GETTING THE DEAL THROUGH

Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide

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Overview

Asim Varma and Marleen Van Kerckhove
Arnold & Porter LLP

In the United States, antitrust enforcement authorities and private litigation in the pharmaceutical sector have in the past few years focused on the antitrust implications of agreements between branded and generic drugs in settling patent litigation and brand name pharmaceutical life cycle management strategies. We anticipate this focus to continue for the next few years as litigation on these issues makes its way through the US appellate courts.

In Europe, enforcement priorities in the pharmaceutical sector have traditionally focused on (intra-brand) competition between producers of patented prescription drugs and parallel traders. More recently, however, the European Comission has started to focus increasingly at practices believed to be aimed at delaying the entry of generics or innovative products, including the opening last spring of a sector-wide enquiry into these issues.

Europe awaits verdict on parallel trade from highest European Court

The protection of parallel trade – that is, cross-border trade between member states – has traditionally been the main focus of the European Commission's enforcement activity in the pharmaceutical sector. It features far less in US antitrust enforcement and litigation. The reason is that the creation and maintenance of a single EU market is one of the key objectives of the European Union. All policy, including antitrust policy, must contribute to the objective of the single market.

Primarily due to differences in national pricing regimes and health care spending, there exist substantial price differences – as high as 70 per cent in some instances – in medicines between member states. This has created a significant parallel trade activity. Wholesalers purchase in low-priced countries in order to sell in high-priced countries at or near the reimbursement price of the medicine in the country of importation, effectively arbitraging to take advantage of the price differentials. Pharmaceutical manufacturers have sought to restrict these parallel imports through unilateral means and also by agreement or concerted practice with their distributors. Such action is potentially in breach of EC competition law, either as a restrictive agreement (article 81 of the EC Treaty) in the case of concerted measures, or as an abuse of a dominant position (article 82 of the EC Treaty) in the case of unilateral measures.

Both issues are currently pending before the European Court of Justice (ECJ). The oral hearing in the *Greek GSK* case (article 82) took place on 29 January 2008 and the advocate-general issued his opinion on 1 April 2008. No dates have been set for the *GSK Dual-Pricing* case (article 81) as yet. Pending these two cases, parallel trade enforcement by the European Commission has been put on the back burner. However, as is illustrated below, the member states remain active in the area. What is more, if the ECJ, like the advocate-general, is more supportive of the Commission's position we may see more Commission activity in this area too.

Meanwhile, EAEPC, the association representing European parallel traders, in March 2008 allegedly brought a complaint before the European Commission claiming that the Spanish government has failed to comply with its obligations under the EC Treaty by promoting dual-pricing practices among branded drug companies. Spain introduced legislation that allows branded drug companies to apply a different price depending on whether their medicines are sold in Spain or to other countries. The use of dual-prices by branded drug companies in Spain is the subject-matter of one of the GSK cases before the ECJ.

Turning to the member states, the United Kingdom's Office of Fair Trading (OFT) has recently issued the results of its market study into the use by branded drug companies of the 'direct-to-pharmacy' sales model. Under this model, the company contracts directly with pharmacies, merely using the logistical support of one or more wholesalers. It gives it more control over prices and also avoids the risk of counterfeits through parallel trade. The OFT is concerned that the model may result in lower discounts for pharmacies and lower service levels in the distribution of medicines. It recommends that the government address the concern over lower discounts in the UK price regulatory system (PPRS) and also set down minimum service standards.

In France, the Competition Council has imposed certain conditions to make the supply quota system in force between a number of branded drug companies and their wholesalers more flexible and transparent, ensuring that the system can adapt to potential growth on the market without distorting competition as between wholesalers. The Council did not object to the supply quota system as such but rather had concerns over its practical implementation.

In the United States, the legal framework is such that hindering 'parallel' imports from third countries is unlikely to amount to an infringement of antitrust rules. Even if a pharmaceutical product is authorised for sale in the US, if the drug is also orginally manufactured in the US, it is a violation of the Federal Food, Drug, and Cosmetics Act (FDCA) for anyone other than the manufacturer to re-import the drug into the US (21 USC section 381(d)(1)). The Food and Drug Administration (FDA) takes the position that virtually all drugs imported into the US (regardless of the country where they are manufactured) also violate US law for other reasons. Generally, such drugs are unapproved drugs under 21 USC section 355, not labelled pursuant to US regulations under 21 USC sections 352 and 353, or dispensed without a valid prescription in accordance with 21 USC section 353(b)(1). The FDA has successfully enjoined attempts by pharmacies to

facilitate the importation of drugs. See, eg, *United States v Rx Depot Inc*, 290 F Supp 2d 1238, 1245-48 (ND Okla 2003).

Under 21 USC section 384, the secretary of health and human services has the authority to promulgate regulations to permit pharmacists and wholesalers to import prescription drugs from Canada and to otherwise grant waivers of the statutory prohibition against importation if the importation poses no additional health and safety risk and if the waiver results in a significant reduction in the cost of drugs. The secretary has declined to make such findings and this section is not in effect. Attempts by state and local governments to force the secretary and the FDA to promulgate regulations or waivers to permit importation have been unsuccessful – *Andrews v HHS*, no. 04-0307, 2005 WL 4826342, at *2-3 (DDC 13 April 2005) (holding FDA's ban on reimportation 'easily withstands rational basis scrutiny' because of the FDA's legitimate interest in ensuring the safety of imported prescription drugs); *Montgomery County, MD v Leavitt*, 445 S Supp 2d 505, 512-13 (D Md 2006). Absent additional legislation, we do not expect the FDA's position precluding importation to change. In the absence of the federal government authorising importation, conduct by pharmaceutical manufacturers asserted to impede importation is unlikely to constitute an antitrust violation. In a recent case, *in re Canadian Import Antitrust Litigation*, 470 F3d 785 (8th Cir 2006), the Eighth Circuit Court of Appeals ruled that consumers could not pursue an antitrust case against pharmaceutical companies for their alleged suppression of the importation of Canadian prescription drugs for personal use. The court held that the Canadian drugs at issue were misbranded and unapproved under FDA regulations and because they could not be legally imported the alleged injury to competition was not cognizable under the antitrust laws.

US focus on patent infringement settlements between branded and generic drug to continue

The US pharmaceutical regulatory framework encourages patent challenges by generic firms by providing for 180-day marketing exclusivity to those firms which assert invalidity or non-infringement of the patents. Patent challenges thus have the potential to yield substantial consumer savings. However, the competitive dynamic between branded drugs and their generic equivalents, creates, some argue, an incentive for brand and generic manufacturers not to resolve their patent discputes but to collude to avoid competition and share the resulting profits. In most cases in which generic entry is contemplated, the profit a generic anticipates is likely to be less than the amount of profit the brand name company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand name product; the difference between the brand's loss and the generic's gain is the money consumers save. Consequently, it is argued, it will typically be more profitable for both parties if the brand manufacturer pays the generic to settle the patent dispute and they agree to defer entry. Although both the brand name and the generic firms are better off, the consumer may lose the possibility of earlier generic entry that may occur if the generic company had prevailed or because the parties would have negotiated a settlement with an earlier entry date, absent a payment.

While all settlements involve some form of consideration flowing between the parties, from the late 1990s the Federal Trade Commission (FTC) has challenged patent settlements that it believes involve sharing the benefits that come from eliminating potential competition, that is, significant payments from the brand name to the generic company. In the FTC's view, these settlements, deemed reverse payment settlements, are anticompetitive. Initially, the FTC's enforcement efforts were successful, resulting in consent orders and for several years such reverse payment settlements stopped. In 2005, two appellate court decisions applied a more expansive standard. In the *Schering* case, the Eleventh Circuit Court of Appeals vacated a decision in which the FTC found two patent settlements violated the FTC Act. The FTC concluded that in each settlement Schering had paid its generic competitors to accept the settlement that provided Schering with more protection than simply proceeding with the litigation or a settlement without a payment. The Court of Appeals disagreed and held that, in the absence of an allegation of sham litigation, until the patent was proved invalid or not infringed, the patent provided Schering with the legal right to exclude the generics and the payment could not support an inference of a collusive agreement to exclude competition. The FTC sought review from the US Supreme Court. The solicitor general (who represents the United States before the Court) filed a brief on behalf of the Antitrust Division of the Department of Justice (DoJ), acknowledging the importance of the issue but arguing that the case was not the right vehicle for the Court to address them. The DoJ disagreed with the FTC's position that reverse payments indicate collusive agreements. The DoJ appears to favour an approach under which the strength of the patent infringement case would be assessed short of a full-fledged trial of the issues that were settled along with an examination of the settlement negotiations.

