GETTING THE DEAL THROUGH

GCR
GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

The application of competition regulation in 28 jurisdictions worldwide

2010

Contributing editor: Marleen Van Kerckhove

Published by
Getting the Deal Through
in association with:

Anderson Mōri & Tomotsune

Arad & Co, Law Offices

Arnold & Porter LLP

Bell Dewar

Blake, Cassels & Graydon LLP

Blake Dawson

BNT Legal & Tax Minsk

ByrneWallace

Chitale & Chitale Partners

Clifford Chance Janicka, Namiotkiewicz, Dębowski i wspólnicy spółka komandytowa

Cornejo, Méndez, González y Duarte, SC

Hájek Zrzavecký advokátní kancelář, sro

Hammarström Puhakka Partners, Attorneys Ltd

HHP Attorneys-at-Law

Homburger

Intuity

Kim & Chang

Labruna Mazziotti Segni

Legal Alliance Company

Lextal Law Firm

LO Baptista Advogados Associados

Oppenhoff & Partner Rechtsanwälte

Preslmayr Rechtsanwälte

Setterwalls Advokatbyrå AB

Wiesner & Asociados Ltda Abogados

YükselKarkınKüçük

GETTING THE DEAL THROUGH

Pharmaceutical Antitrust 2010

Contributing editor:
Marleen Van Kerckhove
Arnold & Porter LLP

Business development manager
Joseph Samuel

Marketing managers
Alan Lee
George Ingledew
Robyn Hetherington
Dan White
Tamzin Mahmoud
Ellie Notley

Subscriptions manager
Nadine Radcliffe
Subscriptions@GettingTheDealThrough.com

Assistant editor
Adam Myers
Editorial assistant
Nina Nowak

Senior production editor
Jonathan Cowie

Chief subeditor
Jonathan Allen
Senior subeditor
Kathryn Smuland
Subeditors
Ariana Frampton
Sara Davies
Charlotte Stretch

Editor-in-chief
Callum Campbell
Publisher
Richard Davey

Pharmaceutical Antitrust 2010
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 1757-6288

Printed and distributed by
Encompass Print Solutions
Tel: 0870 897 3239

Law Business Research

CONTENTS

European Union

Luc Gyselen

Arnold & Porter LLP

Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

Directive No. 2001/83/EC on the Community code relating to medicinal products for human use (the Code Directive) sets out the main requirements related to the granting of marketing authorisations of pharmaceutical products (latest consolidated version of 5 October 2009 published on EUR-Lex). A twin Directive No. 2001/82/EC (OJ L 311/1 of 28 November 2001) does the equivalent for veterinary medicinal products.

As well as containing provisions concerning the labelling and packaging of medicinal products, their wholesale distribution and advertising, etc, the Code Directive stipulates that these products cannot be placed on the market without a marketing authorisation issued by a relevant competent authority.

For some products, the application must be assessed by the European Medicines Agency (EMA) and the authorisation must be issued by the European Commission (Commission) in accordance with the centralised procedure set out in Regulation No. 726/2004 (OJ L 136/1 of 30 April 2004). Product categories which are subject to the centralised assessment are listed in the annex to the Regulation. They include biotech products, orphan drugs within the meaning of Regulation No. 41/2000 (OJ L 180/22 of 19 July 2000) and products containing a new active substance for treating diseases such as cancer, diabetes, AIDS, neuro-degenerative diseases, auto-immune diseases and viral diseases.

For other products, manufacturers can submit their application for a marketing authorisation either to the EMA through the optional centralised procedure or to the competent authorities of the member states. In the latter case, the Code Directive sets out the procedure and provides for the mutual recognition of national authorisations within the EU or through a decentralised procedure. The Code Directive also provides the legal basis for approval of generic products via an abridged procedure.

Pursuant to Regulation No. 469/2009 (OJ L 152/1 of 16 June 2009), medicinal products that are subject to a marketing authorisation procedure can enjoy patent protection beyond the end of the lawful term of the basic patent in the form of a supplementary protection certificate (SPC) to compensate for the time that has elapsed between the application for the basic patent and the grant of the first marketing authorisation in the EU. The SPC has a maximum life of five years.

Pricing and reimbursement fall within the competence of the member states. However, the national policies must satisfy the requirements set out in Directive No. 89/105 concerning the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (the Transparency Directive, OJ L 40/8 of 2 February 1989).

After it published its 'Pharmaceutical Package' in December 2008, the Commission submitted draft legislation on counterfeit medicines to the European Parliament and the Council of Ministers with a view to having it adopted under the co-decision procedure. The legislative proposal focuses on internet trade in counterfeits, adding safety features to branded products and providing monitoring and inspection of the entire supply chain. The Parliament is expected to give the draft a first reading in the summer of 2010.

2 Which bodies are entrusted with enforcing these regulatory rules?

In accordance with article 17 of the Treaty on the Functioning of the European Union (TFEU), the Commission monitors the implementation of the regulatory provisions of the above-mentioned directives and regulations.

