European Union: Pharmaceuticals

Miranda Cole and Andrea Zulli
Covington & Burling

The pharmaceutical sector has continued to be under competition scrutiny this year, both in the context of behavioural investigations and the review of transactions. Much of the behavioural activity this year was at member state level, with the Italian Supreme Administrative Court taking an approach to a patent holder’s request for a divisional patent and related supplementary protection certificate that surprised many.

At European level, the Commission’s approach in assessing a co-promotion agreement between Sandoz and Janssen-Cilag, in its Fentanyl decision, provided a timely reminder that the Commission will look behind the form of agreements to their object. Going beyond Lundbeck, and the finding that there was a coherent overall strategy, Fentanyl suggests that a single anti-competitive agreement may be sufficient.

Returning to the member states, in Italy and France agreements that were characterised as amounting to market sharing, particularly through alleged agreements to artificially differentiate between off-label use of products, on the one hand, and authorised indications on the other, have been under scrutiny. Other conduct under scrutiny at national level includes denigration of generic products by originators, the use of direct-to-pharmacy distribution models, and supply quotas, dual-pricing schemes and other conduct seen as restricting parallel trade.

Recent transactional activity has seen increased focus on market definition and on pipeline competition (both in terms of late-stage programmes competing with each other and marketed products, and overlap in earlier stage programmes raising questions about intention and incentives to maintain parallel development programmes).

Finally, it is also worth noting that licensing practice at many pharmaceutical companies may not reflect the changes in the Commission’s attitude to grant-back clauses and no-challenge and termination clauses, reflected in the 2014 Technology Transfer Block Exemption Regulation and related Guidelines.

Looking forward, the judgments of the General Court in both Lundbeck and Servier will be of particular interest next year—potentially providing further guidance regarding market definition, the scope of the abusive conduct, and the potential scope of ‘by object’ infringements (particularly after the Cartes Bancaires judgment).

Behavioural investigations

The Commission, the EU national competition authorities (NCAs) and national courts have continued to scrutinise the unilateral behaviour of pharmaceutical companies, and the object and effect of co-operation and other arrangements. While a number of the key cases occurred at national level, they have potentially broader application across the EU.

Delaying generic entry

At both EU and national level behaviour that prevents, hinders or delays generic entry has continued to be a key enforcement priority, reflecting the concerns set out in the Commission’s sector inquiry and upheld by the court in AstraZeneca. Regulators have considered a number of strategies by originators that they have concluded delayed or prevented market entry by generic companies, including the use of process patents to create legal uncertainty, and attempts to prevent or delay the grant of marketing authorisations for generics, reverse payment patent settlements and other forms of cooperation.

The key Commission reverse payment patent settlement decisions are Lundbeck and Servier, with cooperation agreements addressed in Fentanyl. At national level, the Italian Supreme Administrative Court’s recent judgment in Pfizer found that seeking a divisional patent amounted to an abuse of right, and the French Competition Authority (FCA) found that marketing campaigns by a dominant entity that systematically denigrate generics can be abusive.

Reverse payment patent settlement agreements

The Commission’s 2013 decision on reverse payment patent settlements found that Lundbeck’s settlement agreements relating to its citalopram drug restricted competition by object and infringed article 101 of the Treaty on the Functioning of the European Union (TFEU). Shortly afterwards, the Commission issued the Servier decision, where it went further and found that Servier’s reverse payment patent settlement agreements restricted competition both by object and by effect (the Commission also concluded that Servier’s commercial strategy was an abuse of dominance under article 102 TFEU).

The Commission’s approach to reverse payment patent settlements under article 101 TFEU can be summarised as follows:

- Potential competitors: The originators and generics were at least potential competitors because potential competition starts when generic producers:
  - develop a ‘commercially viable production process leading to a product that meets regulatory requirements’ and
  - prepare for market entry by taking steps such as applying for marketing authorisations.

- Scope of settlement: The settlement went beyond the scope of Lundbeck’s process patents (the generics agreed not to sell citalopram, even when not manufactured using a patented process, and to limit their efforts to enter one or more EEA markets).

- Value transfer: The value transfer is directly linked to the gener-ic’s commitment to refrain from pursuing market entry. In Servier, the value transfer also included cash payments (in addition to the transfer of licences from Servier to the generics in return for commitments not to enter the market).

