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GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

in 31 jurisdictions worldwide

2013

Contributing editor: Marleen Van Kerckhove

Published by
Getting the Deal Through
in association with:

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Pharmaceutical Antitrust 2013

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Pharmaceutical Antitrust 2013
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ISSN 1757-6288

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Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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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?

On 14 August 2012, the Human Medicines Regulations (SI 2012/1916) (the HMR) came into force, consolidating and replacing nearly all of the UK's existing medicines regulation, including most of the Medicines Act 1968 and the related subordinate legislation that implemented EU legislation (most notably, Directive 2001/83/EC relating to medicinal products for human use). The consolidation exercise has been undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA) and is a welcome development given the complex and fragmented nature of the pre-existing regulatory framework in the UK. In addition to the authorisation of medicinal products for human use, the HMR cover the manufacture, importation, distribution, sale and supply of medicinal products, as well as labelling, packaging and advertising. The HMR also implement Directive 2010/84/EU, which introduces a strengthened pharmacovigilance regime.

In practice, the marketing of pharmaceuticals in the UK is also self-regulated by industry codes, including the Association of the British Pharmaceutical Industry (ABPI) Code, which applies to prescription-only medicines and the Proprietary Association of Great Britain (PAGB) Code, which applies to over-the-counter medicines. While compliance with these codes is not a legal requirement, manufacturers choose to do so.

Statutory powers covering pharmaceutical pricing are contained in sections 260 to 266 of the National Health Service Act 2006. A statutory scheme to limit the maximum price of prescription-only, branded medicines supplied to the National Health Service (NHS) exists, but this only applies to those manufacturers who are not members of the voluntary Pharmaceutical Price Regulation Scheme (the PPRS). The PPRS is a negotiated agreement between the Department of Health (DH) and the pharmaceutical industry, represented by the ABPI. Its aim is to control NHS expenditure on branded medicines. The current version of the PPRS came into force in January 2009. It sets a ceiling on the profits that pharmaceutical companies may make from sales to the NHS. It also aims to encourage innovation by pharmaceutical manufacturers. Following recommendations from the Office of Fair Trading (OFT), the 2009 PPRS included for the first time an element of value pricing. The current PPRS will be replaced in 2014 and the new scheme is expected to include value-based pricing for all new medicines for the first time.

2 Which bodies are entrusted with enforcing these regulatory rules?

The MHRA, which is an executive agency of the DH, is responsible for the regulation of medicines and medical devices for human use on the UK market. Within the MHRA, the Enforcement and Intelligence Group investigates cases and, where appropriate, brings criminal prosecutions. The MHRA carries out its enforcement functions under powers conferred by the HMR. These include the right to enter and inspect any premises, to take samples and require the production of documents (regulations 325 to 328, HMR (formerly sections 111 and 112, MA68)).

The PPRS includes monitoring procedures and a dispute resolution process. Members of the PPRS are required to submit an Annual Financial Return and provide information to the DH about the sales of branded medicines to the NHS. The PPRS also makes provision for biannual liaison between the ABPI and the DH to consider the operation of the scheme and requires the DH to make an annual report to the UK parliament.

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

The regulation of both the licensing and pricing of pharmaceuticals is relevant to the application of competition law in the sense that this regulation shapes the nature of competition in the sector, particularly in relation to medicines sold to the NHS.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Competition Act 1998 (the CA98), as amended, sets out the general framework for competition law in the UK.

Section 2, CA98 prohibits agreements between undertakings, decisions by associations or concerted practices that have an anti-competitive object or effect and may affect trade in the UK (the chapter I prohibition). Agreements that would otherwise be caught by the chapter I prohibition may be exempted if they meet the criteria set out in section 9, CA98. To benefit from an exemption under section 9, CA98, the agreement must improve production or distribution or promote technical or economic progress, while allowing consumers a fair share of the benefit, provided the agreement does not impose unnecessary restrictions on competition or allow the parties to the agreement opportunity to eliminate competition.

