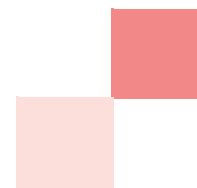


Successful strategies for global competition compliance in the pharmaceutical sector



David Hull and Timothy Hester, Covington & Burling*

www.practicallaw.com/2-201-1034

The impact of competition law on pharmaceutical companies is growing. Government regulators are devoting enormous resources to cartel and other price-fixing investigations, and the criminal and civil exposure from these investigations has increased exponentially. In other areas, competition laws are being used against pharmaceutical companies in new ways, especially in the intellectual property arena. In this complicated environment, maintaining an effective compliance programme is critical to minimise a company's competition exposure.

In view of these developments, this chapter addresses:

- The recent increase in global competition exposure.
- The risks associated with generics.
- The risks associated with pricing.
- Compliance issues relating to agreements.
- The risks associated with restrictions on parallel trade.
- How to successfully implement a compliance programme.

While this chapter focuses on the world's two principal competition jurisdictions (the US and the EU), the issues discussed are likely to be broadly the same in most jurisdictions.

INCREASE IN GLOBAL COMPETITION EXPOSURE

In the US, there has been a proliferation of anti-trust and other regulatory challenges to pharmaceutical industry practices (such as the Medicare and Medicaid Patient Protection Act of 1987 (commonly known as the anti-kickback statute)). Rising healthcare costs have made pharmaceutical companies an attractive target for both federal and state government anti-trust regulators. At the federal level, the Department of Justice (DOJ) continues to expand its criminal anti-trust enforcement activities and the Federal Trade Commission (FTC) has focused extensively on pharmaceutical companies. State anti-trust enforcers are very active in the pharmaceutical area and have even set up a co-ordinating committee to investigate and challenge certain pharmaceutical pricing practices. At both the federal and state levels, private claimants have launched many class action anti-trust claims against pharmaceutical companies, especially challenging the companies' use of patent protections.

In Europe, the pharmaceutical industry has also been under scrutiny by competition authorities. Both the European Commis-

sion and national competition authorities have challenged attempts by pharmaceutical companies to limit parallel trade in their products caused by price differences between EU member states. The UK competition authority has declared that competition in the healthcare sector will be one of its priorities in 2005. Recently, the European Commission imposed a fine of EUR60 million (about US\$73.8 million) on AstraZeneca for allegedly misusing the patent system and pharmaceutical regulatory regime to block or delay the entry of generic products to the market.

As well as being aware of the priority given to competition in the healthcare sector by European competition regulators, pharmaceutical companies must cope with recent changes in the European competition landscape that increase their competition exposure. After the far-reaching changes in EC competition law that took place in May 2004, companies can no longer notify their agreements in exchange for immunity from fines. More importantly, the decentralisation of the enforcement of the EC competition rules to national level has made it easier for complainants to challenge the validity of the strategies implemented by pharmaceutical companies.

The competition exposure of companies is also greater because the risk of fines has increased dramatically in the past four years since the European Commission adopted a corporate leniency programme, which creates strong incentives for whistleblowers. The leniency programme has had the desired effect as it has resulted in the opening of an unprecedented number of new cartel cases over the past few years.

Perhaps most importantly, recent changes in the law mean that company executives now face the possibility of imprisonment if they are involved in a cartel. While EC competition law does not impose criminal sanctions for participating in a cartel, various EU member states have recently enacted legislation that criminalises cartels. For example, under the UK's Enterprise Act 2002, individuals who participate in a cartel can be imprisoned for up to five years.

It is becoming increasingly difficult for pharmaceutical companies to navigate this intersection of competition laws, patent laws, pharmaceutical laws and requirements of sector-specific legislation, such as the US Hatch-Waxman Act of 1984. Behaviour that is permissible under one aspect of the overarching regulatory regime, such as obtaining additional patents related to an existing drug molecule and filing the new patent with a regulator, may result in potential exposure under competition law.

RISKS ASSOCIATED WITH GENERICS

Conduct that delays or restricts the entry of generic versions of branded pharmaceutical products can be subject to significant competition scrutiny. The following are particularly sensitive areas:

- Patent enforcement activities.
- Patent dispute settlements.
- Authorised generics.

The law is far more developed in the US, mainly as a result of extensive Hatch-Waxman litigation, but there is a growing focus on these issues in the EU.

Patent enforcement activities

Unsuccessful patent enforcement actions and other efforts to protect the exclusivity of a brand name pharmaceutical product are being increasingly challenged as anti-competitive in both the US and the EU. US litigation tends to be focused on claims related to allegedly improper acquisitions or enforcement of patent rights, while EU litigation has involved allegations of more general regulatory misuse.