- Intent: Although the parties’ intent is not relevant to establishing a restriction by object, the Commission emphasised the fact that the parties knew, or should have known, that their agreements were anti-competitive. Internal documents were key to this conclusion.
• Additional factors: In Lundbeck, the Commission also noted that:
  • the sum paid by Lundbeck was based on the generic company’s expected turnover/profit, had it successfully entered the market;
  • Lundbeck could not have prevented or delayed entry by enforcing its process patents;
  • a process patent licensor would not have been able to impose the obligations imposed on the generics; and
  • the agreement did not restrict Lundbeck’s ability to start infringement proceedings if the generic company entered the market after the expiry of the agreement. In Servier, the Commission noted that Servier had acquired the technology in 2004, and had never used it other than to prevent generic entry.

These cases add colour to the 2014 Technology Transfer Block Exemption Regulation (TTBER) and the accompanying Guidelines, which state that:
• settlement agreements that delay or limit the ability of a technology licensee to launch a product may be prohibited by article 101 TFEU; and
• non-challenge clauses in settlement agreements may be anti-competitive if the licensor induces (financially or otherwise) the licensee to agree not to challenge the validity of the technology rights.

Given the court’s judgment in Cartes Bancaires, the upcoming judgments in the Lundbeck and Servier appeals should provide valuable guidance regarding what is necessary to establish ‘by object’ infringements of article 101 TFEU in relation to such agreements.

Cooperation agreements
Cooperation agreements remain extremely common in the pharmaceutical sector, whether co-promotion (ie, commercialisation of a product by competitors under a single trademark), co-marketing (ie, selling and marketing of a product by two entities under different trademarks) or joint research and development agreements. In its Fentanyl decision the Commission has provided a timely reminder that the risks of such agreement go beyond those necessarily raised by cooperation between competitors. Care needs to be taken to ensure that they are not construed as delaying generic entry to a market.

In Fentanyl, the Commission analysed a co-promotion agreement between Sandoz and Janssen-Cilag, concluding that the agreement was intended to delay generic entry, rather than to co-promote. The Commission applied a very similar analytical framework to that used in Lundbeck (eg, the co-promotion agreement created strong financial incentives for Sandoz not to commercialise its generic version of Janssen-Cilag’s painkiller, Fentanyl). The amount paid to Sandoz considerably exceeded what Sandoz expected to make if it had launched its own Fentanyl patch. It reflected what Janssen-Cilag understood Sandoz ‘would have made if it had entered the Dutch market with its own fentanyl patch. Finally, the Commission concluded that Sandoz’s promotional activities under the agreement were of limited usefulness to Janssen-Cilag.

Importantly, Fentanyl suggests that an agreement need not be part of a ‘coherent overall strategy’ aimed at delaying generic entry. A single agreement may be sufficient for the Commission to find a restriction of competition by object aimed at delaying generic entry. It also makes it clear that the Commission will ‘pierce the commercial veil’ to identify agreements with the object and aim of preventing, hindering or delaying generic entry, regardless of the form of agreement.

Abuse of right
The Italian Supreme Administrative Court (ISAC) adopted a novel interpretation of the abuse of right concept as a special ‘genus’ of abuse of dominance. The ISAC found that an abuse of rights occurs when:
• a right exists;
• the rights can be used in multiple ways;
• the use made of the right, although formally legitimate, may be challenged on the basis of legal or non-legal criteria; and
• the use made of the right results in an unjustified disproportionate benefit for the rightholder and ‘cost’ for its counterparts.

The ISAC concluded that, although Pfizer’s divisional patent request (and subsequent request for a supplementary protection certificate) for its Xalatan patent was in the abstract legitimate, the use that Pfizer made of the right was ‘abusive’ because Pfizer exercised the right for a purpose other than that for which it was granted (ie, to prevent generic entry). Specifically, the ISAC concluded that Pfizer abused its right since it:
• adopted a complex exclusionary strategy characterised by a clear anti-competitive intent aimed at delaying generic entry;
• created a climate of uncertainty related to the expiry of patent protection;
• marketed no product on the basis of the divisional patent which it obtained; and
• acted to prevent and hinder generic entry (eg, sending injunctions, contacting the Italian Drug Agency with the aim to prevent inclusion of generics in the transparency list, requesting an additional patent extension for paediatric trials).