With respect to marketing authorisations granted centrally, the EMA (with the help of its relevant advisory committees) assists the Commission as well as the member states by providing them with scientific opinions addressing the quality, safety and efficacy aspects of the medicinal products. For marketing authorisations granted nationally under the mutual recognition and decentralised procedures, the procedures are managed by a coordination group. Enforcement and prosecution as a result of a breach of regulatory rules is principally carried out by national authorities, but procedures are harmonised across member states.

For other marketing issues such as advertising, the Code Directive entrusts the member states with the responsibility of ensuring that the legal requirements governing the medicinal products are complied with. In some instances, marketed products may be subject to product monitoring. An official medicines control laboratory will test product samples to ensure that the product meets the required quality standard.

The Commission may also call upon a consultative committee to examine any question relating to the application of the Transparency Directive brought up by either the Commission itself or a member state.

3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

In its decision of 15 June 2005 (case COMP/37.507), the Commission fined AstraZeneca for misusing the patent system and the market authorisation procedure for medicinal products to block or delay market entry for generic competitors. The case is currently still under appeal (case T-321/05). The first alleged abuse concerned giving misleading information to several national patent offices with the aim of obtaining SPCs (see Regulation No. 1768/92), whereas the second one concerned withdrawal of the marketing authorisation of Losec capsules (and replacing these capsules by tablets) in some countries, with the aim of depriving generic capsules of a reference product and thus of the benefit of obtaining a marketing authorisation via the

above-mentioned abridged procedure (see the Code Directive).

Furthermore, in parallel trade cases, the question has arisen whether article 81(2) of the Code Directive is relevant. This provision requires manufacturers and wholesalers to 'ensure appropriate and continued supplies' of the medicines actually placed on the market 'so that the needs of patients in the member state in question are covered'. Put differently, manufacturers and wholesalers must ensure that there is no shortage of supply on the domestic market in any given member state. However, in *Lelos*, the Court of Justice ruled that dominant companies cannot rely on this provision to justify supply policies that restrict parallel exports (see section 75 of the Court's Judgment of 16 September 2008 in cases C-468-478/06, *Lelos and others v GSK*).

Competition legislation and regulation

4 Which legislation sets out competition law?

The basic EU competition law provisions are set out in the Treaty on the Functioning of the European Union. Company conduct is governed by articles 101 and 102 TFEU:

- article 101(1) prohibits anti-competitive agreements with an impact on trade between member states, but companies can demonstrate under article 101(3) that the restrictions of competition are necessary to create efficiencies, that consumers benefit from these efficiencies and that competition is not substantially lessened. For certain types of agreements, the Commission has issued so-called block exemption Regulations in which it applies a presumption that the agreements meet the conditions set forth in article 101(3);
- article 102 prohibits one or more companies from abusing their dominant position by indulging in practices that either exclude competitors from the market (eg, predatory pricing) or exploit consumers (eg, excessive pricing) without there being any objective justification for these practices.

The impact on competition of concentrations between companies is subject to scrutiny under the EC Merger Regulation No. 139/2004 (ECMR).

Article 107 of the EC Treaty prohibits state aid granted to companies, unless such aid can be justified, for example because it addresses a market failure by assisting the companies in making investments in useful projects (eg, research and development) that they would otherwise not make or not make to the same extent.

5 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

The Commission has issued three block exemption Regulations, accompanied by explanatory Guidelines, that are relevant for the pharmaceutical sector:

- Regulation No. 772/2004 on technology transfer agreements and related 2004 Guidelines;
- Regulation No. 2658/2000 on specialisation agreements and Regulation No. 2659/2000 on Research and Development (R&D) agreements and 2000 Guidelines on horizontal agreements (see public consultation on amended draft Regulations and draft Guidelines launched on 4 May 2010); and
- Regulation No. 330/2010 of 20 April 2010 on vertical agreements and related 2010 Guidelines adopted that same day.

6 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive effect of conduct or agreements in the pharmaceutical sector?

A distinction must be made between mergers and market conduct.

The Commission has sole jurisdiction to review pharmaceutical mergers that meet the turnover thresholds set forth in article 1(2) and article 1(3) of the European Community Merger Regulation (ECMR) to present a Community dimension, but the Commission may refer these mergers back to the national competition authorities (NCAs), at the request of the latter (ECMR, article 9) or of the parties themselves (ECMR, article 4(4)). Conversely, upon request of the merging parties (ECMR, article 4(5)) or of the NCAs (ECMR, article 22), the Commission can also review mergers that do not have a Community dimension. Merging parties must demonstrate that the merger would otherwise have to be reviewed by at least three member states.

Under the Regulation on the implementation of the rules on competition laid down in articles 101 and 102 TFEU (Regulation No. 1/2003), the Commission, the NCAs and the national courts share responsibility to review or investigate agreements between companies or unilateral conduct by one or more dominant companies that have as their object or effect to distort competition and affect trade within the common market within the meaning of article 101 or 102 TFEU. Through the European Competition Network (ECN), the Commission and the NCAs regularly discuss who is best placed to handle a case. Companies can bring contractual or civil damages claims based on article 101 or 102 TFEU before national courts. The Commission will assist these courts, if so asked.