Section 18, CA98 prohibits abusive conduct by one or more undertakings holding a dominant position within the UK if it may affect trade in the UK (the chapter II prohibition).

The chapter I prohibition and the chapter II prohibition are closely modelled on articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) respectively. The competition authorities and the courts in the UK are bound by the supremacy of EU law and are required to deal with questions arising in relation to the chapter I and chapter II prohibitions in a manner consistent with the treatment of corresponding questions under EU law (section 60, CA98). The EU competition rules (articles 101 and 102 TFEU) are also applicable in the UK to activities that have an actual or potential impact on trade between EU member states.

The Enterprise Act 2002 (the EA02) introduced a criminal offence for individuals (the cartel offence) and company director disqualification for directors of companies found to have infringed competition

law (see section 9A et seq, Company Directors Disqualification Act 1986). The cartel offence criminalises individuals who dishonestly agree with others to make or implement cartel arrangements, including price fixing, market sharing, limiting supply or production, and bid rigging (section 188, EA02). Note that the requirement for dishonesty is likely to be removed from the definition of the cartel offence in the near future.

The EA02 also sets out the UK merger control rules. The UK merger regime is voluntary (in the sense that there is no mandatory filing requirement), but the OFT will have jurisdiction to review a merger (defined as two or more enterprises 'ceasing to be distinct') if the UK turnover of the target exceeds £70 million or, as a result of the merger, the share of supply of the parties of any goods or services of the same description in the UK (or a substantial part of the UK) exceeds 25 per cent (or an existing share of supply of 25 per cent or more is enhanced). Some mergers involving UK businesses may instead be subject to the merger control regime in the EU Merger Regulation (Regulation 139/2004/EC), if the relevant turnover thresholds are met.

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

There are no competition law guidelines specifically relating to the pharmaceutical sector. However, the OFT's website has a section on active and recently completed work relating to pharmaceutical and health: www.oft.gov.uk/OFTwork/pharmaceutical-and-health. The OFT has produced a large quantity of guidance on the application of competition law generally, which is available from its website (www.oft.gov.uk).

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

Merger control in the UK is administered by the OFT and the Competition Commission (the CC). The secretary of state retains a role in respect of certain mergers that give rise to defined public interest issues. No special rules apply to pharmaceutical mergers.

The OFT carries out a preliminary investigation into mergers that are notified to it and mergers that come to its attention through its own market intelligence or as a result of third-party complaints. If the OFT concludes that there is a relevant merger situation and believes there may be a substantial lessening of competition (SLC), it generally must refer the merger to the CC. The OFT can decide not to refer by accepting undertakings in lieu of making a reference (see question 17). Following a reference from the OFT, the CC conducts an in-depth review and reports on its findings. If the CC identifies competition concerns, it may prohibit the merger or may allow it to proceed subject to agreed structural or behavioural undertakings.

Anti-competitive agreements and conduct are investigated by the OFT under chapter I/chapter II CA98 (and articles 101/102 TFEU where there is an effect on trade between EU member states). The OFT may open an investigation where it has reasonable grounds for suspecting that competition law has been breached. The OFT has extensive powers enabling it to gather information, including written information requests and entering and searching business and domestic premises. OFT decisions can be appealed to the Competition Appeal Tribunal (the CAT).

The OFT may also investigate suspected infringements of the cartel offence using its criminal powers, if there are reasonable grounds do so. The OFT has wider powers of investigation in criminal cases, including the use of intrusive and covert surveillance. Where the case also involves serious or complex fraud, the OFT will make a referral to the Serious Fraud Office (SFO). The cartel offence is triable on indictment before a jury in the Crown Court and prosecutions may be brought by either the SFO or the OFT.

In March 2012, the UK government confirmed that it has decided to create a new Competition and Markets Authority (CMA) and transfer the functions of the OFT and CC to it. It is anticipated that the CMA will be fully operating by April 2014, and a chair and chief executive have been appointed to lead the transition process.