In June 2006, the Supreme Court declined to review the *Schering* appellate decision. The impact of the *Schering* and *Tamoxifen* decisions has been an increase in reverse payment settlements. The FTC indicated an intention to seek another reverse payment settlement to challenge and further develop the law and elicit the Supreme Court to address the issue. In February 2007, the FTC brought suit to challenge brand drug manufacturer Cephalon's settlements with four generic firms (all of whom would have shared the 180-day exlusivity period). Each settlement involved a side-agreement including intellectual property license payments from the brand as well as supply agreements and product development agreements under which the brand paid the generic. The FTC argues that these are agreements not to compete. Unlike previous suits challenging reverse payment settlements, the FTC brought the challenge only against the brand name firm, here Cephalon.

It will take a number of years for the *Cephalon* litigation and other pending cases brought by private litigants to wind their way through the US court system. The FTC is also continuing to support a legislative remedy to address reverse payment settlements. While so far the proposed legislation has not moved forward, a change in administraton may change the political dynamics and make legislation prohibiting all but de minimis consideration as part of a paragraph IV settlement more likely.

Increased scrutiny of life-cycle management on both sides of the Atlantic

The enforcement of patent rights, and the settlement of patent suits in the pharmaceutical industry have for some time been issues of concern to US antitrust agencies and US courts. They have only recently captured the attention of the European Commission. In summer 2006, the Commission imposed a €60 million fine on AstraZeneca for having abused its market power (or 'dominance') by pursuing certain intellectual property (IP) and regulatory strategies aimed at keeping generics off the market. At least two further cases alleging IP-related abuses have been

brought before the European Commission since. In addition, the Commission has recently opened a broad-ranging sector enquiry into IP-related practices believed to hamper competition in pharmaceuticals.

European Commission opens sector enquiry into life-cycle management practices

On 15 January 2008, the European Commission paid surprise visits (so-called dawn raids) to a number of branded drug companies and to several generics companies. Contrary to the Commission's practice to date, these surprise visits were not prompted by allegations that the companies concerned had been involved in illegal practices. Instead, they signalled the start of an industry-wide investigation by the European Commission into certain IP practices in the pharmaceutical industry. The sector enquiry was launched because, in the words of Commissioner for Competition Neelie Kroes, 'innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed'. More specifically, certain practices involving (i) filing or exercising patents, (ii) vexatious patent litigation, and (iii) patent settlements are believed to block innovative and generic competition.

Following the surprise visits, the European Commission has sent extensive questionnaires to most branded drugs and generics companies in Europe, as well as to several pharmaceutical associations and other interested parties. The replies to these questionnaires, together with the materials collected at the surprise visits, will form the basis of an interim report that the Commission plans to issue towards the end of 2008. The definitive report will follow in 2009.

The fundamental differences between the US and EU pharmaceutical regulatory frameworks and their impact on antitrust enforcement

Several commentators have already remarked on the similarity between the subject matter of the EU sector enquiry and antitrust enforcement in the US with regard to both patent strategy by branded drug companies and patent settlements with generics companies. Yet, the legislative framework against which this US antitrust case law is being developed, and hence the rationale for these findings of infringement, is fundamentally different from the European regulations.

A detailed comparative study of the US and EU regimes is beyond the scope of this article, but we briefly touch on the most fundamental differences as we see them.

The mere issuance of a patent has not so far been held to be an infringement under US antitrust law. Rather, under the *Walker Process* doctrine, the enforcement of a patent may constitute an infringement if the patent has been fraudently obtained, the patent owner was aware that the patent had been obtained by fraud when it filed the infringement action, and the attempted enforcement affected competition.

In addition, the US regulatory framework is such that vexatious litigation (or 'sham' litigation) has the potential to be particularly harmful to generic entry. This is not the case in the EU. The US Hatch-Waxman Act encourages generics companies to enter the market prior to the expiry of the innovator's patents. It gives them 180 days marketing exclusivity if they assert (in what is known as a paragraph IV certification) that the patent is invalid or not infringed in their marketing authorisation application. Informed of this challenge, the branded drug company may file a patent suit, in which case the generic's marketing authorisation process will automatically be suspended until the earlier of patent expiration, or a favorable ruling in the patent litigation, or two-and-a-half years from the notice of paragraph IV certification. In the EU, in contrast, there is no such linkage between the grant of marketing authorisation and alleged patent infringement. The relevant authority will grant marketing authorisation, irrespective of such infringement. The patent holder will need to start litigation and, importantly, seek an injunction preventing the entry of the generic drug onto the market. This will require a prima facie case, as opposed to the US, where the stay in the authorisation process is automatic.

Turning to US settlement agreements between branded and generic firms, two points should be made. First, settlements too should be seen against the US regulatory background. If the branded drug company, having filed a patent suit, chooses to settle the case with the first generic applicant, no other generics may be able to enter the market until the first generic has had its (delayed) 180-day exclusivity on the market. In contrast, a settlement in the EU does not stop subsequent generic entrants unless further litigation is successful. By the same token, the impact of a settlement in the EU is bound to be less significant, except in the rare circumstance where only that one generic is expected to enter the market in the short term. Second, there remains significant controversy over whether and, if so, when, settlements risk infringing US antitrust rules. As noted, the FTC takes the position that reverse payment settlements (beyond de minimis payment of litigation costs) indicate collusion between the settling parties and should be close to per se unlawful. The DoJ favours an approach that recognises the public policy supporting settlements in general and pharmaceutical patent rights in particular. Although the contours of how it would be implemented are not clear, the DoJ advocates for a standard that examines in some truncated form the merits of the patent litigation and examines in some detail the settlement negotiations. We expect the antitrust implications of patent settlement agreements to remain in flux in the US.

The European Commission has chosen to conduct a sector-wide enquiry before, or instead of, launching infringement proceedings against individual companies. The enquiry may offer a unique opportunity for industry to influence the Commission's thinking here. At the same time, it is likely to educate the European Commission as to where its future enforcement priorities should lie.

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?

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 (see question 4).

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 body or 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 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'. At this stage, it is unsettled whether this legal obligation might justify restrictive supply or pricing policies, even if these have an effect to restrict parallel trade. Advocate General Jacobs takes the view that it does (see section 86 of his Opinion of 28 October 2004 in *Syfait*, case C-53/03) while Advocate General Ruiz-Jarabo takes a different view (see sections 94-98 of his Opinion of 1 April 2008 in *Lelos*, cases C-468-478/06)

4 Which laws govern the entry or approval of generic drugs?

See question 1. Article 10 of the Code Directive provides the basic framework for approval of generic medicines under the abridged marketing authorisation procedure. Under this procedure, provided certain conditions are met, the generic manufacturer is not required to submit pre-clinical and clinical testing results to the competent authorities.

Competition legislation

5 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, eg, 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.

6 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.

7 Which authorities investigate and decide upon pharmaceutical mergers and the anti-competitive effect of certain conduct 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.

8 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).

9 Do private parties have competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and through which means 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.

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

Not applicable.

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 84 to 92 of its Discussion Paper on article 82 of the EC Treaty). 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 Do non-government groups address antitrust concerns relating 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 reviewing mergers between two pharmaceutical companies?

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 pipeline products 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 2001 Remedies Notice (section 29), the Commission specifies that it 'may accept licensing arrangements (preferably exclusive licenses without any field-of-use restrictions on the licensee) as an alternative to divestiture where, for instance, a divestiture would have impeded efficient, on-going research' and it has adopted this approach in pharmaceutical merger cases.

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 8 and 84 of its 2005 Discussion Paper on article 82).

20 Have there been cartel investigations into 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 to be 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 (i) 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 (ii) 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 6).

22 To what extent are co-promotion and co-marketing agreements considered to be 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 When is an agreement with a competitor (actual or potential) 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).

Anti-competitive unilateral conduct

25 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*).

26 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 2005 Discussion Paper on article 82 of the EC Treaty, 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 Discussion Paper (section 40), 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 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 40 of the Commission's Discussion Paper on article 82).