The ISAC’s judgment seems to go beyond the usual approach to the competitive assessment of the grant and use of IP rights under article 102 TFEU. After all, the right to exclude is at the heart of a patent.

Market sharing
The Italian Tribunale Administrativo Regionale del Lazio (TAR Lazio) recently confirmed a decision of the Italian Competition Authority (ICA) regarding market sharing between Roche and Novartis in the market for ophthalmic drugs for serious vascular eye conditions. In France, an FCA investigation is ongoing.

The ICA found that Roche and Novartis coordinated their strategies in Italy to limit off-label ophthalmic use of Roche’s (cheaper) Avastin (approved for oncology indications) to the benefit of Novartis’ Lucentis (approved for ophthalmic indications and licensed to Novartis by Roche’s subsidiary Genentech). The ICA relied on the parties’ internal documents to conclude that they had colluded to artificially differentiate between the products using safety concerns regarding off-label use of Avastin, thereby partitioning the market. The analysis appears not to take into account the legal and economic context of the conduct, concluding that an analysis of the medical and scientific differences between Lucentis and Avastin and the pharmacovigilance requirements raised by the parties was outside the ICA’s jurisdiction. The TAR Lazio concluded that Novartis and Roche were actual competitors since Lucentis and Avastin (off label) were competing, and confirmed the ICA’s decision. An appeal against the TAR Lazio judgment is pending.
PHARMACEUTICALS

Direct to pharmacy (DTP)

DTP distribution enables pharmaceutical companies to reduce distribution costs by removing the double marginalisation that is inherent in selling through wholesalers, and to better control their supply chains, particularly in relation to risks like counterfeit medicines. However, DTP distribution can raise competition law issues, such as reducing intra-brand competition (since prices are set directly by pharmaceutical companies) and inter-brand competition (since DTP distribution networks could foreclose new entry who would need to rely on distributors with potentially reduced scale), and can be used to limit parallel trade.

DTP distribution has been scrutinised by the Commission and a number of NCAs in recent years. The Commission has not opened investigations to date, but has made clear that it continues to closely monitor the effects of DTP models. In its December 2013 Opinion, the FCA focused on the impact of DTP distribution on the ability of distributors to ensure sufficient volumes for them to stay on the market. The Romanian Competition Council recently published preliminary findings following a sector inquiry focused on DTP, recommending that manufacturers ensure that part of the efficiencies resulting are transferred to consumers, and warning that DTP should not be used to restrict parallel trade.

Parallel trade

Parallel trade in the pharmaceutical sector has come under renewed scrutiny from NCAs. In addition, parallel trade between the EU and Switzerland is one of the top enforcement priorities of the Swiss Competition Authority. The recent sector inquiries by the Lithuanian Competition Council and the FCA reaffirmed that NCAs consider parallel trade to benefit consumers both directly through lower prices and indirectly through increased competition (eg, the FCA concluded that parallel imports enable pharmacies to negotiate better commercial terms with suppliers).

Supply quotas

Supply quotas enable some limitation of parallel trade, especially in member states where wholesalers have a legal obligation to meet the needs of their local market. However, supply quotas may be anti-competitive in certain circumstances. First, the EU Court has found that a dominant entity can only refuse to supply wholesalers or limit volumes supplied when the orders placed are ‘out of the ordinary’, taking into account the size of those orders and the previous business relations with the wholesalers concerned. In September 2014, the Greek Competition Authority (GCA) sent a statement of objections to GSK regarding its alleged refusal to meet wholesalers’ ordinary orders, assessing the ‘ordinary’ character of the orders based on the annual size of orders and supplies per wholesaler, national annual consumption and the pattern of business relations between the pharmaceutical companies and wholesalers over the years prior to the refusal. Second, agreements between a manufacturer and a wholesaler instituting supply quotas may infringe article 101 TFEU. This is important in the context of the Commission’s strict approach to identifying tacit agreements.

Dual-pricing schemes

Historically, some pharmaceutical companies have used dual pricing schemes (ie, charging different prices to wholesalers depending on the final destination of the products – lower prices for domestic sales and higher prices for exports) to limit parallel trade. However, such schemes are coming under increasing scrutiny.