7 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

In the case of infringement of article 101 or 102 TFEU, Regulation No. 1/2003 provides for the following remedies:

- cease-and-desist orders aimed at bringing the infringement to an end. This may involve the prescription of a particular line of conduct for the future (behavioural remedy) or even a structural remedy, namely, one that changes the structure of the infringing company (article 7);
- commitments offered by the companies to meet the Commission's concerns and thus avoid formal cease-and-desist orders (article 9), unless the Commission intends to impose a fine (see below);
- interim measures, which are similar in nature to cease-and-desist orders but reserved to cases where there is a risk of serious and irreparable harm to competition (article 8); and
- pecuniary sanctions, that is, fines of up to 10 per cent of the company's total turnover in the preceding business year (article 23) and, in order to secure compliance with a cease-and-desist order, an interim measure or a commitment, daily penalties of up to 5 per cent of the average daily turnover in that year (article 24).

8 Can private parties obtain competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties may seek a cease-and-desist order or interim measures and may also seek damages by bringing a lawsuit before a national court. Damages claims can be brought in combination with a request for a finding of an infringement, but are likely to be more successful following such a finding by the Commission or an NCA, given the need to present solid evidence of an infringement of article 101 or 102 TFEU. On 2 April 2008, the Commission issued a White Paper on damages actions outlining measures to encourage the private enforcement of article 101 or 102 TFEU.

9 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

According to article 17 of Regulation No. 1/2003, the Commission can conduct sector inquiries 'where the trend of trade, the rigidity

of prices or other circumstances suggest that competition may be restricted or distorted within the common market' and in the course of such an inquiry, the Commission can make use of its traditional powers of investigation (ie, with formal requests for information and dawn raids), to the extent 'necessary for giving effect to' article 101 and article 102 TFEU'.

On 15 January 2008, the Commission initiated a sector inquiry into pharmaceuticals based on the preliminary view that competition in this sector is not functioning optimally in terms of innovation (ie, allegedly less new medicines) as well as in terms of pricing (ie, delayed market entry of generic medicines).

On 28 November 2008, the Commission published its Preliminary Report and on 8 July 2009 it published its Final Report on the sector inquiry into pharmaceuticals. The tone – if not the substance – of what the Commission observed in the Final Report differed from what it had stated in its Preliminary Report.

To begin with, the Commission initially seemed ready to challenge individual company behaviour that was not only widespread in the industry, but also in line with settled patent law. In its Final Report, the Commission used more cautious language indicating that enforcement actions would be carefully selected and that it would bear in mind that the protection of intellectual property rights is a key element in the promotion of innovation, particularly in the pharmaceutical sector 'because of the necessity to address current and emerging health problems and the long life cycle of medicines (including long development periods)'.

In addition, while the Commission had initially turned a blind eye to possible restrictions of price competition between generic companies, it discarded any misunderstandings in its Final Report. Although competition between generic companies was important, it was not the focus of the sector inquiry 'as any price fixing and/or market allocation agreements between competitors would be caught by article 101 TFEU'. In other words: everybody knows – or should know – that these agreements are per se unlawful and a sector inquiry was neither a necessary nor an adequate tool to detect or assess outright cartel behaviour.

While the Commission had initially underestimated the regulatory barriers to market entry of generic medicines (and indeed of patented medicines), it opined in its Final Report that there was considerable room for improving the regulatory framework in the area of patent law and of marketing authorisations, pricing and reimbursement regimes.

In its Final Report, the Commission does not reveal much about its enforcement priorities in the pharmaceutical sector in the near future. That being said, it continues to express concern about certain practices whereby originator companies might have designed and implemented strategies aimed at ensuring continued revenue streams for their medicines either by delaying or blocking generic companies' market entry or by restricting competition from other originator companies.

See also questions 25, 30, 31 and 32.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition distinct from the general competition rules?

No .

11 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

The analytical framework for assessing company conduct under article 101 or 102 TFEU mandates a balancing test which is limited to the weighing of the anti-competitive effects of such conduct against its pro-competitive effects 'by way of efficiency gains' (see section 33 of the Commission's Notice on article 101(3) TFEU, and sections 6 and 30 of its Guidance Communication on enforcement priorities for applying article 102 TFEU to exclusionary conduct). Strictly speaking, there is no room for industrial policy considerations if these are not related to efficiency gains in terms of contributions to 'improving the production or distribution of goods or promoting technical or economic progress' (see article 101(3) TFEU).

As a consequence, references to industrial policy considerations will be rare and, if made, they will be made in passing.

12 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

Associations of undertakings and consumer associations can lodge complaints, provided they show a legitimate interest by showing that they (or their members) are directly and adversely affected by the alleged infringement. A mere reference to the general interest will not be good enough (see section 38 of the Commission's 2004 Notice on the handling of complaints).

These associations also have a right to express their views in sector inquiries launched pursuant to article 17 of Regulation No. 1/2003, such as the one launched for pharmaceuticals in January 2008.