28 To what extent can the application for the acquisition 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

Update and trends

On 15 January 2008, the Commission initiated a sector inquiry in pharmaceuticals. Article 17 of Regulation No.1/2003 gives it the power to launch such an enquiry 'where the trend of trade, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market'. In the course of such an inquiry, the Commission can make use of its traditional powers of investigation (ie, formal requests for information and surprise visits) to the extent that this is 'necessary for giving effect to' articles 81 and 82 of the EC Treaty.

In its January 2008 decision, the Commission identifies three types of conduct that might be anti-competitive: the use of patents, including 'de facto extended patent protection through unilateral conduct or agreements'; vexatious litigation; and collusive agreements, in particular settlement agreements in relation to patent disputes.

At the end of March 2008, the Commission sent out very detailed questionnaires to dozens of companies. It intends to issue an interim report in autumn 2008 and a final report in spring 2009.

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'.

29 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).

30 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. However, the EC Commission has identified patent settlements as possible infringements in its recent sector enquiry (see 'Update and trends').

Yet, 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).

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.

32 Does the practice of authorised generics raise issues under the competition law?

In the US, when a company's patent for a given medicine expires, re-labels 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.

Arnold & Porter LLP

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

Koloniënstraat 11
1000 Brussels
Belgium

Tel: +32 2 517 63 31
Fax: +32 2 517 66
www.aporter.com

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.

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise be infringing 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, Advocate-General Ruiz-Jarabo declined to do so. See question 3.

United Kingdom

Tim Frazer
Arnold & Porter LLP

Pharmaceutical regulatory law

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

The control of medicines in the UK is achieved primarily through the system of licensing and conditional exemptions from licensing laid down in EC legislation, the Medicines Act 1968 and in relevant subordinate legislation. Many of the provisions of the Medicines Act have now been superseded by regulations implementing EC legislation on medicines. This legislation covers, inter alia, the systems by which licences to manufacture, market, distribute, sell and supply medicinal products are granted by ministers (the Licensing Authority) (or, in the centralised system, by the European Commission) once they are satisfied about the safety, efficacy and quality of the product. There are controls also on clinical trials, on the claims that may be made in advertising, on quality control, manufacture of unlicensed products and imports. The Licensing Authority is also required to monitor the safety of licensed medicinal products, assess the public health implications of certain adverse effects and, if required, take appropriate regulatory action.

The statutory powers covering pharmaceutical pricing are in the National Health Service Act 2006 and subordinate legislation. In addition to the statutory scheme, the prices of branded medicines are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The 2005 PPRS is the latest in a series of voluntary agreements reached between UK governments and the pharmaceutical industry. Both the voluntary 2005 PPRS and the statutory scheme are administered by the Department of Health (DoH) staff in the Medicines, Pharmacy and Industry – Pricing and Supply Branch. Following a review by the Office of Fair Trading (see question 6), the 2005 PPRS is currently under discussion between the Department of Health and the pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry). It is likely that the scheme will change in relation to how new medicines are priced in the future.

2 Which body or bodies are entrusted with enforcing these regulatory rules?

The Medicines and Health Care products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe under normal conditions of use. The MHRA was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). The MHRA is accountable to the relevant health ministers in the UK for the discharge of functions they exercise collectively or singly as the Licensing Authority. Ministers of the Department of Health are accountable to parliament on matters concerning human medicines regulation. The Licensing Authority is advised by the Commission on Human Medicines (CHM), a statutory advisory body, on matters specified in the Act relating to medicinal products. Another statutory advisory committee established under the Medicines Act is the British Pharmacopoeia Commission which advises on matters relating to the quality and standards of medicines. Expert advisory groups may be established to advise on specialised topics relating to assessment of safety, quality and efficacy of medicines. The MHRA and the ministers are advised by a number of advisory committees set up to address issues relating to the development of regulatory policies on medical devices – eg, the Committee on Safety of Devices.

The MHRA Enforcement and Intelligence Group (E&I) has responsibility for enforcing medicines legislation in England and does so in Scotland and Wales on behalf of the Scottish parliament and Welsh Assembly. The E&I investigates cases and, where appropriate, brings criminal prosecutions. Department of Health solicitors usually advise on prosecutions. Officers have broad powers conferred by the Medicines Act 1968 and subordinate legislation to enter any premises to inspect, to take samples and to require production of any books or documents for the purposes specified in that Act. The E&I group is in close liaison with, among others, the UK police forces, HM Revenue and Customs, the Prescription Pricing Authority, and regulatory authorities throughout Europe and elsewhere in the world (eg, the US Food and Drug Administration).

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

Two of the main aspects of the legislation relevant to the application of competition law to the pharmaceutical sector are the regulations governing the approval of generic medicinal products and parallel trade in medicinal products in the EU. In particular, legislation impacts on systems adopted by pharmaceutical manufacturers and marketing authorisation holders to manage the effects of parallel trading and to delay the entry of generic competitors on the market.

4 Which laws govern the entry or approval of generic drugs?

The approval of generic medicinal products is governed by the same legal framework mentioned in question 1. In particular, the Medicines for Human Use (Marketing Authorisation etc) Regulations 1994 implement the relevant Community provisions relating to the approval of marketing authorisations for generic (or abridged) applications.

Competition legislation

5 Which legislation sets out competition law?

The Competition Act 1998 (the 1998 Act), as amended by the Enterprise Act 2002 (the 2002 Act) provides for general competition law in the UK. Chapter I of the 1998 Act prohibits agreements between undertakings, decisions of associations of undertakings or concerted practices that may affect trade within the UK and that have an anti-competitive object or effect (section 2(1)). There is an exception in sections 4 and 9 for agreements that improve production or distribution or that promote technical or economic progress, while allowing consumers a fair share of the benefit and which do not incorporate unnecessary restrictions or eliminate competition on the market. Chapter II prohibits the abuse of a dominant position if it may affect trade in the UK. The 1998 Act is expressed in terms very similar to articles 81 and 82 of the EC Treaty. Courts and agencies in the UK are required to ensure consistency in interpretation as between UK competition law and EC competition law.

The 2002 Act introduced the 'cartel offence', which imposes criminal liability on individuals who dishonestly agree, or cause others to agree, to enter into cartels. In addition, individuals may be disqualified from acting as directors of companies for up to 15 years for culpable breaches of competition law.

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

There are no guidelines specific to the pharmaceutical sector. The Office of Fair Trading (OFT) has issued a large number of guidelines on its website (www.oft.gov.uk/advice_and_resources/resource_base/legal/competition-act-1998/publications#named1), including many of relevance to the application of UK competition law to the pharmaceutical sector:

- Agreements and concerted practices (OFT 401);
- Abuse of a dominant position (OFT 402);
- Market definition (OFT 403);
- Powers of investigation (OFT 404);
- Enforcement (OFT 407);
- Trade associations, professional and self-regulating bodies (OFT 408); and
- Assessment of market power (OFT 415).

In addition to these guidelines, the OFT has conducted two 'market studies' into the pharmaceutical sector in the UK. The reports published by the OFT following these studies provide a useful insight into the way in which the OFT assesses pricing and distribution issues specific to the pharmaceutical sector. The two reports are:

- Pharmaceutical Price Regulation Scheme (2007) (www.oft.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation); and
- Distribution of Medicines in the UK (2007) (www.oft.gov.uk/advice_and_resources/resource_base/market-studies/medicines).

7 Which authorities investigate and decide upon pharmaceutical mergers and the anti-competitive effect of certain conduct in the pharmaceutical sector?

Mergers, including pharmaceutical mergers, are investigated by the OFT under the provisions of the 2002 Act. An investigation may be commenced proactively by the OFT or following notification by the parties. Notification is voluntary in the UK and, unless the OFT has issued an order preventing it, parties are free to complete a merger prior to obtaining consent. The OFT may only investigate mergers where the target's UK turnover exceeds £70 million or where the merger is horizontal and the combined market share is above 25 per cent. Where the OFT believes that a merger (proposed or completed) may lead to a substantial lessening of competition in any UK market, it will refer the transaction to the Competition Commission (CC). The parties may offer remedies in lieu of a referral to the CC. The CC will undertake an in-depth investigation and rule definitively on whether the merger is permitted or prohibited (or permitted subject to conditions).

Mergers affecting UK markets that exceed the thresholds laid down in the EC Merger Regulation will be determined by the European Commission unless the European Commission consents to an application by the UK authorities or the parties for the merger to be transferred to the OFT and CC, in whole or in part.