While the Commission recently rejected a 1999 complaint against GSK relating to its agreements with several Spanish wholesalers because the case was not a priority, scrutiny by the NCAs continues. Following a judgment from the Spanish Supreme Court reviewing a decision by the National Competition Commission not to open an investigation, its successor authority, the National Competition and Markets Commission, initiated formal proceedings against Pfizer in March 2015. The Supreme Court found that Pfizer’s system may constitute a restriction by object as its contracts with distributors could prevent export to other member states.

Dual-pricing systems may also be assessed under article 102 TFEU. While companies are allowed to set different prices in different member states, the difference must be based on the conditions of competition in the different geographic markets, particularly in view of the regulatory framework (eg, differences in national price and reimbursement regulations).

Generic denigration

Recent decisions by the FCA make it clear that originators must take care when promoting their products over generics, particularly using ‘denigration strategies’ specifically aimed at entry by generics. The FCA has found that marketing campaigns by a dominant company specifically and systematically aimed at denigrating generic products may not amount to ‘competition on the merits’, such that they may be an abuse of dominance.

For example, in Sanofi-Aventis, the company sought to convince health-care professionals to limit their prescriptions of generic versions of its branded product by denigrating those generics. The FCA acknowledged that companies can highlight the objective qualities of their products, but cannot emphasise differences with competing products by misleading doctors as to their quality and safety. This type of conduct could be abusive because health-care professionals:

- are generally risk-averse and tend to favour products they know, especially in the case of generics;
- trust and rely on companies’ reputations; and
- are influenced by large companies’ promotional efforts and often rely on the information they provide.

Given this, the provision of negative or incomplete information about competitors’ generic products could constitute abusive denigration by a dominant company. As a result, comparative promotional material should be limited to objective characteristics and be complete and transparent in describing differences.

Transactions

Mergers and acquisitions

The pharmaceutical sector has seen significant mergers and acquisitions in recent years, many of which were cleared by the Commission in Phase I. Key elements of the Commission’s substantive assessments worth noting include:

Market definition

With the increasing role of orphan drugs and the adoption of more nuanced treatment protocols designed for individualised treatment, case-by-case market definition increasingly takes into account the variation in treatment regimes, the adoption of new protocols, and the role and substitutability of individual molecules in protocols. As a result, in some cases relevant markets have been defined more broadly, without differentiating by lines of treatment, mechanism of action or form of administration. However, where products are
used sequentially (ie, one product is always used after another – first, second or third-line treatment), European competition authorities have continued to find that such products do not compete (or fall into the same relevant product market). NCAs also take this approach (eg, the German FCO in relation to the GOLD treatment protocol for COPD).

**Assessment of pipeline competition**

The Commission focused on pipeline competition in several recent cases, including **Medtronic**, **Novartis** and **Actavis**, looking at both ‘market to pipeline’ competition (ie, closeness of competition of Phase III pipeline products with existing products and other Phase III products) and ‘pipeline to pipeline’ competition (ie, dynamic competition between Phase I and II products).

**Market to pipeline**

Potential competition between Phase III and existing products is assessed by reference to their characteristics, intended therapeutic use, and expected therapeutic and economic substitutability. In **Medtronic**, the Commission assessed the potential for the elimination of future competition using the criteria in the Horizontal Merger Guidelines for the elimination of actual competition. In assessing the closeness of competition of the parties’ advanced pipeline/existing, for drug-coated balloon devices (DCB), the Commission used both the responses to its market test and the parties’ internal documents to assess the characteristics/efficacy of the products and the quality of the clinical trial data (which the market test suggested was a basis for the selection of DCB devices, rather than price). Having concluded that Covidien’s Phase III device was viewed by the market as the future closest competitor to Medtronic’s existing device, the Commission assessed Medtronic’s business strategy in relation to Covidien’s pipeline device. Medtronic’s internal documents showed that it intended to cease developing Covidien’s pipeline device. As a result, Covidien’s pipeline DCB device was divested.