Finally, the Commission also recognises the right of these associations to bring collective redress claims based on article 101 or article 102 TFEU to national courts (see White Paper).

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

When defining the relevant product market, the Commission will usually rely on the product classification developed by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by it and by Intercontinental Medical Statistics (IMS). Geographic markets are considered to be national, especially given the lack of harmonisation of national legislation in the field of pricing and reimbursement.

When it comes to assessing the impact of the merger on competition in the relevant market, the Commission's focus will usually be on competition in innovation rather than on price competition. Innovation is the main driving factor for competition in this sector whereas national pricing and reimbursement authorities ultimately set the price that can be charged and the cost that patients will bear.

14 How are product markets and geographic markets typically defined in the pharmaceutical sector?

In general, demand substitutability determines the scope of the relevant markets. It is measured with reference to a product's characteristics, intended use and price (see the Commission's 1997 Notice on the definition of the relevant market for the purposes of Community competition law).

In the pharmaceutical sector, information about a medicine's characteristics and intended use can be found in the Anatomical Classification (AC) developed by EphMRA or in the WHO's Anatomical Therapeutic Chemical (ATC) classification. While these classifications are designed to serve as a tool for drug utilisation research, they offer the Commission a useful assessment tool for the definition of the relevant product market. At the highest level, both classification systems group the medicines according to their anatomical composition. Within each group, the systems create three or four supplementary levels differentiating the medicines on the basis of their pharmacological, therapeutic and chemical features (including their active substance).

As said, in merger cases, the Commission usually relies on EphMRA's classification system and assesses the substitutability of medi-

cines at level 3 of this classification system thereby grouping medicines with similar therapeutic indications. The Commission usually accepts that these medicines belong to the same product market because they have a similar 'intended use'. However, there are exceptions and the merging parties themselves sometimes propose these exceptions (eg, level 4 based on the medicines' mode of action). For instance, in the recent merger decisions *Teva/Barr* (2008), *Pfizer/Wyeth* (2009) and *Novartis/Ebewe* (2009), the Commission assessed the substitutability of oncology products at level 4 of the classification system.

Cross-price elasticity (ie, the responsiveness of demand for one product to a price change for another product) may also be examined. However, in merger control cases, the Commission does not normally go into that level of detail. Looking at prices, it will distinguish between prescription medicines (which are often reimbursed) and over-the-counter medicines (which are usually not reimbursed).

Geographic markets are considered to be national, given, inter alia, the variety of pricing and reimbursement systems within the Community (see question 13).

15 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

Horizontal mergers between firms have traditionally been considered as potentially problematic when the aggregate market share of the merging firms exceeds 40 per cent, provided the increment caused by the merger is not negligible. See, for example, *Schering Plough/Organon* (2007), *Sanofi-Synthelabo/Aventis* (2004) and *Pfizer/Warner Lambert* (2000). However, in the recent merger decisions *Pfizer/Wyeth, Novartis/Ebewe, Merck/Schering-Plough* and *GSK/Steifel Laboratories* (all from 2009), the Commission focused its investigation on affected markets where the parties' combined market share exceeded 35 per cent and the increment exceeded 1 per cent.

The Commission may also intervene when the overlap between the merging parties' products has not yet materialised. In other words, potential competition from pipeline products is also taken into account if there is a reasonable chance that these products will make it to the market (see question 16).

16 When is an overlap with respect to products that are being developed likely to be problematic?

According to the Commission, 'effective competition may be significantly impeded by a merger between two important innovators, for instance between two companies with 'pipeline' products related to a specific product market' (see section 38 of its 2004 Notice on horizontal mergers).

The Commission will focus its analysis on the impact of pipeline products in phase III of clinical trials on competition in existing or future product markets (see *Pfizer/Pharmacia* (2003), where in two product markets one party held more than a 40 per cent share while the other party possessed a pipeline product).

Occasionally, the presence of phase II products or even preclinical R&D projects has been considered relevant for this assessment, but these cases are very rare (see *Ciba-Geigy/Sandoz*, 1996). After all, even pipeline products that have reached clinical phase III of their development statistically still have a substantial chance of not making it to the market and, even if they are successful, these products may be several years away from market launch.

We are not aware of any recent merger decisions in which the Commission has ordered the divestiture of phase 3 pipeline projects.

17 Which remedies will typically be required to resolve any issues that have been identified?

In principle, the Commission considers divestiture to be the most effective remedy in order to create the conditions for the emergence of a new competitive entity or for the strengthening of existing competitors. Divestiture tends to offer a lasting solution for the competition problem in the relevant national product markets (see the cases mentioned in question 15).