Anti-competitive conduct under chapter I or II of the 1998 Act is investigated by the OFT, which also has the power to determine whether the conduct infringes the 1998 Act and impose a fine. Investigations of the cartel offence are carried out by or on behalf of the OFT but can only be determined by the criminal courts in the UK.

Anti-competitive conduct that affects trade between EU member states must be assessed under EU law, and may be investigated by the European Commission or the OFT.

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

The OFT may impose penalties for infringements that are committed intentionally or negligently. It also has the power to impose interim orders to prevent or require conduct in the period prior to the final determination of an investigation. Penalties may not exceed 10 per cent of worldwide turnover. The OFT has published a detailed guidance on the calculation of penalties (www.oft.gov.uk/shared_oft/business_leaflets/ca98_guidelines/oft423.pdf). Under the approach adopted by the OFT, the starting point for the penalty is a percentage of the undertaking's turnover in the market affected by the infringement. This will depend on the seriousness of the infringement but will not be greater than 10 per cent of such turnover. This is then adjusted upwards (or downwards) based upon the duration of the conduct and to ensure that the penalty has a deterrent effect. Further adjustments are made for aggravating and mitigating factors.

There are also penalties for failure to comply with orders and directions made by the OFT or the CC. Criminal penalties may be imposed on individuals for the cartel offence of up to five years in prison and/or an unlimited fine.

In relation to pharmaceutical companies, the OFT fined Napp Pharmaceuticals £3.2 million (reduced to £2.2 million on appeal) in 2001 for predatory pricing in the hospital sector and charging excessively high prices in the community sector. Genzyme was fined £7 million (reduced to £2 million on appeal) in 2003 for margin-squeezing a competitor in a downstream market.

9 Do private parties have competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and through which means can they be obtained?

Private parties may bring actions in civil courts for damages and other civil remedies (such as an injunction) in connection with an

alleged infringement of UK or EU competition law. In addition, an action for damages may be brought before the Competition Appeal Tribunal, but only after the OFT or the European Commission has decided that UK or EU law has been infringed (so-called 'follow-on actions').

The National Health Service brought civil actions against certain generics manufacturers in an alleged price-fixing cartel. These were settled. In *Devenish Nutrition v Sanofi-Aventis and others* (2007), concerning a follow-on damages action in relation to a vitamins cartel, the High Court decided that only single compensatory damages were available for injury caused by price-fixing cartels.

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

The regulatory bodies are specified in question 2. They have no jurisdiction to apply or enforce competition law in the UK. The OFT and the CC are the only enforcing agencies for competition law (outside the regulated utility sectors). Since the pharmaceutical regulatory regime does not extend to competition law issues, no conflict arises. Certain elements of the regulatory regime, such as pricing, reimbursement and caps on the profitability of UK-based innovator pharmaceutical manufacturers, have an impact on the competitive nature of the UK pharmaceutical sector, but do not infringe UK competition law. This is fully discussed in the two OFT reports of 2007 on the pharmaceutical sector referred to in question 6.

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

As for all agreements assessed under the Competition Act 1998, there is an exemption for agreements that contribute to the improvement of production or distribution or which promote technical or economic progress. The need for stronger research and development capacity or other economies of scale or scope will be relevant in assessing the applicability of the exemption. However, pure industrial or regional policy factors (such as the need to strengthen regional industry or employment) could not be used to excuse an anti-competitive agreement or abusive conduct, or to ease concerns over a merger that would lead to enhanced market power.

12 Do non-government groups address antitrust concerns relating to the pharmaceutical sector?

The following organisations address antitrust concerns arising in the pharmaceutical industry: the Association of the British Pharmaceutical Industry; the Bio Industry Association; the British Association of European Pharmaceutical Distributors; the British Association of Pharmaceutical Wholesalers; the British Generic Manufacturers Association; the Ethical Medicines Industry Group; the National Pharmacy Association; and Which?.

Review of mergers

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

Sector-specific features are taken into account insofar as each merger assessed by the OFT or the CC is determined on its own facts. Otherwise, mergers in the pharmaceutical sector are not subject to any special legal regime or distinct analytical framework. Most mergers involving pharmaceutical companies active in the UK are assessed under the EC Merger Regulation by the European Commission. For that reason, the OFT and the CC have relatively little case law except in relation to mergers concerning pharmaceutical distribution companies.

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

The OFT and the CC have not recently examined a merger relating to overlaps in pharmaceutical products, but have examined a number of transactions relating to pharmaceutical distribution and pharmaceutical-related products. In pharmaceutical-related mergers assessed by the OFT, the following market definitions have been used: over-the-counter medicines supplied by wholesalers to pharmacies in the UK: the supply of ethical medicines to dispensing doctors, retail pharmacies and hospitals in a region of the UK; the supply of non-sterile 'specials' (unlicensed medicinal products prescribed when a licensed product does not last) to hospitals and pharmacies in the UK; and specialised pharmaceutical data services.

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

Overlaps between product markets in the UK will be seen as problematic where it might be expected to lead to a substantial lessening of competition. Combined market shares of less than 25 per cent will not usually give rise to concerns. Overlaps will be assessed not only in relation to actual competition, but also in relation to pipeline products (potential competition) so long as the pipeline products are reasonably close to the marketing stage.

16 When is an overlap with respect to pipeline products likely to be problematic?

See question 15.

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

Divestment of overlap products to suitable purchasers will be the preferred remedy. It is open to the CC to require licences on suitable terms as a form of remedy. Remedies that clearly remove identified concerns can be offered to the OFT in lieu of a reference to the CC.

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?

Under the 2002 Act, a merger situation arises where an undertaking acquires control over an enterprise – defined as the activities or part of the activities of a business. An enterprise may consist of a patent or a licence if it comprises a business activity – in other words if it has turnover associated with it that can be transferred to the acquiror. If there is no such identifiable turnover, or if it cannot be transferred, then the acquisition of a patent or licence will not be a merger subject to control under the UK legislation.

Anti-competitive agreements

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

UK law on agreements and practices is contained in the 1998 Act as amended by the 2002 Act (see question 5). Any agreements

that have as their object or effect the prevention, restriction or distortion of competition within the UK and that may affect trade in the UK, are prohibited. Any abuse of a dominant position in the UK, which may affect trade in the UK, is also prohibited.

20 Have there been cartel investigations into the pharmaceutical sector?

An investigation into an alleged cartel relating to generic antibiotics and Warfarin was launched by the Serious Fraud Office as a criminal fraud case (prior to the introduction of the 'cartel offence' under the 2002 Act). Criminal charges were laid against a number of company directors in 2006. In March 2008, the House of Lords ruled that price fixing did not in itself amount to a conspiracy to defraud. The case may now be re-presented to the criminal courts in an amended form. The NHS brought parallel civil actions for damages in relation to the loss suffered by the public. These actions were settled without admission of liability on payment of monies by several generics manufacturers.

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

Consistent with the approach of the European Commission, a technology licensee may not be obliged to share its own improvements to or new applications of the licensed technology with the licensor. Other 'hard-core' and non-exemptible licence provisions are listed in the EC block exemption for technology transfer licensing agreements (Regulation (EC) No 772/2004), eg, restraints on the pricing freedom of the other party or reductions on output.

Assuming there are no hard-core or non-exemptible restrictions, licences will be automatically exempt under the block exemption if the shares of the parties in the product or technology markets do not exceed 20 per cent combined if the licensor and licensee are competitors in either such market, or 30 per cent each if they are not competitors.

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

Co-promotion and co-marketing agreements can be efficiency-enhancing where they lead to products being introduced to markets in the UK that would otherwise have been inaccessible to the licensor. Like all licence agreements, co-promotion and co-marketing agreements may have an anti-competitive effect where concluded between actual or potential competitors – eg, if they have the effect of a market-sharing agreement or where they exclude the possibility of competing on price. As noted in the EU chapter on EC law, the European Commission has not objected to co-promotion or co-marketing agreements between competitors.

23 When is an agreement with a competitor (actual or potential) likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

Agreements with competitors are more likely to have an anti-competitive effect merely because of their horizontal nature. Any agreement between pharmaceutical companies who are active in the same therapeutic area (or have pipeline products in the same area) may affect competition between them. This will be particularly important where they are both active in the UK. Any agreement that affects the way in which they may compete for UK purchasers will likely be prohibited unless clear efficiency justifications may be demonstrated.