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

If the OFT finds an infringement of the chapter I or chapter II prohibitions, it may give directions to bring the infringement to an end or require the agreement or conduct concerned to be modified (sections 32 and 33, CA98). For example, following a finding of an abuse of dominance, Napp Pharmaceuticals was directed to reduce the NHS List Price of its morphine product by 15 per cent and to maintain its hospital prices at a minimum level.

The OFT can impose fines up to a statutory maximum of 10 per cent of an undertaking's worldwide turnover (section 36, CA98). The OFT published new fining guidelines in September 2012, which set out its approach to calculating penalties. Among other things, the new guidelines increase the maximum starting point for penalty calculations from 10 per cent to 30 per cent of relevant turnover. The stated aim of this change is to give the OFT the ability to set penalties that better reflect the gravity of different types of infringement, particularly hard-core cartel infringements, and to bring the OFT's approach in line with that of the European Commission (EC). Three pharmaceutical companies have been fined by the OFT for abuse of dominance: Napp, £3.21 million (reduced to £2.2 million on appeal) in 2001; Genzyme, £6.8 million (reduced to £3 million on appeal) in 2003; and Reckitt Benckiser, £10.2 million in 2011 (see question 26).

On indictment for the cartel offence, individuals can be sentenced to up to five years in prison and/or receive a fine. So far, three individuals have received prison sentences in the UK, albeit as part of a plea bargain agreed in the US.

The OFT has the power to adopt interim measures if this is required to prevent serious and irreparable damage to a particular person or to the public interest (section 35, CA98). It can also agree legally binding commitments with parties under investigation in order to address competition concerns (section 31A, CA98 et seq).

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 can bring actions in the UK courts based on competition law, usually as an action in tort for breach of statutory duty. Claimants may seek damages, injunctive relief or a declaration of unenforceability.

Damages claims can be either 'follow-on' or 'stand-alone' claims. In a follow-on claim the claimant can rely on an OFT or EC decision as proof of an infringement, but must show causation and loss. Follow-on claims may be brought in either the High Court or the CAT. Stand-alone claims can only be brought in the High Court and the claimant must prove the breach of competition law. Given the evidential difficulties of proving a breach of competition law, follow-on claims are more common than stand-alone claims.

A follow-on damages claim has been brought against Reckitt Benckiser by the NHS in the High Court. It is understood that the damages claimed amount to nearly £89 million. Several years ago, the secretary of state for health sued a number of pharmaceutical companies, claiming damages arising out of alleged anti-competitive agreements to fix the prices of certain generic drugs. Those cases all settled with substantial payments being made to the NHS. A damages claim has also recently been brought in the High Court by the NHS against Les Laboratoires Servier, arising from alleged anti-competitive practices in relation to perindopril, a hypertension drug.

The High Court handed down a judgment on 14 January 2013, staying the damages action against Servier because of the ongoing EC investigation into alleged anti-competitive agreements and practices relating to perindopril. The action is stayed until after the oral hearing in the EC's administrative procedure, at which point the parties will be required to begin standard disclosure – even though trial will not take place until after the determination of the EU proceedings.

Interim injunctions can be granted by the High Court in relation to competition law issues, for example, to require a defendant to cease its involvement in an anti-competitive agreement or end its abusive behaviour. An application for an interim injunction can be a successful strategy in forcing the termination of the infringing behaviour, but it also holds risks for the claimant, not least in terms of costs and the possibility of having to give a cross-undertaking to protect the defendant and third-party competitors, should the action be unsuccessful at full trial.

In 2007, an application for an injunction by AAH Pharmaceuticals and various other pharmaceutical wholesalers against Pfizer and UniChem was rejected by the court. Following the conclusion by Pfizer of a supply agreement with UniChem, the claimants had asked the court to restrain Pfizer from terminating its supply agreements with them and refusing to supply the claimants with its prescription drugs under article 102. The court refused to grant the injunction on the grounds that the loss suffered by the claimants could be compensated in damages and that there was a serious risk of disruption and reputational damage to Pfizer and UniChem (see *AAH Pharmaceuticals and others v Pfizer and UniChem* [2007] EWHC 565 (Ch)).