However, the Commission may accept other types of remedies, such as the termination of existing exclusive agreements or the grant of access to key technology (see sections 148 and 149 in its decision *Roche/Boehringer Ingelheim* of 1998 providing for the grant of non-exclusive licences of a technology for in vitro diagnostic applications to any interested third party, and sections 29 to 31 in its decision *Glaxo/Wellcome* of 1995 providing for the grant of an exclusive licence of a pipeline compound for the development of an anti-migraine medicine to a viable competitor). In its 2008 Remedies Notice (section 38), the Commission specifies that it 'may accept licensing arrangements as an alternative to divestiture where, for instance, a divestiture would have impeded efficient, on-going research'. It adds that these licences 'will normally be exclusive licences and have to be without any field-of-use restrictions and any geographical restrictions on the licensee'. For examples in the pharmaceutical sector, it refers, inter alia, to the *DSM/Roche Vitamins* case of 2003.

As the recent merger decisions *Pfizer/Wyeth* (2009) and *Abbott/Solvay Pharmaceuticals* (2010) illustrate, behavioural remedies can accompany structural remedies. For instance, the Commission can insist on the provision of necessary technical assistance to allow the purchaser(s) to manufacture the products or to make the necessary arrangements for third-party manufacturing, as well as the transfer of personnel, transitional supply arrangements and adequate technical assistance and personnel in order to ensure the rapid replacement of the merging parties as distributors by the purchaser.

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

According to the Commission's 2007 Consolidated Jurisdictional Notice (see section 24), the acquisition of intangible assets such as patents may be considered to be a concentration if those assets constitute a business with a market turnover. The same is true for the transfer of a patent licence if it is an exclusive licence on a lasting basis and if this will enable the acquirer to take over the turnover-generating activity relating to this licence.

Anti-competitive agreements

19 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

Agreements between non-dominant firms and unilateral conduct of one or more dominant firms are subject to an identical two-tier antitrust analysis.

The first question is whether the companies' conduct distorts the competitive process to a significant extent. In this respect, the key question is whether this conduct prevents or delays market access for new entrants or growth for existing competitors.

If the conduct does, it creates 'foreclosure effects' and the analysis will move on to the second question, that is, whether there are objective justifications or efficiencies for the conduct that outweigh its foreclosure effects. It is for the firms to prove that there are such justifications or efficiencies. For agreements between non-dominant firms, the second level of the analysis takes place in the context of article 101(3) TFEU, but the Commission has indicated that, for reasons of consistency, this Treaty provision applies by analogy to unilateral conduct of dominant firms (see sections 6 and 30 of its 2008 Guidance Communication on article 102 TFEU).

20 Have there been cartel investigations in the pharmaceutical sector?

There have been no cartel cases at EU level involving medicinal products. The Commission's decision to initiate a sector inquiry refers to

collusive agreements but at this stage, it remains unclear whether this will lead to concrete enforcement activity. However, in the course of the sector inquiry, the Commission conducted several surprise inspections at the premises of several pharmaceutical companies. In some instances, the Commission was particularly interested in settlement agreements between originators and generic companies (see question 30) whereas in others, the subject matter of the inquiry was less clear but may concern other forms of allegedly collusive activity.

For the sake of completeness, in November 2001, the Commission fined eight pharmaceutical companies a total of €855.22 million for participating in a market-sharing and price cartel covering several vitamin products.

21 To what extent are technology licensing agreements considered anti-competitive?

An agreement whereby a company licenses its technology (eg, patents or know-how) to another company is in principle pro-competitive, provided the licensee is not obliged to share its own improvements to or new applications of the licensed technology with the licensor. This is why the Commission has issued a block exemption Regulation for technology transfer licensing agreements (see Regulation No. 772/2004).

The parties to the agreement will benefit from this block exemption if their market shares do not exceed a certain level (20 per cent combined when licensor and licensee are competitors and 30 per cent each when they are not) and if their agreement does not contain hard-core anti-competitive clauses, for example, clauses stipulating that the licensor and the licensee will agree on the sales price of the licensed products, on output restriction or on the allocation of markets or customers (although the Regulation contains a long list of exceptions with regard to market or customer allocation).

As for other block exemption Regulations, the Commission has clarified the scope of the transfer of technology licensing block exemption in Guidelines (see question 5).

22 To what extent are co-promotion and co-marketing agreements considered anti-competitive?

Co-marketing and co-promotion agreements are quite common in the pharmaceutical industry.

Co-promoting firms sell the medicine under the same trademark while co-marketing firms sell that medicine under different trademarks. In the case of co-promotion, there is usually one party that sets the sales price and handles the actual distribution. While the other party will have invested in the success of the co-promotion venture and will receive a share of the sales revenue, it will usually not be involved in the sales strategy and the distribution activity.

In the case of co-marketing, there is always competition between the two parties. Not only do they sell under different trademarks but each of them is normally responsible for its own marketing strategy, including the sales price, and each of them keeps the sales revenue for itself.

So far the Commission has not raised objections of principle against co-promotion or co-marketing agreements, even if the contracting parties are competitors. Although these agreements imply some degree of joint activity at the level of commercialisation, the Commission seems to accept that these agreements must be distinguished from genuine joint sales agreements which only fall outside the scope of article 101(1) TFEU if the parties' combined market share does not exceed 15 per cent and if they do not agree on the sales price.

