the *GSK Greece* case, there would not seem any ready means to achieve such a compromise with respect to dual pricing.

B. Spain: European Commission investigation

In January 2012, the European Commission opened an investigation into the pricing and distribution of medicines in Spain, explaining that it is investigating '*current parallel trade and dual pricing issues in Spain more generally, including pricing practices implemented by companies other than GSK*'.⁵⁶ While there have been no public reports of recent activity related to this investigation, a response by the Commission of August 2015 to a Parliamentary Question indicates that the investigation remains ongoing.⁵⁷ Thus, it cannot be excluded that the Commis-

sion might again take a proactive role in attempting to define what restrictions on parallel trade are allowable.

C. Romania: GlaxoSmithKline (GSK)

In Romania, a case against GSK has also been in progress since 2013, but now may be close to resolution. In September 2015, the Romanian competition authority published draft commitments submitted by GSK aimed at resolving allegations that GSK's distribution system harmed competition on the Romanian market and restricted parallel trade in violation of Romanian and EU competition laws.⁵⁸

The case arose following complaints by wholesalers against GSK's restructuring of its distribution system for some of its products, pursuant to which it ceased sales to independent wholesalers and instead implemented a direct-to-pharmacy system, under which it sold its products directly to pharmacies up to supply quotas set for individual pharmacies as well as for the Romanian market as a whole.

In the context of the authority's 2013–2014 sector inquiry into the distribution of medicines, the authority initially found that GSK's restructuring from four to only one wholesaler resulted in less competition, with the result that discounts were no longer offered by wholesalers to pharmacies.⁵⁹ The authority thereafter launched a specific investigation into allegations that GSK's actions constituted a potential abuse of a dominant position with respect to GSK's products Avodart and Seretide.

In order to resolve the investigation without any acknowledgment of an infringement, GSK has offered commitments, pursuant to which it commit to supply products sufficient to meet the demands of the Romanian market (based on IMS data), plus a safety margin and buffer. These products would be supplied to at least three independent wholesalers in parallel with GSK's own direct-to-pharmacy sales channel. The volumes sold to independent wholesalers will be depending upon the preferences expressed in a survey of pharmacies, in which each pharmacy may select its desired distribution channel. The decision of the competition authority on whether to accept these commitments is still pending.

D. Poland, Bulgaria, and Slovakia: regulations limiting parallel trade

Due to the problems caused by the export of medicines from lower-income countries, governments in these

⁵⁵ Judgment of the Audiencia Nacional (13 June 2011).

⁵⁶ See Case 36957, *Glaxo Wellcome* (27 May 2014), reporting details of its ongoing investigations in Spain.

⁵⁷ See Response of the European Commission to Parliamentary Question E-008304/2015 (27 August 2015).

⁵⁸ See 'The Competition Council launches for public debates the commitments formulated by S.C. GLAXOSMITHKLINE S.R.L.', Romanian Competition Council Press Release (9 September 2015).

⁵⁹ See 'Use of the medicines limited distribution system has reduced the level of discounts transferred to pharmacies', Romanian Competition Council Press Release (April 2014).

countries have adopted additional measures to limit parallel trade. For example, on 7 May 2015, the Polish government adopted changes to its pharmaceutical laws to control parallel trade by monitoring stock levels, identifying potential shortages, and limiting exports where shortages exist. These measures are similar to the measures implemented in Bulgaria in January 2014.

In the notification of these measures to the European Commission,⁶⁰ the Polish government provided the following justification for the resulting restrictions on the free movement of goods: 'The life and health of Polish patients is at risk due to the lack on the Polish pharmaceutical market of many medicinal products of therapeutic value. The absence of these products stems from excess export, brought about by the significantly lower prices of medicinal products in Poland, primarily of refunded products, in comparison to prices in other EU Member States.'

Despite the compelling interest of governments to control parallel trade, such measures are not immune to challenge. In a judgment of January 2015, the Bulgarian constitutional court annulled the system set up by the Bulgarian government to prevent exports, as it found the measures adopted to be disproportionate. In addition, the European Commission has issued a formal letter of notice to Slovakia relating to allegations that measures requiring wholesalers to notify exports do not comply with the EU Treaties.⁶¹ These actions illustrate that, even when measures are adopted by national governments, significant uncertainty remains concerning the extent to which parallel trade may be restricted.

VI. Sector inquiries

There have been a number of sector inquiries conducted or completed by national competition authorities in the past year, analysing competition among innovative pharmaceutical suppliers, wholesalers, and pharmacies.

In Italy, the ICA launched a sector inquiry on 27 May 2015 into the market for human vaccines, which costs the Italian health system represent over €300 million per year.⁶² The sector inquiry is aimed at increasing competition in the sector, apparently by investigating possible improvements to the public tender procedures to improve the buying power of the payors, and also investigating possible obstacles to competition implemented by vaccine suppliers in violation of the Italian and

EU competition laws. Past cases in other EU countries in the vaccine sector indicate that potential issues that will likely be investigated include collusive tendering among suppliers and abusive bundling practices.

In connection with the sector inquiry, the ICA opened a public consultation, which closed on 10 July 2015.

In Lithuania, the national competition authority initiated a sector inquiry in May 2015 into the market for reimbursable medicine, assessing the competitive effect of pricelist restrictions.⁶³ The decision points out that the market for reimbursable drugs is important for consumers. The inquiry aims at conducting a detailed analysis of the market and identifying potential competition issues. The inquiry follows a 2013 inquiry focussed on parallel trade.

Finally, with respect to competition at the wholesale and pharmacy levels, the national competition authorities in Denmark⁶⁴ and Spain⁶⁵ conducted sector inquiries in the last year. In Poland,⁶⁶ the national competition authority announced the results of its sector into the retail pharmaceutical market, noting that, since the beginning of 2014, the number of pharmacies run by pharmacy chains has increased by 30 per cent.

VII. Conclusion

The past year may be a lull before the storm in terms of enforcement activity at the EU level. The European Commission seems to be waiting for the General Court's judgments in *Lundbeck* and *Servier* before pursuing further cases on reverse-payment settlements. The robust use of Article 102 to counter late life cycle management strategies in *Servier* may signal increased enforcement activity with regard to issues such as product hopping in the context of generic entry. Pricing is likely to continue to be a focus of enforcement activity. While the European Commission does not seem inclined to intervene as it sees pricing in this sector as primarily a national issue, it would not be surprising to see continued activity at the national level in light of the increasing concern over the impact of high-priced drugs on national healthcare budgets. Enforcement efforts may also reflect technological trends, such as the emergence of biologics and the increasingly close relationship between pharmaceutical products and medical devices.

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60 See Notification 2015/144/PL, Private members' draft Act on the Amendment of the Pharmaceutical Act and certain other Acts.

61 See Response of the European Commission to Parliamentary Question P-006245/2015 (3 June 2015).

62 'Sector inquiry on vaccines for human use', ICA, Ref. IC50, 27 May 2015.

63 'Lithuanian authority analyses reimbursable drug market', MLex (19 May 2015).

64 Danish Competition and Consumer Authority, Press Release, 7 September 2015.

65 CNMC, *Study of the market for the retail distribution of medicines in Spain*, E/CNMC/003/15 (15 October 2015).

66 'Poland's Competition Authority Completes Analysis of Retail Pharmaceutical Market', Polish Office of Competition and Consumer Protection Press Release (21 May 2015).