In a recent judgment, the High Court similarly refused an application for an injunction by Chemistree Homecare against AbbVie, relating to the supply of Kaletra, a protease inhibitor used to treat HIV patients. The Court held that Chemistree had failed to show that it had a real prospect of proving that AbbVie had a dominant market position and had been disingenuous by failing to mention its wholesale business when AbbVie had repeatedly asked for an explanation about Chemistree's sharp increase in demand (*Chemistree Homecare Limited v AbbVie Limited, High Court Chancery Division*, 11 February 2013 (unreported)).

It is also possible to obtain declaratory relief from the courts. In the context of competition law this can be useful for parties seeking a declaration on whether a particular clause is void and unenforceable.

In January 2013, the UK government published proposals to reform private actions in competition law. The proposals include:

- allowing stand-alone claims to be brought in the CAT;
- allowing the CAT to grant injunctions;
- creating a fast track for simpler cases in the CAT; and
- introducing a limited opt-out collective actions regime to allow consumers and businesses to collectively bring cases, subject to certain safeguards.

If adopted, these proposals are likely to increase the number of competition law actions in the UK courts and will significantly enhance the role of the CAT in private competition litigation.

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 conducts 'market studies' to see whether a particular market is working well for consumers and can suggest proposals and recommendations for making it work better. The OFT has conducted two market studies relating to pharmaceuticals:

- The PPRS (February 2007): The OFT concluded that the PPRS should be reformed by replacing profit and price controls with a value-based approach to pricing. The OFT's view was that this would ensure the price of drugs reflects their clinical and therapeutic value to patients and the wider NHS.
- Medicines Distribution (December 2007): The OFT launched a market study following the increasing use by pharmaceutical manufacturers of 'direct-to-pharmacy' (DTP) distribution schemes. The OFT recognised that pharmaceutical manufacturers should be free to choose the most efficient distribution method and commented that DTP distribution was unlikely to raise competition issues. However, it recommended that the government make further changes to the PPRS to safeguard discounts obtained by pharmacies as a result of DTP arrangements and seek manufacturers' agreement on minimum service standards.

The CC is currently investigating the private health-care industry, although pharmaceutical pricing is not a focus of the investigation. Where the OFT has reasonable grounds for suspecting that any features of a market may 'prevent, restrict or distort' competition, it may make a 'market investigation reference' to the CC (section 131, EA02). If the CC finds an adverse effect on competition, it has extensive powers at its disposal to order remedies. To date, there have been no market investigations into the pharmaceutical sector.

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

The pharmaceutical regulatory bodies do not have responsibility for regulating competition in the pharmaceutical sector. However, the government is committed to introducing competition within the NHS. It has set up an advisory Cooperation and Competition Panel and, in March 2012, passed legislation providing for a health-care regulator, Monitor, with competition powers. Under the Health and Social Care Act 2012, Monitor will have concurrent powers with the OFT to apply competition law in relation to the provision of health care services in England.

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

Generally, no. Industrial-policy type arguments are unlikely to be successful in defending antitrust concerns, unless they directly relate to pro-competitive economic efficiency gains. When assessing whether an agreement may be exempted from chapter I/article 101(1), the OFT undertakes a narrow, economics-based, competition-specific analysis. A similar approach is undertaken in the context of analysing whether conduct falling within chapter II may be objectively justified.

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

NGOs, trade associations and consumer groups have only a limited role, beyond providing input into consultations or market studies undertaken by the OFT. However, there are opportunities for them to bring competition law concerns to the attention of the authorities as third parties may make complaints to the OFT about suspected breaches of competition law. In addition, certain nominated bodies, including Which? (formerly known as the Consumers' Association), may make a 'super-complaint' to the OFT (section 11, EA02). Following a super-complaint, the OFT must publish a report within 90 days on what action it intends to take. Which? can also bring follow-on claims for damages on behalf of consumers in competition law cases (section 47B, CA98).