In the US, the FTC and the private claimants' bar have focused extensively on the alleged misuse of patents and the regulatory scheme for approval of generic pharmaceuticals by brand name manufacturers. The Hatch-Waxman Act specifies a particular process for the entry of generics (*see Generic Drug Entry Prior to Patent Expiration: An FTC Study (FTC, 2002), available at www.ftc.gov*). In general, brand name manufacturers must list patents covering their products in a publication issued by the Food and Drug Administration (FDA), known as the *Orange Book*. A generic manufacturer that wishes to gain FDA approval for the generic version of a product must certify that its product does not infringe the brand name manufacturer's patents listed in the *Orange Book*. After this certification, the manufacturer can sue for patent infringement, which triggers a 30-month stay of generic entry pending resolution of the patent infringement claim against the generic manufacturer.

US anti-trust exposure can arise when patents listed in the *Orange Book* are successfully challenged, or when a brand name manufacturer is unsuccessful in a patent infringement claim. In these cases, the FTC and private claimants can claim that the company's patent protection efforts constitute improper monopolisation efforts. For example, the FTC brought an anti-trust claim against Bristol-Myers Squibb for alleged monopolisation of markets for several drugs (*FTC v Bristol-Myers Squibb Company, No. C-4076 (consent order issued 14 April 2003)*). In the FTC's view, the company's illegal anti-competitive conduct included:

- Filing false information with the FDA to list a patent in the *Orange Book* and improperly gain a 30-month stay of generic competition.
- Filing baseless patent infringement claims against potential generic competitors.

Many class action claims – based on similar allegations – were filed against the manufacturer of OxyContin after a federal judge

ruled that its patents were unenforceable due to inequitable conduct in the patent prosecution (*see, for example, Connecticut Citizen Action Group v Purdue Pharma Co., No. 3:04cv14 (D. Conn.) (complaint filed 6 January 2004)*). Many anti-trust challenges related to the Hatch-Waxman process concern secondary patents listed in the *Orange Book* a long time after the original drug was approved and relatively soon before expiry of the primary patents on the active pharmaceutical ingredient.

In Europe, most enforcement attention has been focused on life-cycle management strategies such as withdrawing products to prevent generic companies from using the abridged procedure, which allows generic companies to rely on the results of the clinical trials of a product when gaining marketing approvals for their generic versions of that product. Similar to the FTC's claims against Bristol-Myers Squibb, the European Commission recently fined AstraZeneca EUR60 million (about US\$73.8 million) for misusing administrative procedures, including concealing information from the patent authorities, to delay the entry of generic competition for its ulcer drug Losec (*Commission Communication IP/05/737, 15 June 2005*). The following EC legislation, which enters into force in Autumn 2005, includes provisions aimed at making it more difficult for companies to use such strategies for delaying generic entry:

- Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
- Regulation (EC) No. 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency.

There is also a risk in Europe that an aggressive patents policy, or strategies to extend the period of data exclusivity, could result in allegations of an abuse of a dominant position. Although neither the European Commission nor the European courts in Luxembourg have directly addressed this issue, the Italian competition authority has recently opened an investigation against GlaxoSmithKline and Merck for refusing to license active ingredients that were allegedly indispensable for the production of generics to be used in countries where the patents did not exist or had already expired (*Cases 14070 and 14078, 23 February 2005, Bulletin No. 8/2005*).

Patent dispute settlements

The FTC has focused extensively on the anti-trust implications of patent settlements between brand name and generic manufacturers. To encourage generic manufacturers to provide alternatives to brand name drugs, the Hatch-Waxman Act gives the first generic manufacturer to file for FDA approval a 180-day exclusivity period before other generic manufacturers are allowed to introduce their generic products. This gives generic manufacturers an incentive to challenge the validity of the brand name manufacturer's patents. The process for obtaining FDA approval can often trigger patent litigation because the generic manufacturer may have to challenge the validity of a brand name manufacturer's patent that is listed in the *Orange Book*. These claims can result in settlements under which the generic manufacturer agrees to delay its entry into the market.

The FTC and private claimants have argued that settlements of patent litigation between brand name and generic manufacturers that delay the entry of the generic version of a drug into the market is illegal under Section 1 of the Sherman Act of 1890. In the FTC's view, these agreements are a restraint of trade leading to higher prices in the market for that drug. In 2003, for example, the FTC secured a consent decree against Bristol-Myers Squibb relating to three drugs after bringing monopolisation claims against the company for conduct including settling patent litigation against a would-be generic competitor (*Bristol-Myers*).