A similar approach was adopted by the Commission in **Novartis**, with regard to the analysis of the parties’ B-Raf and MEK inhibitors for targeted treatment of skin cancer. The Commission’s analysis took into account B-Raf and MEK inhibitors for skin cancer that were on the market (Roche’s inhibitor) and in Phase III (the parties’ pipeline inhibitors). The Commission concluded that the transaction would have created a duopoly and led to the abandonment by Novartis of its pipeline inhibitors in favour of GSK’s.

**Pipeline to pipeline**

In a number of recent cases the Commission assessed dynamic competition between Phase I and Phase II pipeline products, in terms of impact of a concentration on innovation and future new markets, in light of the scope of the parties’ clinical trial programmes.

In **Novartis**, the Commission identified the relevant competing clinical research programmes by reference to the mechanism of action of the pipeline products, the cancer type for which the pipeline products are being trialed in clinical studies and the phase of these clinical trials. The parties’ clinical trial programmes B-Raf and MEK inhibitors concerned four types of cancer and faced credible competition from only one competitor clinical trial programme. The Commission concluded that the concentration would have lessened competition in innovation by curtailing the parties’ R&D efforts – also in terms of a potential broader scope of these clinical trial programmes – given the likely risk that one of the parties’ clinical trial programmes would be abandoned. The assessment of this risk reflected several factors, including the high costs involved, the uncertainty of outcomes, and the expected cannibalisation of sales should both programmes be successful (confirmed by the market investigation). The Commission concluded that the abandonment of one clinical trial programme would have reduced the number of inhibitors available on the market in the future.

**Licensing and the New Technology Transfer Block Exemption Regulation (TTBER)**

The 2014 TTBER and the accompanying Guidelines provide a framework for the analysis of licences of patents, know-how, design rights, or software copyrights for the production of goods or the provision of services. Subject to the conditions listed in the TTBER, licences between companies with limited market power fall within the block exemption. The Guidelines provide criteria for assessing licences that fall outside this safe harbour. Most relevant for the pharmaceutical sector, the Guidelines address exclusive grant-back, non-challenge and termination clauses. Many older licences may well reflect an approach to these issues that is inconsistent with the TTBER and Guidelines.

**Exclusive grant-backs**

Grant-back clauses require the licensee to grant back improvements made to a licensed technology to the licensor. They can provide a means for licensors to protect their interests and investments. While the TTBER exempts non-exclusive grant-backs, exclusive grant-backs are not exempted. The new regime no longer differentiates between severable and non-severable improvements. All exclusive grant-back clauses require an individual assessment based, inter alia, on the consideration paid by the licensor in return for the grant-back, the licensor’s market position on the relevant technology market and the existence of parallel networks of licences containing grant-backs in the market. The favouring of non-exclusive grant-backs protects licensees, who can continue to use their improvements to the technology.

**Non-challenge and termination clauses**

Non-challenge clauses prevent a licensee from challenging the validity of the licensed intellectual property rights. The TTBER maintained the requirement that these clauses be individually assessed. However, it goes further, taking a strict approach to clauses that enable the licensor to terminate a licence if a licensee challenges the validity of the intellectual property rights. The TTBER does not exempt termination clauses in non-exclusive licensing agreements, because they usually have a similar competitive effect to non-challenge clauses. However, it does exempt termination clauses in exclusive agreements, because exclusive licensees generally have no incentive to seek to invalidate the licensed intellectual property rights. As a result, these rules can be seen as encouraging small innovators to license out their technology on an exclusive basis. However, it risks creating complex commercial relationships if licensors must maintain their relationships with exclusive licensees that attack the validity of their intellectual property rights.