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?

Mergers are reviewed on a case-by-case basis. The specific features of the pharmaceutical industry are taken into account to the extent these are relevant to the competition analysis.

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

The OFT adopts the same approach to market definition in the pharmaceutical sector as the EC. For example, in its decision against Reckitt Benckiser, the OFT took account of the framework used by the EC in *AstraZeneca*.

Generally, the starting point for analysing pharmaceutical product characteristics is the third level of the Anatomical Therapeutic Chemical (ATC) classification system, which groups medicines in terms of their therapeutic indications. However, if the circumstances of the case show that ATC3 is not appropriate (for example, if other products act as a competitive constraint), the OFT will begin the analysis using other levels of ATC classification. It will also have regard to other evidence. The primary determining factor is the substitutability of products as viewed by the purchasing decision-maker (for prescription medicines this would be the relevant medical practitioner), not simply the physical, technical or chemical properties of the products. The OFT has adopted the EC's approach that over-the-counter medicines form a separate product market from prescription medicines.

The OFT has consistently followed the EC's approach in defining the relevant geographic market for pharmaceutical products as being national in scope. In *Napp*, the OFT stated that the relevant market was not narrower than the UK because national players competed for each local tender, regardless of their location.

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

An overlap between two merging parties may give rise to a SLC if:

- the merged entity gains the incentive and ability to exercise market power in a way that is harmful to competition, for example by raising prices (unilateral effects); or
- the likelihood of coordination by the firms remaining in the market is increased, for example by increasing prices, reducing quality or innovation, or curtailing output (coordinated effects).

Loss of potential competition is taken into account as part of the competitive assessment, for example if there is evidence a new entrant would have entered the market in the absence of the merger or if one of the parties to the merger is a perceived potential entrant who would enter the market if the existing firms raised their prices. The OFT and the CC have published detailed joint merger assessment guidelines (OFT 1254/CC2 (Revised)).

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

The OFT and the CC will take into account pipeline products when reviewing the effect of a merger. In its review of a joint venture between GlaxoSmithKline and Pfizer in 2009, the OFT adopted a cautious approach and assessed the parties' overlaps in pipeline products at each phase of clinical trials. An overlap in respect of pipeline products may, for example, be considered problematic if, after the completion of the transaction, the merged entity is likely to slow down or terminate the development of its pipeline.

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

The OFT may accept proposals to remedy a potential SLC in lieu of making a reference to the CC. The OFT will only accept 'clear-cut' remedies and accordingly is unlikely to accept behavioural remedies. Usually an acceptable remedy will be the upfront divestment of one of the overlapping businesses.

The CC has broad powers to take action to remedy a SLC. In addition to divestiture remedies in the form of the disposal of business assets by the merging parties (for example, of an overlapping product), the CC may agree to intellectual property (IP) remedies, for example the assignment of patents, but IP licences are likely only to be an acceptable remedy in exceptional circumstances. The CC has not reviewed a merger between pharmaceutical manufacturers so there is little sector-specific guidance on the approach it would take to remedies, but it has produced detailed general guidance (Merger Remedies: CC Guidelines, CC8).

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?

For a merger to fall under the OFT's jurisdiction, two enterprises must 'cease to be distinct'. The term 'enterprise' is defined very broadly as the activities, or part of the activities, of a business (section 129, EA02). The OFT considers that the transfer of intangible assets, such as intellectual property, on its own will only constitute an enterprise if it is possible to identify turnover directly related to the transferred intangible asset that will also transfer to the buyer. If any other business assets, such as marketing authorisations, are being transferred with the intellectual property then it would be prudent to consider the merger control rules carefully.

Anti-competitive agreements

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

The general framework for assessing anti-competitive agreements (including decisions by associations and concerted practices) is set out in chapter I of the CA98 and article 101 TFEU (see question 4). Agreements that clearly restrict competition, such as price fixing, market sharing, restrictions of supply and bid rigging will be considered to do so by 'object'. Horizontal agreements of this nature are characterised as cartels. If an agreement does not restrict competition by 'object', it is necessary to conduct an in-depth analysis to establish whether it has the 'effect' of restricting competition.