However, some agreements between actual or potential competitors may be efficiency-enhancing, where they facilitate more effective competition in the market and do not incorporate any unnecessary restrictions. Cross-licences of intellectual property rights in the context of a joint research agreement, agreements for the development of composite therapies or advances delivery methods, joint bidding agreements, and joint purchasing agreements may all be efficient or have no anti-competitive effect in certain circumstances, or both. It will be important to take account of all market features in assessing such agreements, including market shares, the nature of competition between the relevant products or technologies, the impact on other activities of the participants, etc. It is also important to consider the impact of such agreements in the technology licensing market as well as the product market concerned.

In some cases, the EC Commission may insist on internal arrangements to ensure that there is no unnecessary exchange of information between parties to a cooperation agreement.

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

The OFT's report into the distribution of medicines in the UK (see question 6) drew attention to competition concerns that arise where pharmaceutical manufacturers agree with wholesalers to deal exclusively with one wholesaler, or where they deliver direct to pharmacies (through their own infrastructure or by using a logistics agent). The OFT confirmed that pharmaceutical companies are free to organise distribution according to their own needs, and that exclusive arrangements may be more efficient. However, it also drew attention to concerns about intra-brand competition where significant numbers of pharmaceutical manufacturers opt for exclusive arrangements or direct-to-pharmacy delivery. The OFT highlights reduction in price competition (through lower levels of discounts to pharmacies) and lower service levels as being potential dangers.

Competition issues may also arise in vertical agreements in relation to export or import bans within the EU, reserved customers lists and resale price maintenance. Vertical agreements in the UK are not subject to any specific UK block exemption, but benefit from the approach identified by the EU in Regulation (EC) No. 2790/1999 (vertical block exemption regulation) and in the European Commission's guidelines on vertical restraints.

Anti-competitive unilateral conduct

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

Abuse of dominance under the 1998 Act is assessed in the same way as article 82 of the EC Treaty. In the UK, two abuse cases have been decided against pharmaceutical companies. In *Napp Pharmaceuticals*, the OFT fined Napp for heavily discounting sales of its sustained-release morphine tablets and capsules to the hospital sector, and then charging what were regarded as excessive prices in the community sector once patients had began treatment with the product.

In *Genzyme*, the OFT fined Genzyme for squeezing the margin of a service provider in a downstream activity (home health care) by selling the product to the competitor at a price at which it could not compete with Genzyme's own activities in that downstream market.

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

The definition of dominance in the UK follows the approach of article 82 of the EC treaty. Dominance is defined as 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 its consumers.

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

Ownership of a patent or an exclusive patent licence does not itself denote dominance. The question of dominance requires an assessment of the substitutability of other patented or unpatented products or processes. Where the patent constitutes an important barrier to entry because of lack of substitutability from other products or processes, that may confer on its owner or exclusive licensee, or both, the power to behave independently of competitors, customers and consumers. Such power is an indicator of dominance.

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

An application for (or enforcement of) a patent might give rise to antitrust liability where it forms part of a 'patent ambush'strategy associated with the development of a standard. However, even in these cases, there is a strong argument that the application or enforcement itself is not an antitrust infringement, but the exercise of patent rights may be (such as charging discriminatory or excessive royalties).

The misuse of patent applications may also give rise to liability, as the European Commission found in the *AstraZeneca* case.

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

As in the EU, patent enforcement by a dominant enterprise that is an abuse of the court process, because intended only to raise rivals' costs rather than as a genuine attempt to protect legal rights, may be regarded as an abuse of dominance.

Update and trends

The renegotiation of the Pharmaceutical Price Regulation Scheme will have a significant impact on the pricing and reimbursement of medicines in the UK. The OFT report into the distribution of medicines in the UK, while not requiring any specific changes in the conduct of agreements of pharmaceutical companies, has highlighted the possible concerns of a widespread migration of manufacturers to exclusive distribution or exclusive logistics agreements or direct-to-pharmacy arrangements.

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

A patent settlement agreement can be assessed, in the same way as any other agreement, for its anti-competitive object or effect. Particular care should be taken when the settlement divides the product market between the disputing parties along geographical lines (rather than by separating the parties' rights by reference to technology or end-application markets). Normally, genuine attempts to settle patent disputes where the outcome of the dispute is uncertain, disproportionately expensive or time consuming, or both, will be safe from antitrust attack so long as the solution is the least restrictive way that the dispute may reasonably be settled.

However, patent settlements under which generics manufacturers are compensated for refraining from bringing new products to market, often in consideration for a cash settlement, will attract potential scrutiny. The EU sector enquiry concerning generic competition in pharmaceutical concerns the UK industry in the same way as in other member states.

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

Life-cycle management strategies may be examined under UK competition law if they unfairly delay or limit generic competition. See also question 30.

Arnold & Porter LLP

Tim Frazer **tim.frazer@aporter.com**

Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6124
Fax: +44 20 7786 6299
www.arnoldporter.com

32 Does the practice of authorised generics raise issues under the competition law?

Authorised generics may raise concerns where the first-mover advantage of the authorised manufacturer, or other elements of the arrangements between the parties, limits competition on the generics market or causes the price of generics to be pegged at a level higher than it would have been in the absence of an authorisation arrangement.

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

The pricing and demand structure in pharmaceutical markets are specific to that sector, and are relevant in assessing the possible anti-competitive effect of conduct. Demand for medicines is to a large extent in the hands of public authorities, who also determine the price at which drugs are reimbursed by the state. Patients (consumers) do not generally select which drugs to consume; that decision is taken on their behalf by physicians, who do not participate in the purchasing decision. The OFT and UK courts will have regard to the findings of the EU's Court of First Instance that have accepted the relevance of these features. However, this is currently subject to ambiguity following the Opinion of Advocate General Ruiz-Jarabo in the ECJ case *Sot Lélos v GlaxoSmithKline*.

United States

Asim Varma and Barbara Wootton
Arnold & Porter LLP

Pharmaceutical regulatory law

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

The US laws governing the authorisation and marketing of pharmaceuticals (that require a doctor's prescription) are codified in the Food, Drug and Cosmetic Act (FDCA) and enforced by the Food and Drug Administration (FDA) (see 21 USC section 355). Generally, the FDA regulates every facet of pharmaceuticals including testing, manufacturing, labelling, advertising, marketing, efficacy and safety.

There is no legislation in the United States that regulates the pricing of pharmaceuticals to commercial payers. The Medicaid Drug Rebate Statute (the drug rebate statute) requires manufacturers to enter into rebate contracts with the federal government in order to have their products covered by government insurance programmes (see 42 USC section 1396r-8). The rebate agreements require the manufacturers to supply their products to the government at the lowest price (net of rebates) offered to other purchasers, that is, the manufacturer's 'best price'. Other statutes also cap prices for drugs purchased by certain government entities or entities that receive government funding to treat low income individuals (see, eg, 38 USC section 8126 (Veterans Health Care Act); 42 USC section 256b).

In addition, the marketing of pharmaceuticals is subject to the Medicare-Medicaid Anti-Fraud and Abuse Act (the anti-kickback statute), which, subject to certain safe-harbour provisions, prohibits providing or receiving anything of value to induce a person to use a drug paid for by a federal government insurance programme (42 USC section 1320a-7b(b)(2)). Many states have similar laws. Some states have also imposed limits on gifts that pharmaceutical companies can give physicians and other states require companies to report all gifts provided to physicians in the state (see, eg, California Health & Safety Code, section 119402; Maine Revised Statutes Annotated, title 22, section 2698-A).

2 Which body or bodies are entrusted with enforcing these regulatory rules?

The FDA has the responsibility to authorise and regulate the marketing of pharmaceuticals. The Centers for Medicare and Medicaid Services administers the Medicaid Drug Rebate Program. The anti-kickback statute and the drug rebate statute are enforced by the Department of Justice (DoJ) and the Office of the Inspector General of the Department of Health and Human Services. Individual states enforce their own anti-kickback laws and can enforce the drug rebate statute under state False Claims Acts.

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

The FDCA and federal and state statutes governing drug marketing or drug rebate programmes do not directly address the application of competition law in the pharmaceutical sector. However, the FDCA provisions relating to the approval of generic drugs, described in response to question 4, have encouraged competition from generic drugs and established a framework to balance the incentives that patent rights provide for continued innovation by brand-name firms with entry by generic drug firms.