Co-promotion or co-marketing agreements are often part of a broader cooperation between two companies that includes R&D and production. Objections of principle are even less likely in such situations. Article 4 of the Commission's block exemption Regulation No. 2659/2000 on R&D cooperation allows the joint exploitation of the results of this cooperation for seven years after the product has been put on the market. While the same provision specifies that competitors can only jointly exploit the results of their R&D cooperation if their combined market share does not exceed 25 per cent, the Commission qualifies this in its Guidelines on horizontal restraints: it will not hold the 'first mover advantage' (often resulting in temporary monopoly power) against the parties whose cooperation has led to an entirely new product (section 73 and also section 54).

23 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

As explained above, certain agreements with competitors, such as price cartels, will be per se unlawful, meaning that they are in principle always prohibited whatever their actual or potential effect on competition in the relevant market. In contrast, other agreements, such as R&D or production joint ventures, will be subject to an effects-based analysis. In some cases, the EC Commission may insist on the creation of 'Chinese walls' in other to ensure that the exchange of information between the cooperating parties does not go beyond what is necessary for the success of the joint venture.

24 Which aspects of vertical agreements are most likely to raise antitrust concerns?

In the past 20 years, the EC Commission has only intervened against distribution arrangements whereby the manufacturer aimed at preventing or restricting parallel trade.

While its first decision in 1987 (*Sandoz*) concerning an obsolete (ie, not enforced) contractual export ban was upheld by the General Court, the Commission's second and third decisions were (in whole or in part) annulled.

In *Bayer* (1996), the Commission failed to demonstrate that wholesalers had given their consent to the manufacturer's restrictive supply quota policy. On 6 January 2004 (joined cases C-2 and 3/01), the Court of Justice confirmed the General Court's judgment of 26 October 2000.

In *GlaxoWellcome* (2001), the General Court held on 27 September 2006 (case T-168/01) that the Commission was right in finding that GSK's dual pricing policy had anti-competitive effects within the meaning of article 101(1) TFEU but wrong in rejecting the manufacturer's defence that this policy aimed at preserving its R&D investments for the benefit of consumers, and merited an exemption under article 101(3) TFEU. On appeal (joined cases C-501, 513, 515 and 519/06P), the Court of Justice upheld the General Court's judgment on 6 October 2009. It specified, however, that contrary to what the General Court had concluded, even in the absence of consumer harm, GSK's policy had an anti-competitive object within the meaning of article 101(1) TFEU (sections 62 to 64).

25 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

Under EU law, a dominant company may abuse its dominant position if it indulges in conduct aimed at unduly foreclosing business opportunities for existing or potential competitors (exclusionary abuses) or at charging customers unreasonable terms and conditions (exploitative abuses).

So far, the Commission has once examined an allegation that a pharmaceutical company had engaged in an exploitative abuse, namely excessive pricing, but it closed the case without pursuing the matter further. As mentioned in question 3, a complaint concerning an exclusionary abuse led the Commission to adopt a prohibition decision with fines in 2005 (*AstraZeneca*).

In its Final Sector Inquiry report, the Commission suggests that dominant companies may be abusing their market power by engag-

ing in certain practices that aim at restricting competition from other originator or generic companies. It refers to a 'toolbox' of instruments. It devotes an entire section of its Report (and a separate Fact Sheet, annexed thereto) to this theme, explaining how the combined use of several or all of the above-mentioned life-cycle instruments may significantly increase legal uncertainty on the side of generic companies and, as a consequence, significantly increase the likelihood of delays to generic entry (sections 1050 to 1081). However, the Commission hastens to add that 'this does not purport to imply that if legitimate uses of several instruments are combined, such a combination would not be legitimate' (section 1065) and 'causality can only be established on a case-by-case basis' (section 1058). It therefore remains to be seen under which circumstances the use of one or more of these instruments might be considered abusive.

It can be expected that the Commission's Guidance Paper on enforcement priorities regarding exclusionary abuses (published in February 2009) will provide the basis for the assessment of any specific type of allegedly anti-competitive conduct. Leaving aside the characteristic features of any such conduct and the concerns it may give rise to (see questions 30 and 31), it is useful to recall that the Commission bears the burden of proving that a defendant is truly dominant, that its conduct produces significant, actual or potential, foreclosure effects to the detriment of its competitors and of consumers, and that the targeted competitors have no means of putting into effect a countervailing strategy. Unfortunately, in its Guidance Paper the Commission does not recognise that it should also prove that the allegedly abusive conduct makes no commercial sense but for the aim of excluding (or substantially lessening) competition.

Anti-competitive unilateral conduct

26 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

According to settled case law, dominance is a position of economic strength enjoyed by an undertaking that enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.

Power over price is the hallmark of substantial market power. However, evidence of such power is usually not readily available. The Commission will look for indirect evidence of dominance. According to the 2008 Guidance Communication on article 102 TFEU (sections 12 to 18), a company's high market share (at the very least 40 per cent), combined with much lower shares held by its competitors and the absence of countervailing buying power in the hands of its customers, will be indicative of dominance if it can be shown that the company has held its high market share for some time and is likely to do so for the foreseeable future. This will be likely if entry barriers to the relevant market are high.