If the agreement restricts competition, it is then necessary to consider whether the exemption in section 9, CA98 or article 101(3) applies. Regard may be had to the various block exemptions and guidelines adopted by the EC (for example, in relation to vertical restraints, R&D agreements, and specialisation agreements), as well as the EC's Guidelines on the application of article 101(3). It is no longer possible to notify and obtain an individual exemption for an agreement; instead companies must carry out a self-assessment.

20 Describe the nature and main ramifications of any cartel investigations in the pharmaceutical sector.

To date, there have not been any cartel investigations in the pharmaceutical sector in the UK under the CA98 or EA02. In 2006, following an investigation into price fixing and market sharing by suppliers of generic drugs, the SFO brought criminal proceedings against several companies and their executives based on the common law offence of conspiracy to defraud (note that the investigation started before the cartel offence had been introduced into law). The case collapsed when the House of Lords (now the Supreme Court) ruled that mere price fixing did not amount to conspiracy to defraud and the SFO's attempts to amend its indictment were rejected.

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

The UK does not have any specific competition legislation on technology licences and the OFT has not published any guidance on the subject. As a general principle, technology licences may be considered to be pro-competitive as they can improve economic efficiency, promote innovation and lead to the dissemination of technologies. Accordingly, the EC has adopted a block exemption for certain technology transfer agreements (EC Regulation 772/2004), which also applies to purely UK-related technology licensing agreements (section 10, CA98).

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

Co-promotion and co-marketing agreements can generate efficiency gains, for example through economies of scale or by allowing market entry, meaning that they often enhance competition. In analysing such agreements, the OFT will have regard to the EC's Guidelines on horizontal cooperation agreements.

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

Many types of horizontal agreement, such as joint R&D agreements or licensing agreements, are beneficial to competition because they generate efficiencies and allow pharmaceutical companies to enter new markets. Competition law does not seek to prohibit these types of agreements, but care should be exercised to ensure that the nature and content of the agreement, as well as the characteristics of the relevant market, do not mean that the agreement has the effect of restricting competition. The EC has adopted block exemptions relating to R&D agreements and specialisation agreements, as well as detailed guidelines on the applicability of article 101 TFEU to horizontal cooperation agreements. An agreement may have the effect of restricting competition if it limits competition between the parties or reduces the parties' decision-making independence. Competition issues are more likely to arise if one or more of the parties have significant market power.

Exchange of commercially sensitive information between competitors, for example about current and future prices, customers or production costs, is likely to be considered to be restrictive of competition. In 2011, the OFT fined the Royal Bank of Scotland £28.5 million for disclosing generic as well as specific confidential and commercially sensitive future pricing information to Barclays (who approached the OFT for leniency). The extent of any information exchanged in the context of a cooperation agreement should be carefully thought through and should be ancillary to the objective of the agreement. Confidentiality provisions or 'Chinese walls' may help to restrict the flow of such information and reduce competition risk.

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

Vertical agreements are less likely to raise antitrust concerns than horizontal agreements. However, certain restrictions included in vertical agreements can be anti-competitive. The EC has adopted a block exemption that provides a safe harbour for vertical agreements between companies, provided that the market shares of the parties on the relevant buying and selling markets do not exceed 30 per cent and the agreement does not contain certain 'hard-core' restrictions. Hardcore restrictions include imposing fixed or minimum resale prices on the buyer and restricting the territory or customers to which the buyer can resell. Non-compete obligations exceeding five years and post-term non-compete obligations are excluded from the benefit of the block exemption, subject to certain limited exceptions.

