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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), as amended, sets out the main requirements related to the granting of marketing authorisations of pharmaceutical products (for the latest consolidated version, see Offical Journal (OJ) L 311/67 of 28 November 2004). Directive No. 2001/82/EC, also amended, does so for veterinary medicinal products.

Apart from 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.

- For some products, the application must be assessed by the European Medicines Agency (EMEA) and the authorisation must be issued by the European 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 and products containing a new active substance for treating diseases such as cancer, diabetes, AIDS, neuro-degenerative diseases and, from May 2008 onwards, auto-immune and viral diseases.
- For other products, manufacturers can submit their application for a market authorisation either to the EMEA 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 EC or through a decentralised procedure. The Directive also provides the legal basis for approval of generic products via an abridged procedure.

Pursuant to Regulation No. 1768/92 (OJ L 182/1 of 2 July 1992), 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 EC. 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).

2 Which bodies are entrusted with enforcing these regulatory rules?

In accordance with article 211 of the EC Treaty, the European Commission (the Commission) monitors the implementation of the regulatory provisions of the above-mentioned Directives and Regulations.

With respect to marketing authorisations granted centrally, the EMEA (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 other marketing authorisations granted nationally under the mutual recognition procedure and decentralised procedure, 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 through a concerted effort so that a harmonised approach is taken.

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.

Last, the Commission may 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 procedure for marketing medicinal products to block or delay market entry for generic competitors. The case is currently 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 abovementioned 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 ECJ 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 EC Treaty. Company conduct is governed by articles 81 and 82 of the EC Treaty:

- article 81(1) prohibits anti-competitive agreements with an impact on trade between member states, but companies can demonstrate under article 81(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 81(3);
- article 82 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 87 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 its 2004 Guidelines on the application of article 81 to such agreements;
- Regulation No. 2658/2000 on specialisation agreements and Regulation No. 2659/2000 on R&D agreements and its 2000 Guidelines on horizontal agreements, which expand on these and other forms of cooperation between competitors; and
- Regulation No. 2790/1999 on vertical restraints and its 1999 Guidelines on vertical agreements, including commercial agency arrangements.

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 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 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 81 or 82 of the EC Treaty. 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 81 or 82 of the EC Treaty 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 81 or 82 of the EC Treaty, 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, ie, 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, ie, 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 81 or article 82 of the EC Treaty. On 3 April 2008, the Commission issued a White Paper outlining measures to encourage the private enforcement of article 81 or article 82 of the EC Treaty.

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 EC Regulation 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

surprise visits), to the extent 'necessary for giving effect to Art. 81 and Art. 82 EC Treaty'.

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, there are fewer 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. It repeatedly states that its report only contains the results of its fact finding and does not seek to identify wrongdoing by individual companies. However, with regard to competition on innovation, the Commission observes that 'originator companies have designed and implemented strategies aimed at ensuring continued revenue streams for their medicines' and that '[…] the successful implementation of these strategies may have the effect of delaying or blocking such entry'. With regards to price competition, the Commission notes that 'the preliminary findings of the inquiry also suggest that originator companies develop and practise defensive patenting strategies primarily in order to block the development of new competing products'.

While the sector inquiry focuses on company conduct, the Commission's preliminary report also advocates some improvements in the regulatory framework. More particularly, the Commission sees a need for a single Community patent and the creation of a unified and specialised patent judiciary in Europe. It also acknowledges that there are 'bottlenecks in the procedures for approval and marketing of medicines (including pricing and reimbursement status) which may contribute to delays in bringing products to market'.

The Commission's final report is due by the summer of 2009.

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 81 or 82 EC 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 81(3) of the EC Treaty, and sections 6 and 30 of its Guidance Communication on enforcement priorities for applying article 82 of the EC Treaty 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 81(3) of the EC Treaty).

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 33ff of the Commission's 2004 Notice on the handling of complaints).

These associations will 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 (see below).

Last, the Commission also recognises the right of these associations to bring collective redress claims based on article 81 or article 82 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 legislations 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 more on competition in innovation 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. Level 3 of this classification system groups 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).

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 are 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, eg, *Schering Plough/Organon* (2007), *Sanofi-Synthelabo/Aventis* (2004) and *Pfizer/Warner Lambert* (2000).

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 pre-clinical 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.

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 indeed 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 29-31 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.

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 the same 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 so-called foreclosure effects and the analysis will move on to the second question, ie, 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 81(3) of the EC Treaty, 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 82).

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 enquiry refers to collusive agreements but at this stage, it remains unclear whether this will lead to concrete enforcement activity.

However, 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, eg, 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 EC 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 81(1) 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 last 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 CFI, 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 ECJ confirmed the CFI's judgment of 26 October 2000. In *GlaxoWellcome* (2001), the CFI 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 81(1) of the EC Treaty 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 81(3) of the EC Treaty. The case is now under appeal (joined cases C-501, 513, 515 and 519/06P). An oral hearing is scheduled for 17 March 2009.

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

There is no EC 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 a 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 81-1 of the EC Treaty (section 204).

However, the EC Commission has identified patent settlements as possible infringements in its recent sector enquiry, especially when they give rise to so-called reverse payments or other side deals that might delay generic market entry. It remains to be seen whether the Commission will in the end challenge these settlement agreements.

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?

Under EC 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 more. 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 sector inquiry preliminary report (see question 9), the Commission suggests that dominant companies may be abusing their market power by engaging in certain practices that aim at restricting competition from other originator or generic companies. It refers to a 'toolbox' of instruments. However, it remains to be seen under which circumstances the use of one or more of these instruments might be considered abusive.

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

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 EC Commission will look for indirect evidence of dominance. According to the 2008 Guidance Communication on article 82 of the EC Treaty (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.

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

No. Intellectual property rights include, by their very essence, the right to exclude competitors from the field covered by the IPR. However, intellectual property rights do not as such confer dominance on the holder (see section of the Commission's Guidance Communication on article 82).

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

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 82 of the EC Treaty.

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). In its Discussion Paper (section 60), the Commission described this conduct as an exclusionary practice that was 'clearly not competition on the merits'.

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

Patent enforcement can lead to an infringement of article 82 of the EC Treaty 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 82. In order to assess whether the litigation is vexatious, the EC Commission will apply the criteria set forth by the CFI in *ITT Promedia NV* (judgment of 17 July 1998 in case T-111/96).

The sector inquiry preliminary report (see question 9) suggests that there may be other instances in which patent enforcement may give reason to concerns under article 82 (eg, patent clustering, defensive patenting). Here too, it is too early to tell whether the Commission will challenge any of these practices.

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.

However, in its sector inquiry preliminary report (section 887), the Commission observes that 'a toolbox of measures/instruments can be used throughout the product life cycles to maximise the revenue stream from existing pharmaceutical products by delaying or dampening the effect of generic entry.' It remains to be seen whether it will challenge company conduct that consists of making cumulative use of several instruments in the toolbox, even if such use is entirely lawful under patent law.

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 long 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 an alternative sources of supply for a cheap medicine.

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 82 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* and, more recently, in *Lelos* – two cases in which the ECJ 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 82 of the EC Treaty 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 and 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 ECJ 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, 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).

Update and trends

As indicated in question 9, the EC Commission is expected to issue its final report in its ongoing sector inquiry by the summer of 2009. This report is likely to clarify where the Commission believes its enforcement priorities under article 81 and article 82 EC Treaty lie. The preliminary report suggests that some types of agreements might run foul of article 81 EC (see question 25) and that certain practices might be unlawful under article 82 EC (see questions 26, 29, 30 and 31). However, only time will tell whether the Commission will effectively challenge these agreements or practices.

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