There is no exhaustive list of entry barriers. In its Guidance Communication (section 17), the Commission refers to a number of advantages enjoyed by the allegedly dominant company: it may hold patents, achieve economies of scale or scope, have access to key resources (eg, capital) or run a highly developed distribution network. Furthermore, its actual or potential competitors may face production capacity constraints, customer loyalty, etc.

27 When is a party likely to be considered dominant or jointly dominant?

No. Intellectual property rights (IPR) include, by their very essence, the right to exclude competitors from the field covered by the IPR. However, IPR do not as such confer dominance on the holder (see section of the Commission's Guidance Communication on article 102 TFEU).

28 Can a patent holder be dominant simply on account of the patent that it holds?

Subject to the judicial review of the Commission's decision in *AstraZeneca*, this decision indicates that patent applications may give rise to antitrust liability. However, this will only be the case in exceptional circumstances and, in any event, the applicant must be found to hold a dominant position within the meaning of article 102 TFEU.

In *AstraZeneca*, the Commission recognised that companies can seek the extension of their basic patent protection via SPCs, even if possession of the latter delays market entry by generic companies. However, it took the view that the company had 'misused the patent system' by providing misleading information to the patent offices in order to obtain these SPCs (see question 3).

29 To what extent can an application for the grant of a patent expose the patent owner to liability for an antitrust violation?

Patent enforcement can lead to an infringement of article 102 TFEU if it leads to vexatious litigation on behalf of the patent holder and if that company holds a dominant position within the meaning of article 102 TFEU. In order to assess whether the litigation is vexatious, the Commission will apply the criteria set forth by the General Court in *ITT Promedia NV* (judgment of 17 July 1998 in case T-111/96).

The Sector Inquiry Preliminary Report suggests that there may be other instances in which patent enforcement could give rise to concerns under article 102 TFEU (eg, patent clustering, defensive patenting, etc). Judging from the tentative approach adopted by the Commission it is too early to tell whether the Commission will challenge any of these practices.

30 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

There is no EU law precedent so far.

As a matter of fact, in its 2004 Guidelines on Technology Transfer agreements, the Commission accepts that licensing agreements that serve as a means to settle an intellectual property rights dispute or to prevent one party from asserting its intellectual property rights against the other party, are 'not as such restrictive of competition' but the 'individual terms and conditions of such agreements' may be caught by article 101(1) TFEU (section 204).

However, agreements between originator and generic companies that restrict the generic company's ability to market its medicine and also contain a value transfer from the originator company to the generic company, either in the form of a direct payment or in the form of a licence, distribution agreement or a 'side-deal', appear to be the Commission's short-term top priority. In its Final Report, the Commission announced 'further focused monitoring' while acknowledging that 'this monitoring would have to take duly account of the administrative burden imposed on stakeholders and will be limited in time until the Commission has gathered sufficient information on the subject matter to decide whether further action is needed'.

On 12 January 2010, the Commission announced that it had addressed requests for information to certain pharmaceutical companies – originators as well as generic companies – asking them to submit copies of patent settlement agreements they had entered into between 1 July 2008 and 31 December 2009 relating to the EU or EEA. In two instances, the Commission has taken its investigation a step further by initiating formal proceedings against companies that had entered into settlement agreements, whereby the originator had made reverse payments or operated other value transfers to one or more generic companies in return for a delay in their market entry. It did so on 8 July 2009 in a case involving Servier and on January 2010 in a case involving Lundbeck. In both cases, it had conducted surprise inspections.

31 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

Life cycle management strategies that aim at taking full benefit of the patent system do not as such raise antitrust concerns, even if they prevent or delay market entry by potential competitors, in particular generic companies. For antitrust concerns to arise, the companies that apply these strategies must possess a dominant position, their strategy must create substantial foreclosure effects on the market and; most importantly, there must be no objective justification for that strategy other than the aim to prevent or delay market entry by potential competitors (see already question 25).

In its Final Sector Inquiry Report, the Commission reviews a number of practices and classifies these in two categories: those that might have an impact on competition between originators and generic companies and those that might affect competition between originators.

Apart from the settlements with reverse payments, the first category covers, inter alia, patent clustering, divisional patent applications, launching follow-on products and interventions before regulatory authorities.

As far as patent clustering (ie, the filing of numerous patent applications for the same medicine) is concerned, the Commission keeps a low profile. While it observes that documents gathered in the course of the Sector Inquiry confirm that 'an important objective' of this approach is to delay or block the market entry of generic medicines, it recognises that all patent applications need to be evaluated 'on the basis of the statutory patentability criteria by the patent offices, not on the basis of underlying intentions of the applicant'.

With respect to 'divisional patent applications' (which seek to split an initial parent application), the Commission observes that these usually extend the examination period of the patent office and thus also delay generic market entry but it recognises that these applications are as such 'legitimate' and it notes that, in any event, in March 2009, the European Patent Office (EPO) took measures to 'raise the bar' by limiting the circumstances and time periods in which voluntary divisional patent applications can be filed.