4 Which laws govern the entry or approval of generic drugs?

The Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 USC section 355, known as the Hatch-Waxman Act, governs the approval of generic drugs. The Act allows FDA approval of a drug through the abbreviated new drug application (ANDA) process, which permits the generic drug manufacturer to rely on the FDA's finding of safety and efficacy of a previously approved brand-name drug without submission of a full new drug application (NDA).

At the time an NDA is filed it must include information about patents that claim the drug. The FDA is required to list the patent information in an agency publication entitled 'Approved Drug Products with Therapeutic Equivalence', commonly known as the Orange Book. The ANDA application must include a certification regarding any patents listed in the Orange Book that claim the referenced brand name drug. Under one form of certification, known as a 'paragraph IV certification', the ANDA applicant certifies that the patents listed in the Orange Book are either invalid or unenforceable or will not be infringed by the manufacture, use or sale of the generic drug. The paragraph IV certification must be provided to the patent owner and NDA holder for the listed drug. If the NDA sponsor or patent owner files a patent infringement suit within 45 days of the receipt of the certification, the FDA may not approve the ANDA until the earliest of (i) the date the patent expires; (ii) a court decision in the patent infringement case; or (iii) the expiration of 30 months from receipt of the paragraph IV certification. To encourage generic drug manufacturers to challenge patents, the Act provides that the first generic manufacturer to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity.

Since January 2004, agreements (including settlements of paragraph IV litigation) between a brand name company and a generic applicant relating to the 180-day exclusivity or which concern the manufacture, marketing or sale of the brand drug or of the generic drug must be filed with the Federal Trade Commission (FTC) and the DoJ. See title XI, subtitle B, section 1112 of

the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

The Act does not include biologics, ie, drugs created from living cells or through biotechnology, in the ANDA approval process. Biologics are approved pursuant to a biologics licensing application (BLA) instead of an NDA and, as of March 2008, no avenue exists for the approval of generic copies of BLA drugs.

Competition legislation

5 Which legislation sets out competition law?

The principal US competition laws are the Sherman Act, the Clayton Act, the Robinson-Patman Act, and the Federal Trade Commission Act (FTC Act). Section 1 of the Sherman Act prohibits concerted activity that unreasonably restrains trade. Section 2 of the Sherman Act outlaws monopolisation, attempted monopolisation, and conspiracies to monopolise. Section 7 of Clayton Act prohibits mergers and acquisitions where 'the effect of such acquisition may be to substantially lessen competition, or to tend to create a monopoly.' Section 7A of the Clayton Act, otherwise known as the Hart-Scott Rodino Act, requires parties to mergers and acquisitions meeting certain thresholds to file notifications with the US antitrust authorities prior to consummating such transactions. The Robinson-Patman Act prohibits price discrimination in the sale of commodities, including pharmaceuticals. Section 5 of the FTC Act prohibits 'unfair methods of competition'. The FTC has asserted authority under section 5 to challenge conduct that may not violate the Sherman Act. See, eg, *In re Negotiated Data Servs*, FTC file no. 051 0094, (23 January 2008). State antitrust laws generally have been construed to apply the same standards as federal antitrust laws.

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

There are no guidelines promulgated by the US antitrust authorities that are specifically directed at the pharmaceutical sector. The FTC and the Antitrust Division of the DoJ have jointly issued generally applicable competition guidelines, including the Antitrust Guidelines for the Licensing of Intellectual Property (1995), the Horizontal Merger Guidelines (1992) and the Antitrust Guidelines for Collaborations Among Competitors (2000).

7 Which authorities investigate and decide upon pharmaceutical mergers and the anti-competitive effect of certain conduct in the pharmaceutical sector?

The DoJ and the FTC share jurisdiction for the enforcement of US antitrust laws. There is no statutory allocation of responsibility between the agencies and responsibility for investigating matters is determined through an informal 'clearance' process between the agencies based on each agency's industry expertise. The FTC generally handles investigations relating to pharmaceutical markets, including review of pharmaceutical mergers. The DoJ has sole authority to prosecute cartel activity such as price fixing and bid rigging as antitrust criminal violations for all industry sectors. State attorneys general also have jurisdiction to investigate conduct under either federal antitrust or state antitrust laws.

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

For criminal antitrust violations, the DoJ may seek fines against offending companies in an amount double the gain obtained by cartel participants or double the loss suffered by victims of the cartel. Individual executives also can be subject to fines and imprisonment. For certain procedural civil violations, such as HSR Act violations, and breach of consent decrees, the agencies can seek civil fines. For substantive civil violations, the agencies may seek injunctive relief. Some courts have interpreted the express authorisation to seek broad equitable remedies, such as injunctions and restraining orders, as implied authority to seek all equitable remedies including restitution and disgorgement. To date only the FTC has exercised its implied authority to seek monetary equitable remedies. See *FTC v Mylan Labs*, 62 F Supp 2d 25 (DDC 1999) (upholding FTC right to seek disgorgement).

9 Do private parties have competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and through which means can they be obtained?

Private parties are entitled to recover treble their damages from the anti-competitive conduct as well as attorneys' fees and injunctive relief (15 USC sections 15(a) and 26). Competitors and direct purchasers, such as drug wholesalers, generally have the right to sue for damages under federal antitrust law. Indirect payers, which in the United States can include consumers and private insurers, can sue for damages under many state antitrust or consumer protection laws. Direct and indirect purchaser suits often are brought as class actions. State attorneys general also can sue under the federal antitrust laws on behalf of the state as a direct purchaser or proceeding as parens patriae on behalf of its citizens, ie, on behalf of indirect purchasers.

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

The FDA implements the Hatch-Waxman Act but does not address or apply general competition rules to the pharmaceutical sector.

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

Antitrust concerns cannot generally be addressed by industrial policy arguments.

12 Do non-government groups address antitrust concerns relating to the pharmaceutical sector?

Non-governmental groups are active in petitioning the government on the authorisation, marketing and pricing of pharmaceuticals. From time to time, they address antitrust concerns relating to the use of intellectual property and life-cycle management strategies and their effect on competition. Non-governmental entities have also assisted consumers and direct purchasers in bringing litigation challenging settlements of paragraph IV patent litigation.

Review of mergers

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

The US antitrust authorities apply the same substantive test for mergers in the pharmaceutical sector that they apply in other

sectors (see Horizontal Merger Guidelines (1992)). The ultimate question is whether the transaction will lead to a substantial lessening of competition in a goods market or reduced innovation in an innovation market. Unique features of the pharmaceutical industry, such as substantial sunk costs and long timelines involved in the extensive research and development and regulatory approval process are taken into account in assessing whether entry sufficient to counteract the anti-competitive effects of the merger likely would occur in a timely manner.

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

Courts and the federal enforcers have adopted a variety of product market definitions relating to pharmaceuticals. In some cases, the relevant product market has been defined by the treatment or disease indications for the which the drug is approved (or, if in clinical trials, will be seeking approval), though prescription and non-prescription drugs are generally deemed to be in separate markets. In other cases, markets are defined more narrowly, often on the basis of a mechanism of action (for example, two drugs that treat a specific cancer through different mechanisms would not be deemed in the same market). Other cases have limited markets to drugs used to treat a specific condition that have the same dosage form (such as injectable versus tablet). The agencies have also taken the position that in some cases a product market can be defined to include only a brand name and its generic equivalents or even just generic equivalents, excluding the branded drug. The geographic relevant market is generally viewed as the US domestic market because the FDA's drug authorisation authority is restricted to the US.

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

The focus of government merger analysis is on structural competitive effects. The government applies two broad analytical frameworks in assessing competitive effects: (i) does the merger increase market power by facilitating coordinated interaction among rival firms and (ii) does the merger enable the merged firm to unilaterally raise price or otherwise exercise market power? In pharmaceutical markets, the primary concern is usually unilateral effects. Regardless of the theory of competitive harm, market share and concentration play an important role in the analysis. A merger in a market in which all participants have low shares usually requires no significant investigation while mergers in markets with high concentrations, which is not uncommon for pharmaceutical product overlaps, require additional analysis. Section 1.51 of the 1992 Horizontal Merger Guidelines sets forth the general standards, based on market shares and concentration, that the government uses to determine whether a proposed merger ordinarily requires further analysis. See also FTC and DoJ Commentary on the Horizontal Merger Guidelines (2006). Generally, the unilateral effects challenges made by the government involved combined shares of more than 35 per cent.