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

Although no-challenge clauses in settlement agreements have been recognised by the EC as generally being considered to fall outside article 101(1) (EC Guidelines on Technology Transfer Agreements, paragraph 209), they have recently been under considerable scrutiny in the context of settlements between originator companies and generics manufacturers. The EC, in its Pharmaceutical Sector Inquiry, raised the concern that generic entry might be restricted by the owner of a patent agreeing to a 'value transfer' in a settlement agreement, where the aim was to induce the generic company that had challenged the patent not to enter (or delay entry to) the market and is reported to be investigating a number of cases. Originator companies should, therefore, exercise care when entering into settlements with generics manufacturers where the agreement includes a 'reverse payment' from the originator to the generic company and the effect of the settlement is to delay generic entry.

The OFT has confirmed on its website that in August 2011 it opened an investigation into certain patent litigation settlement agreements relating to paroxetine. GlaxoSmithKline and Generics UK have confirmed that they have been contacted by the OFT.

Anti-competitive unilateral conduct

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

Under the chapter II prohibition and article 102 TFEU, a dominant firm has a special responsibility not to allow its conduct to impair undistorted competition. Abusive conduct includes conduct that:

- exploits customers or suppliers (for example, charging excessively high prices); and/or
- excludes competition from existing competitors or removes or weakens potential competition.

Examples of exclusionary conduct include predatory pricing, margin squeeze, tying and bundling, certain rebate and discount schemes, and refusal to supply in certain circumstances. The chapter II prohibition does not contain provisions exempting certain behaviour, but conduct may not be regarded as an abuse if it can be objectively justified.

The OFT has pursued a limited number of chapter II cases, three of which have involved pharmaceutical manufacturers:

Napp

In 2001, the OFT fined Napp £3.21 million for supplying morphine tablets to hospitals at lower prices than to customers in the community; targeting competitors by offering higher discounts to hospitals where it faced competition; supplying morphine tablets to hospitals at excessively low prices; and charging excessively high prices to customers in the community. The OFT found that Napp had the intention of eliminating competition. The CAT upheld the OFT's findings, but reduced the fine to £2.2 million on the basis of certain mitigating factors, including the uncertainty of the law on this issue.

Genzyme

In 2003, the OFT fined Genzyme £6.8 million for margin squeezing in relation to the drug Cerezyme and for bundling the home delivery of Cerezyme with ancillary home services required by the NHS. The CAT upheld the OFT's finding on the margin squeeze, but annulled the finding on bundling leading to the reduction of the fine to £3 million.

Reckitt Benckiser

In 2011, the OFT fined Reckitt Benckiser £10.2 million for abuse of dominance by withdrawing and delisting Gaviscon Original Liquid, which no longer had patent protection, from the NHS prescription computer system before a generic name had been agreed on. The

Update and trends

The OFT has confirmed that it has opened an investigation into patent litigation settlements relating to paroxetine, a medicine used in the treatment of disorders such as depression and anxiety disorder. This appears likely to have been influenced by the findings of the Sector Inquiry and the EC's own investigations into patent litigation settlements. However, the OFT has a track record of enforcement action in the pharmaceuticals sector – particularly in relation to abuse of dominance – and its activity in this area has not noticeably increased. There is a general trend for follow-on damages actions to be launched in the UK courts in the wake of infringement decisions by the OFT and EC, and it seems to be an ongoing trend for the NHS to seek damages when pharmaceutical companies breach competition law.

More generally, the UK's competition regime is currently being reformed. The most significant changes include:

- establishing a single Competition and Markets Authority (CMA), to which the existing functions of the OFT and CC will be transferred;
- removing the 'dishonesty' element from the UK cartel offence; and
- introducing statutory timetables for Phase I merger decisions and Phase I market studies.

The relevant draft primary legislation, the Enterprise and Regulatory Reform Bill, is currently making its way through the UK parliament. The UK government anticipates that the CMA will be established and fully operational by April 2014.

effect of the conduct was that doctors searching for Gaviscon were presented with Gaviscon Advance Liquid – a second-generation product still protected by a patent – rather than a competing generic product. This undermined the ability of doctors to prescribe the generic version of the product.