It would also seem unlikely that the Commission will challenge the practice consisting in the launch of a second generation medicine, typically some time before the loss of exclusivity of the first generation medicine, by which the originator company might seek to limit the impact of market entry of generic products corresponding to the first generation product by shifting prescribers and patients to the new product (which will not face generic competition), unless the launch is combined with other practices that merely aim at frustrating generic market entry, as was the case – according to the Commission – in the *AstraZeneca* case.

In contrast, given their statistically much poorer success record, originators' interventions before the national regulatory authorities that are competent to grant market authorisations, approve prices, or take reimbursement decisions seem to meet with more skepticism. While the Commission seems to take the view that it is not normally the best placed antitrust authority to look into the merits of these practices, it invites injured parties to bring the matter under the attention of the 'relevant' (ie, national) competition authorities in case of 'clear indications that a submission by a stakeholder intervening […] was primarily made to delay the market entry of a competitor/applicant'.

So-called defensive patenting belongs to the second category. This practice refers to patent applications regarding inventions that the applicant considers to have little or no prospect of being developed or commercialised or which, once granted, the company holds primarily to protect itself against actual or potential competition. All in all, the Commission warns that 'defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a licence on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked'. However, the Commission seems to recognise that defensive patenting should not raise serious concerns if these other originator companies can either obtain a licence from the successful applicant or build on the information disclosed in the patent applications.

Update and trends

As indicated above, following the publication of its Final Sector Inquiry Report, the Commission seems to have singled out patent settlement agreements with reverse payments as an enforcement priority.

32 Do authorised generics raise issues under the competition law?

In the US, when a company's patent for a given medicine expires, relabels that product and then markets it as an 'authorised generic', it deprives the third party that is the first to successfully file an abbreviated new drug application (ANDA) under the Hatch-Waxman Act of the benefit of a 180-days exclusivity period during which no other potential competitor can market the same generic medicine. The prospect of having to compete with the former patent holder during that period creates a financial disincentive for the first successful ANDA applicant, but it is an open question whether the launch of the authorised generic raises antitrust liability on behalf of the patent holder.

The regulatory framework in the EU is different and the specific issue set out above does therefore not arise. Nor is there authority for the proposition that a patent holder could not launch its own generic following patent expiry, even if this means that new entrant generic companies face competition from that product. In fact, it could be argued that this practice is pro-competitive in that it offers patients alternative sources of supply for a cheap medicine.

There is no clear precedent but in *Sanofi-Aventis/Zentiva* (M.5253 of 4 February 2009), the Commission seems to agree with this analysis. After observing that the effect of the authorised generic on the market 'would vary in function of national regulations and was only likely to be sizeable in cases where such regulation specifically provides for a premium to the first generic entrant', the Commission went on to say that 'even in such cases, while there may be a negative effect on competitors, any effect on consumer welfare is ambiguous' and 'were problems to arise, they could be addressed by adapting the regulations in question'.

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

In article 102 TFEU cases, dominant companies have sought to advance objective justifications for their allegedly anti-competitive conduct. Specific features of the pharmaceutical sector are relevant in this respect, since the antitrust analysis of that conduct is effects-based and must thus take into account the market realities. For instance, innovation is the prime driver of competition. Further, there is a complex demand side comprising the patients (who consume medicine), the doctors (who prescribe medicines) and the national authorities (who set the sales price and co-finance the purchase of medicines via the reimbursement schemes). Also, manufacturers and wholesalers must ensure adequate supply of medicines at all times for patients in a given country.

The issue of the extent to which these sector-specific features can justify anti-competitive conduct of an allegedly dominant company has arisen in *Syfait* (case C-53/03) and, more recently, in *Lelos* (cases C-468-478/06) – two cases in which the European Court of Justice was asked to give a preliminary ruling on whether GlaxoSmithKline's refusal to meet all orders by wholesalers based in Greece constituted

an infringement of article 102 TFEU because it restricted parallel trade out of Greece. In the first case, Advocate-General Jacobs relied on sector-specific features to justify GlaxoSmithKline's conduct. In the second case, the Court issued a more nuanced ruling. For instance, it observed that a pharmaceutical company 'cannot base its arguments on the premise that the parallel exports which it seeks to limit are of only minimal benefit to the final consumers' in the pharmaceutical sector due to the fact that exporters, wholesalers or pharmacies may not pass on the price advantage to the patients or the reimbursement authority in the high price country (section 57). With regard to the existence of national price regulations in the pharmaceutical sector, the European Court of Justice held, on the one hand, that 'the degree of regulation regarding the price of medicines cannot prevent any refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse' but, on the other hand, that 'such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests' (section 69).

Arnold & Porter LLP

Luc Gyselen **luc.gyselen@aporter.com**

11 Rue des Colonies
Koloniënstraat 11
1000 Brussels
Belgium

Tel: +32 2 290 7831
Fax: +32 2 290 7899
www.aporter.com

PHARMACEUTICAL ANTITRUST 2010 ISSN 1757-6288