16 When is an overlap with respect to pipeline products likely to be problematic?

Pipeline products play a role in the competitive effects analysis for pharmaceuticals because of the long timeline and large sunk costs associated with drug development and FDA approval. While the agencies have not drawn any bright lines, a drug in the later stages of pre-approval clinical trials (phase II or phase III) will usually be treated the same way as a marketed product for purposes of analysing competitive effects. A merger of firms also involves the combination of research and development programmes, which has the potential to reduce competition in overlap areas and result in one or both firms forgoing the development of pipeline drugs in the pre-clinical stage. Thus, the government also assesses the competitive effects of a pharmaceutical merger on innovation markets and will assess the potential impact on pre-clinical pipeline products.

One interesting example involved the effect of a pipeline product on impact of competition from generic entry. In the *Cephalon/Cima Labs* merger, Cephalon marketed the only FDA approved product and was in the process of developing a new formulation for launch. Cima had a product in phase III clinical trials. The FTC alleged that the acquisition could delay or end the launch of the Cima product and also 'undermine generic entry' by allowing Cephalon to shift patients to the patent-protected product 'prior to generic launch, depriving consumers of the full benefits of generic competition' (Analysis of Proposed Consent Order to Aid Public Comment, *In re Cephalon, Inc and CIMA Labs, Inc*, FTC File No. 041-0025 (9 August 2004). The FTC required Cephalon to license and transfer all know-how for its approved product to a generic manufacturer).

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

The remedy preferred by US agencies in any transaction that they believe is likely to result in anti-competitive effects is divestiture of one of the merging firm's assets in the market adversely affected. The government will either require that the package of divested assets include all components of the business or that those components not included be otherwise economically available. Such components generally include manufacturing facilities, research and development capability, technology and other intellectual property, access to personnel, marketing and distribution capabilities, customer relationships, capital resources and anything else necessary to compete effectively. In some cases, the FTC has accepted licensing of IP rights rather than divestiture as remedy to restore pre-merger levels of competition. For example, in the *Amgen/Immunex* merger, Amgen had a TNF inhibitor in development while Immunex had one of two drugs already on the market. Competitors had two other drugs in development. A third competitor, Sereno was developing a drug in Europe but did not have the patents rights necessary to sell the product in the US. The FTC required Amgen to license patent rights to Sereno so it could compete in the US and thereby maintain pre-merger levels of competition. Amgen retained rights to develop its product (*In re Amgen, Inc and Immunex Corp*, docket no. C-4056 (12 July 2002)).

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?

The acquisition of a patent is subject to reporting requirements if it is valued at or above the HSR reporting thresholds. This reporting requirement applies even if the acquiring party is required to give the seller a licence or the acquiring party must take the intellectual property rights subject to pre-existing licence grants. The grant of an exclusive patent licence (one that is not subject to existing licences) is also reportable if the regulatory reporting thresholds are met.

Anti-competitive agreements

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

Section 1 of the Sherman Act prohibits agreements that unreasonably restrain trade. Horizontal agreements, ie, agreements between competitors, are subject to stricter scrutiny than vertical agreements, eg, agreements between a manufacturer and its distributor. Certain categories of horizontal agreements are per se unlawful, including agreements:

- fixing prices or other terms of sale;
- to limit output;
- to allocate geographic territories or customers; and
- that are deemed group boycotts.

Agreements between competitors that may produce efficiencies, such as research and development agreements or joint production agreements, are analysed under the rule of reason. Under a rule of reason analysis, courts review the totality of circumstances, including market structure and the economics of the agreement to determine whether the pro-competitive effects exceed the anti-competitive effects of the conduct. The Antitrust Guidelines for Collaborations Among Competitors (2000) (Competitor Collaboration Guidelines) describe the analytical framework the agencies will apply in analysing competitor collaborations including safe harbours where the participants collectively account for no more than 20 per cent of any affected relevant market.

20 Have there been cartel investigations into the pharmaceutical sector?

In the past decade, the US enforcement agencies have not made public any cartel investigations in the pharmaceutical sector.

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

Technology licensing agreements in the pharmaceutical sector are examined under the same antitrust framework as technology licensing agreements in other sectors. The Antitrust Guidelines for the Licensing of Intellectual Property (the IP Guidelines) set forth the approach of the antitrust agencies in analysing whether licenses are anti-competitive. The IP Guidelines proceed from three general principles:

- the antitrust agencies regard intellectual property as essentially comparable to other forms of property;
- intellectual property is not presumed to create market power; and
- intellectual property licensing generally is pro-competitive because it allows firms to combine complementary factors of production.

Licensing restrictions are analysed under the rule of reason, unless they involve conduct that traditionally is viewed as per se unlawful under US antitrust law (eg, horizontal price-fixing). For licensing restrictions that are not subject to per se condemnation, the IP Guidelines provide a 'safety zone' where the parties involved account for less than 20 per cent share of each market affected by the licensing arrangement.

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

The Competitor Collaboration Guidelines describe the analytical framework the US enforcement agencies apply in analysing co-promotion and co-marketing arrangements. The agencies evaluate whether such agreements involve a true integration of resources in a way that is efficiency-enhancing, ie, may lead to lower prices, better products, faster time to market or otherwise benefit consumers. Such arrangements will be considered anti-competitive if they increase market power or facilitate the exercise of market power by limiting independent decision-making or by combining in the collaboration control over competitively significant assets.

23 When is an agreement with a competitor (actual or potential) likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

So-called 'naked' agreements among competitors that involve coordination on pricing, output, or allocate customers raise serious antitrust concerns and are typically deemed illegal per se, without regard to any purported pro-competitive justifications. However, joint ventures that have the potential to increase efficiency, reduce costs, or bring new products to market (including research, manufacturing or marketing joint ventures), will generally be analysed under the rule of reason and will not raise antitrust concerns if on balance their competitive impact will be neutral or benign. A common concern in even pro-competitive joint ventures is that they may result in anti-competitive 'spillover' effects on products that are not included in the joint venture. Parties can reduce the risk that a collaboration will be found to facilitate collusion if they establish appropriate safeguards to govern information exchange; for example, by limiting access to competitively sensitive information only to certain individuals or to independent third parties.

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

Vertical agreements are evaluated under the rule of reason to determine whether the anti-competitive effects outweigh pro-competitive effects. While vertical agreements can be challenged under either section 1, as unreasonable restraints of trade, or section 2, as exclusionary conduct by a dominant firm, vertical agreements that raise antitrust concerns are alleged to unreasonably foreclose competitors' opportunities to compete. In the pharmaceutical sector, recent vertical agreement challenges involve exclusive dealing, loyalty discounts, and bundling. For example, the FTC and state attorneys general brought restraint of trade and monopolisation claims alleging that drug manufacturer Mylan Laboratories' exclusive licensing arrangements for the supply of an essential raw material for a drug foreclosed competition and allowed Mylan to dramatically increase the price of the drug (see *FTC v Mylan Labs, Inc*, 62 F Supp 2d 25 (DDC 1999)). Private parties also have challenged as unlawful exclusive dealing pharmaceutical manufacturer's contracts with private insurers where rebates were provided in exchange for coverage of the drug (see, eg, *JBDL et al v Wyeth-Ayerst Labs*, 485 F3d 880 (6th Cir 2007)).

Anti-competitive unilateral conduct

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

Section 2 of the Sherman Act prohibits monopolisation, attempts to monopolise and conspiracies to monopolise. Illegal monopolisation requires the possession of monopoly power and the

Update and trends

The hot topic in pharmaceutical and antitrust regulation will continue to be the treatment of reverse payment settlements of paragraph IV patent infringement litigation between brand name and generic firms.

In February 2008, the FTC brought a complaint in federal court challenging brand drug manufacturer Cephalon's settlement agreements with four generic firms with pending ANDAs to sell the drug Provigil. The FTC alleges that these settlements, which involved side agreements providing payments by Cephalon to the generic firms, caused the generic firms to delay entry until 2012 (Complaint, *FTC v Cephalon Inc*, No.: 1:08-cv-00244 (DDC 13 February 2008)).

