GETTING THE DEAL THROUGH

GCR
GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide

2009

Contributing editor: Marleen Van Kerckhove

Published by
GETTING THE DEAL THROUGH
in association with:

Arnold & Porter LLP

United Kingdom

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Pharmaceutical regulatory law

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

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 Many of the provisions of the Medicines Act have now been superseded by regulations implementing EC legislation on medicines.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 2009 PPRS is the latest in a series of voluntary agreements reached between UK governments and the pharmaceutical industry. Both the voluntary 2009 PPRS and the statutory scheme are administered by Department of Health (DoH) staff in the Medicines, Pharmacy and Industry Group – Pricing and Supply Branch.

Following a review by the Office of Fair Trading (OFT) (see question 5), the 2009 PPRS reflects certain recommendations made by the OFT, and the outcome of discussions between the DoH and the pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry and the BioIndustry Association). In particular, value-based pricing has been introduced to the scheme, as discussed in question 9.

2 Which bodies are entrusted with enforcing these regulatory rules?

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicinal products are safe, efficacious and of acceptable quality; and that medical devices are designed and manufactured in such a way that will not compromise the clinical conditions of safety in the recipients. 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 DoH 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 Medicine 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 – such as the Committee on Safety of Devices.

The MHRA Enforcement and Intelligence Group (E&I) has responsibility for enforcing medicinal product and medical device 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. DoH 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 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.

Competition legislation

4 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 distribu-

tion 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 in 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.

5 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 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 (see question 9). 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/completed/price-regulation); and
- Distribution of Medicines in the UK (2007) (www.oft.gov.uk/advice_and_resources/resource_base/market-studies/completed/medicines).

6 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive effect of conduct or agreements 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 merged entity supplies or acquires 25 per cent or more of a particular good or service. 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 it 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.

7 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, an unlimited fine, or both.

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.

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

Private parties may 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 (follow-on actions).

The National Health Service (NHS) 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. This decision was appealed to the Court of Appeal, where the court confirmed that victims of a cartel are only entitled to be compensated for actual loss suffered. The Court of Appeal rejected an argument that restitutionary damages should be available purely on the basis that cartelists may make a profit from their breach of competition law. The

Court of Appeal explained that it would have to be shown that the case was exceptional and that compensatory damages were not a sufficient remedy to address the wrong that had occurred.

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

The OFT can conduct market studies pursuant to section 5 of the 2002 Act. The OFT uses such powers as a means of identifying and addressing aspects of market failure, including competition issues, consumer detriment and the effect of government regulations. The OFT has published guidance discussing the factors it will consider when deciding whether or not to open a market study (Market Studies – www.oft.gov.uk/shared_oft/business_leaflets/enterprise_act/oft519.pdf).

In 2007, the OFT conducted two market studies into the pharmaceutical sector in the UK (see reports referenced in question 5): one in relation to the Pharmaceutical Price Regulation Scheme (the method by which the UK government seeks to control the prices of branded prescription medicines sold to the UK's NHS); and a second in relation to direct to pharmacy distribution arrangements.

The OFT's study into the Pharmaceutical Price Regulation Scheme (PPRS) found that a number of drug prices were significantly out of line with patient benefits. The OFT recommended that the prices of on-patent branded prescription drugs be set according to 'value-based principles', where the prices paid for medicines by the NHS reflect the therapeutic benefits the drugs bring to patients. Following this study, the PPRS was re-negotiated and re-issued with effect from 1 January 2009.

The OFT's study into direct to pharmacy (DTP) distribution arrangements considered the impact of Pfizer's exclusive DTP scheme with UniChem, and the likely impact of other manufacturers introducing DTP distribution arrangements or reducing the number of distributors they use. The study found that there was a significant risk that such arrangements would result in higher costs to the NHS, and that DTP schemes could affect services to pharmacies and patients by, for example, increasing waiting times to receive medicines. The OFT recommended that further changes be made to the PPRS to ensure that NHS medicine costs do not increase as a result of changes in distribution.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition 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 5.

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 Act 1998 Act, there is an exemption for agreements that contribute to the improvement of production or distribution or that 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 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

The following organisations address antitrust concerns arising in the pharmaceutical industry: the Association of the British Pharmaceutical Industry; the BioIndustry 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 mergers between two pharmaceutical companies are being reviewed?

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 exist) 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 products that are being developed 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 acquirer. 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 4). 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 in the pharmaceutical sector?

An investigation into an alleged cartel relating to generic antibiotics and Warfarin was launched by the Serious Fraud Office (SFO) 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 SFO therefore sought to amend the indictment, but its application was rejected in July 2008. The SFO sought leave to appeal the Crown Court's decision, but the application was refused.

The NHS brought parallel civil actions for damages in relation to the loss suffered by the public (discussed in question 8). 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 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 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 of this book, the European Commission has not objected to co-promotion or co-marketing agreements between competitors.

23 What other forms of agreement with a competitor are 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 advanced 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 European 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 questions 5 and 9) drew attention to competition concerns that arise where pharmaceutical manufacturers agree with wholesalers to deal exclusively with one wholesaler, or where they deliver DTP (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 DTP 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.

25 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 all three, 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 of a cash settlement, will attract potential scrutiny. The EU sector enquiry concerning generic competition in pharmaceuticals concerns the industry in the UK in the same way as in other member states.

Anti-competitive unilateral conduct

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

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 begun 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.

Update and trends

As in many other member states, the UK authorities will closely scrutinise the European Commission's final report into the pharmaceutical sector, when it is published later this year. In addition, the new Pharmaceutical Price Regulation Scheme, which took effect from 1 January 2009, introduced a number of changes to the dynamics of the industry.

27 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 in 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.

28 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 un-patented products or processes. Where the patent constitutes an important barrier to entry because of lack of substitutability with other products or processes, it 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.

29 To what extent can an application for the grant 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.

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30 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 it is intended only to raise rivals' costs rather than as a genuine attempt to protect legal rights) may be regarded as an abuse of dominance.

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.

32 Do 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 infringe 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 has accepted the relevance of these features, though to a limited extent following the ECJ's judgment in *Sot. Leos Kia Sia E.E* and others (Cases C-468/06 to Case C-478/06).