---

2 Case C-457/10 P AstraZeneca AB and AstraZeneca plc v European Commission [2012].

---

The authors would like to thank Jennifer Boudet and Anne Robert for their assistance in producing the chapter.
6 Consiglio di Stato Judgment No. 693 of 12 February 2014.
7 Lundbeck Decision, at para. 616.
8 Lundbeck Decision, at para. 604.
10 A non-challenge clause may also be anti-competitive when the intellectual property right was granted following the provision of incorrect or misleading information. See Technology Transfer Guidelines, at paras. 242-273.
13 Fentanyl Decision, at para. 220.
14 Fentanyl Decision, at para. 220.
15 Lundbeck Decision, at para. 806.
16 Case C-255/02 Halifax plc, Leeds Permanent Development Services Ltd and County Wide Property Investments Ltd v Commissioners of Customs & Excise [2006] ECR I-1609.
17 Consiglio di Stato, Judgment No. 693 of 12 February 2014.
18 Italian Administrative Court, Roche and Novartis, Case 12168/2014, 2 December 2014.
19 AGCM, Decision No. 24823 Case I760, Roche-Novartis/Farmaci Abastin e Lucents.
22 In its Press Release on preliminary findings of sector inquiry, the Romanian competition council noted in relation to its investigation into GSK’s DTP model in Romania that GSK’s own distributor, despite receiving discounts similar to those received in previous years, did not transfer them to pharmacies (April 2014).
24 For instance, on 10 March 2015, the Swiss Competition Authority opened an investigation into General Electric’s health care, alleging that the group restricted parallel and direct imports of their ultrasound equipment into Switzerland. See https://www.news.admin.ch/message/index.html?lang=fr&msgId=56504.
27 Jointed Cases C-468/06 to C-478/06 Sot. Lelos Kai Sia E.E (Lelos) and Others v GlaxoSmithKline AEVE Farmakeftikon Proizonton [2008] ECR I-7139, at para. 73.
28 Commission Decision of 10 January 1996 in Case N/34.279/F3 – Adalat, at para. 156.
30 Commission Decision of 27 May 2014 in Case AT.36957 – Glaxo Wellcome. The conduct took place many years ago and had ceased, there were no persisting effects and, national courts and authorities are well placed to handle the issues.
31 Spanish Supreme Court, Judgment of 3 December 2014.
33 French Competition Authority, Decision 13-D-11 of 14 May 2013 relating to practices implemented in the pharmaceutical sector (Sanofi Aventis) and Decision 13-D-21 of 18 December 2013 regarding practices implemented on the French market for high-dosage Buprenorphine sold in private practices (Schering-Plough). In Sanofi-Aventis, the analysis of the FCA was upheld on appeal. The case is, however, pending on appeal before the Court of Cassation. In Schering-Plough, an appeal is also pending before the Paris Court of Appeal.
37 Novartis/GlaxoSmithKline Oncology Business, at para. 17.
38 The TTBER also applies to the assignment of technology rights to the extent that ‘part of the risk associated with the exploitation of the technology remains with the assignor’. Article 1.(c)(ii) of the TTBER.
39 The TTBER exempts licensing agreements concluded between companies that have market share not exceeding 20 per cent for agreements between competitors and 30 per cent for agreements between non-competitors.
40 Under the old regime, exclusive grant-back licences were covered by the block exemption if they concerned severable improvements. On the contrary, exclusive grant-back licences of non-severable improvements were excluded from the benefit of the block exemption. An improvement is severable if it can be exploited without infringing upon the licensed technology, see article 1(n) of Regulation 772/2004 of 27 April 2004 on the application of article 81(3) of the Treaty to categories of technology transfer agreements, OJ L 123.
41 This is especially the case where a licensee has made substantial investments or where the technology is an essential input.
Miranda Cole is a partner based in the firm’s Brussels office. She practises competition and communications law and policy, and has more than 18 years of experience in the field. Chambers Global notes that she ‘takes a proactive, holistic approach’ (2014).

Ms Cole’s competition law expertise encompasses merger control, actions under articles 101 and 102 TFEU, advisory work and actions before the European courts in Luxembourg. She has particular expertise in advising companies active in the life sciences, technology, online and communications sectors. In the life sciences sector she has extensive experience advising in connection with mergers and acquisitions, collaborative arrangements, licensing and the application of articles 101 and 102 to conduct in the sector, working regularly with the life sciences regulatory group to develop solutions that are consistent with both competition law and applicable regulation.

Andrea Zulli advises on all aspects of EU, Italian and international competition law, including merger control, cartels and other restrictive practices, compliance and abuses of a dominant position.

Mr Zulli has an extensive knowledge of a variety of sectors, with a particular focus on life sciences, food and beverages, energy, financial services (specifically private equity and venture capital) and consumer and luxury goods. Mr Zulli has represented major international businesses in relation to merger control notifications to the EU, Italian and other national competition authorities, and has defended major international companies in a number of cartel investigations and other behavioural matters. He has in-depth experience on the interplay between the regulatory rules governing life sciences companies and the competition law principles.