The FTC has challenged similar settlements in the past resulting in consent orders with the brand name and generic firms (see, eg, *In the Matter of Abbott Labs*, Docket No. C-3945 (26 May 2000); *In the Matter of Hoechst Marion Roussel Inc*, Docket No. 9293 (4 April 2001)). However, litigation, including one filed by the FTC, has not been as successful, with courts reaching diverging conclusions as to the appropriate standard to apply in determining whether reverse payment settlements are anti-competitive. In *Schering-Plough Corp v FTC*, 402 F3d 1056 (11th Cir 2005), the Eleventh Circuit Court of Appeals reversed a unanimous decision by the FTC and held that a reverse payment settlement was lawful under the antitrust laws. The Eleventh Circuit found that the payments were bona fide consideration for drug licences from the generic firm and not payments to keep generics off the market. Moreover, since the date generics could enter was prior to the expiration of the patent the settlements were deemed to be within the patent's lawful exclusionary power and therefore not anti-competitive. Similarly, the Second Circuit Court of Appeals held that reverse payment patent settlements do not constitute a per se antitrust violation and held that the focus of the analysis should be on whether the exclusionary effects of the settlement exceeded the exclusionary scope of the patent. *In re Tamoxifen Citrate Antitrust Litigation*, 429 F3d 370 (2d Cir 2005).

The US antitrust enforcement agencies are themselves split over how to assess the competitive effects of reverse payment settlements. The FTC takes the position that any cash consideration (beyond de minimus litigation costs) to the generic is to compensate the generic for delaying market entry and therefore a restraint in trade. While the DoJ also has concerns about such settlements, differences between the agencies' views on how they should be evaluated came to light when the solicitor general of the United States (the government's advocate in the Supreme Court) and the Antitrust Division of the DoJ filed a brief opposing the FTC's petition for a writ of certiorari to the Supreme Court for review of the Eleventh Circuit's ruling in *Schering*. The DoJ argued that the FTC's position does not adequately take into consideration public policy in favour of settling litigation or the patent grant permitting right of patentees to exclude competition within the scope of the patent. According to the DoJ, the proper standard for evaluating such reverse settlements should include an objective assessment of the merits of the patent claims, viewed ex ante, and other relevant factors surrounding the parties' negotiations of the reverse payment settlement (Brief for the United States as Amicus Curiae, *FTC v Schering-Plough Corp*, 126 S Ct 2929 (2006) (No. 05-273).

Following the appellate setbacks in the *Schering-Plough* and *Tamoxifen* cases the number of reverse payment settlements increased. The FTC threatened to bring another reverse payment challenge to create a split among the US Courts of Appeals and thereby increase the chances that the US Supreme Court will review the issues presented. The *Cephalon* complaint is an attempt to do exactly that.

acquisition, enhancement, or maintenance of that power through exclusionary conduct. Attempted monopolisation requires showing that a defendant (i) engaged in exclusionary conduct, (ii) with a specific intent to achieve a monopoly, and (ii) with a 'dangerous probability' of success. Section 2 does not prohibit the possession of monopoly power, but rather prohibits the abuse of monopoly power by exclusionary conduct. Types of exclusionary conduct that can create antitrust liability under section 2 include vertical restrictions limiting competitors' access to markets or supplies (eg, exclusive dealing, tying, loyalty discounts, and bundling), predatory pricing, misuse of governmental and standards-setting processes, and improper patent enforcement. In rare cases, a refusal to deal with a competitor has been deemed anti-competitive.

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

To be considered dominant, ie, have monopoly power, a party must have the ability to control price or exclude competition in a properly defined relevant market. While there are no bright lines and an assessment of the competition in the relevant market is necessary, most cases require a market share of at least 70 per cent to support a monopolisation claim, and courts have rarely found monopoly power where shares are below 50 per cent. The 'dangerous probability of success' required for an unlawful attempt to monopolise claim generally requires a share of at least 50 per cent, and shares below 30 per cent have rarely sufficed to support an attempt claim. US antitrust law does not recognise joint dominance of a market.

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

A patent holder will not be presumed to have market power simply because it holds a patent. See *Illinois Tool Works v Independent Ink*, 547 US 28 (2006). Courts and the antitrust enforcement agencies will examine the effect of the patent on competition in assessing the degree to which it confers market power. See IP Guidelines.

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

Application to the patent office and the issuance of a patent does not, standing alone, expose the patent owner to liability for an antitrust violation. However, if the patent is granted as a result of fraud or inequitable conduct before the patent office, liability

may arise if and when a patent owner attempts to improperly enforce such patent. Acquisition of a patent from a third party is subject to the rules governing asset acquisitions.

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

Enforcement of a patent can create antitrust liability if the patentee knowingly enforces a fraudulently obtained patent or, alternatively, if the patent owner filed an infringement suit (i) that was 'objectively baseless' in that no reasonable litigant could realistically expect success on the merits, eg, the patent owner bringing the suit knew the patent was not infringed, not enforceable, or not valid; and (ii) for the purpose of harming a competitor.

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

The FTC and private parties have challenged as antitrust violations 'reverse payment settlements' of Hatch-Waxman patent litigation. In reverse payment settlements, the NDA holder pays the generic ANDA filer cash or non-cash consideration to settle the patent challenge and delay entering the market. (See 'Update and trends' for more detailed discussion.)

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

Recently, antitrust plaintiffs have challenged product or market 'switching' practices whereby a brand drug company introduces a new drug when an older drug is about to lose patent protection, in some cases withdrawing the NDA for the old drug, thereby precluding an ANDA application for a generic version. Private parties have alleged such practices are anti-competitive attempts to switch patients to new, but not necessarily better, drugs and hamper generic competition. In *Abbott Labs v Teva Pharm USA*, 432 F Supp 2d 408 (D Del 2006), plaintiffs alleged that Abbott and Fournier's product reformulation and simultaneous withdrawal of the NDA of an earlier formulation of TriCor had the intent and effect of precluding generic entrants and constituted illegal monopolisation. The court held that plaintiffs had adequately plead an antitrust claim and focused on the withdrawal of the NDA as potentially reducing consumer choice (id at 422). In contrast, another court dismissed a monopolisation claim where plaintiffs alleged Astrazeneca introduced patent-protected Nexium, a 'virtually identical drug' to its prior formulation, Prilosec, in an effort to switch patients away from Prilosec before it went off-patent and would be subject to state laws mandating generic substitution (*Walgreen Co v AstraZeneca Pharms*, no. 06-2084 (RWR) (DDC 25 February 2008)). Significant to the court's decision to dismiss the antitrust claims was the fact that Astrazeneca had not removed Prilosec's NDA and therefore not prevented generic entry upon patent expiration, but rather had introduced additional products and increased consumer choice.

The FTC and private plaintiffs also have challenged the improper listing of patents in the Orange Book as a means to impede generic competition (see, eg, *In the Matter of Bristol-Myers Squibb Co*, docket no. C-4076 (2003)). Additionally, the FTC and private plaintiffs have alleged that pharmaceutical companies' filing of 'citizen petitions' with the FDA constituted sham government petitioning intended to delay generic competition.

32 Does the practice of authorised generics raise issues under the competition law?

An authorised generic is one that the brand drug manufacturer authorises to be marketed under the NDA for the brand drug. The brand manufacturer either sells the authorised generic itself or licenses a generic firm to do so. With increasing frequency, brand drug manufacturers have begun to market authorised generics at the beginning of 180-day marketing exclusivity period awarded a paragraph IV generic. The likely effects of the practice have been debated. In the short run, an authorised generic increases competition during the 180-day period. However, the potential introduction of such a product, some argue, may decrease the expected value of the 180-day exclusivity period granted to the first ANDA filer. The increased introduction of authorised generics by brand manufacturers may, in the context of paragraph IV litigation, also provide leverage to the brand manufacturer and increased incentive to the generic manufacturer to settle.

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

The specific features of the pharmaceutical sector are taken into account in assessing the competitive effects of any challenged conduct or an acquisition. However, once a violation of the antitrust laws is found, specific features of the pharmaceutical sector do not provide any objective justification for the infringement.

Arnold & Porter LLP

Asim Varma **asim_varma@aporter.com**
Barbara Wootton **barbara_wootton@aporter.com**

555 12th St NW
Washington, DC 20004
United States

Tel: +1 202 942 5000
Fax: +1 202 942 5999
www.arnoldporter.com