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

The OFT follows EU case law in determining whether a firm is dominant. Dominance arises where an undertaking has a position of economic strength such that it is able to prevent effective competition being maintained on the relevant market by operating independently of its competitors, customers and, ultimately, of consumers. The OFT will consider whether a firm faces constraints on its ability to behave independently by taking into account factors such as barriers to entry, strength of existing and potential competitors, presence of powerful buyers, and relevant regulatory constraints.

There are no market share thresholds for defining dominance, but an undertaking will be presumed to be dominant if it has a market share persistently above 50 per cent. The OFT considers it unlikely that an undertaking would be dominant with a market share of less than 40 per cent, except in exceptional circumstances.

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

Although a patent confers an exclusive right to use the technology it covers, the mere ownership of the patent does not necessarily give rise to a dominant position. If other technologies can be used to manufacture products that compete with the patent holder, then it is less likely that the patent holder will have sufficient market power to be considered dominant. Similarly, if other technologies exist that are substitutable for that covered by the patent, then downstream producers may have alternative sources of supply for the technology.

In circumstances where there are no (or limited) substitutes available for the technology covered by the patent, then the ownership of the patent may mean that the holder is dominant. Note, however, that the OFT is clear that the legitimate exercise of an intellectual property right is not an abuse.

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

A legitimate application for the grant of a patent should not give rise to an antitrust violation, but the abuse of the application procedures may in some limited circumstances give rise to antitrust concerns, for example see the EC's decision in *AstraZeneca*.

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

The legitimate enforcement of a patent should not expose the patent owner to liability for an antitrust violation, even if it is dominant. However, should a patent owner holding a dominant position engage in vexatious litigation in an attempt to enforce the patent, this could amount to an abuse, albeit in very limited circumstances (see *Case T-111/96 ITT Promedia NV v Commission* [1998] ECR II-2937).

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

The EC's Pharmaceutical Sector Inquiry highlighted potential competition concerns regarding the various strategies used by originator companies to extend the commercial life of their medicines. The EC identified 'patent clusters' or 'patent thickets', patent settlement agreements, and interventions before marketing authorisation authorities as potentially raising concerns, but it has not clarified in what circumstances an infringement would occur. As noted in question 25, the OFT has opened an investigation into patent settlement agreements.

32 Do authorised generics raise issues under the competition law?

There is no equivalent in the UK to the exclusivity period under the US Hatch-Waxman Act, therefore authorised generics do not give rise to the same issues. Generic versions manufactured by the originator company may be regarded as being pro-competitive in the sense that they offer competition to new entrant generics on expiry of the patent.

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 OFT has acknowledged that the pharmaceutical sector has certain specific features, including the fact that it is highly regulated; that the decision-maker for the purchase of prescription products (the doctor) is not the same as the ultimate consumer (the patient); and that the decisions of doctors are not typically driven by price considerations, but tend to be based on what is most therapeutically appropriate and effective. However, the OFT is unlikely to accept that these specific features would allow a pharmaceutical company to objectively justify otherwise abusive conduct. For example, in *Napp*, the OFT rejected arguments that the regulatory pricing constraint imposed by the PPRS meant that Napp could not be considered dominant.

34 Has there been an increase in antitrust enforcement in the pharmaceutical sector in your jurisdiction? If so, please give an indication of the number of cases opened or pending and their subject matters.

The OFT has not noticeably increased its scrutiny of the pharmaceutical sector, although it has recently opened an investigation into patent litigation settlements. The OFT's Annual Plan for 2012/13 included a commitment to focus on intellectual property in the context of competition in high-innovation markets.

35 Is follow-on litigation a feature of pharmaceutical antitrust enforcement in your jurisdiction? If so, please briefly explain the nature and frequency of such litigation.

Follow-on litigation is common in the UK, including following decisions against pharmaceutical companies. In particular, it is clear that the NHS is likely to pursue infringing companies for damages.

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PHARMACEUTICAL ANTITRUST 2013 ISSN 1757-6288