The federal courts have had a mixed reaction to this theory. The Sixth Circuit has held that these patent settlements are illegal. In *Andrx Pharmaceuticals*, the court found a temporary settlement, in which the generic manufacturer agreed not to produce the generic version pending resolution of patent litigation against the brand-name manufacturer, to be *per se* illegal (*Andrx Pharmaceuticals Inc. v Kroger Co. et al.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied* (2004)). Other courts, however, have focused on the fact that settling legitimate disputes is a proper business objective and can be more efficient in the long run than continued litigation. In two different cases, the Eleventh Circuit has refused to rule that these settlements were *per se* illegal, finding instead that they must be considered under a rule-of-reason analysis, and the court rejected the FTC's contention that a recent settlement involving Schering-Plough breached the anti-trust laws (*Schering-Plough Corp. v FTC*, 402 F.3d 1056 (11th Cir. 2005) and *Valley Drug Co. v Geneva Pharmaceuticals Inc.*, 344 F.3d 1294 (11th Cir. 2003)).

There have not yet been any cases in the EU challenging a pharmaceutical patent settlement on competition grounds, but there is certainly a risk of such actions in the future. Although the unique features of the Hatch-Waxman Act mean that patent settlements are of particular concern in the US, it is certainly possible that similar concerns could arise in the EU. More specifically, an agreement that had the effect of preventing or delaying the entry of a generic product could be challenged as a restrictive agreement that is in breach of Article 81 of the EC Treaty.

Authorised generics

In the US, companies should be aware of the potential anti-trust risks of agreements between brand name and generic manufacturers to produce an authorised generic version of a drug. Under these agreements, the brand name manufacturer licenses a company to produce an authorised generic product that enters the market at the same time as, or even before, the generic produced by the first-filing generic manufacturer. For the first-filing generic manufacturer, the presence of the authorised generic can greatly decrease the benefits it can expect to receive from the 180-day exclusivity period.

To date, there have not been any successful challenges to an authorised generic agreement, and several decisions have rejected arguments that an authorised generic product is anti-competitive or contrary to federal law (see *Teva Pharmaceuticals Industries, Ltd. v Crawford*, 2005 US App. LEXIS 10175, at *12 (D.C. Cir. 3 June 3 2005); *SmithKline Beecham Corp. v Apotex Corp.*, 2004 US Dist. LEXIS 20348, at *14 (E.D. Pa. 29 September 2004); *Eon Labs Manufacturing v Watson Pharmaceuticals, Inc.*, 164 F. Supp. 2d 350, 361-64 (S.D.N.Y. 2001)). Nevertheless,

given the stakes involved, generic drug companies can be expected to continue litigating anti-trust and other challenges to these agreements, and at least one court has suggested that they could potentially be seen as improper, as a form of anti-competitive conduct that could further a monopoly position and eliminate generic competition in the long term (*Mylan Pharmaceuticals Inc. v Thompson*, 207 F. Supp. 2d 476 (N.D. W. Va. 2001)).

RISKS ASSOCIATED WITH PRICING

The main risks associated with pricing relate to:

- Price-fixing, bid-rigging and market allocation.
- Resale price maintenance.
- Discounts and rebates.
- Price increases.

Price-fixing, bid-rigging and market allocation

Agreements to participate in cartels or otherwise engage in price-fixing with competitors are the most serious competition violations under both US and EC law. In addition to heavy fines, these violations can lead to individual criminal sanctions in the US and some EU member states.

Agreements that indirectly affect prices can also lead to competition exposure. For example, the FTC obtained a US\$100 million (about EUR80.3 million) settlement from Mylan Laboratories over charges that the company used exclusive licensing agreements to restrain the supply of the raw ingredient for Lorazepam and Clorazepate tablets. According to the FTC, these agreements allowed Mylan to increase prices for these generic drugs (the complaint also charged Mylan with monopolisation based on the same conduct) (*FTC v Mylan Laboratories et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999)). In the pharmaceutical context, a group of companies is currently defending allegations that their joint discount prescription programme was used as part of a price-related conspiracy (*In re Pharmaceutical Industry Average Wholesale Price Litigation*, 307 F.Supp.2d 196 (D. Mass. 2004)). Also, several pharmaceutical companies are defending an anti-trust claim alleging a conspiracy to raise drug prices in the US by restricting the import of foreign drugs (see *Clayworth v Pfizer, No. RG04172428 (Cal. Sup. Ct.) (filed 26 August 2004)*).

Resale price maintenance

Resale price maintenance occurs when a manufacturer agrees resale prices with its distributors or retailers. It is well established that setting minimum resale prices is illegal under both EC and US law. Agreements on maximum resale prices, while not necessarily lawful, can have pro-competitive benefits, and are evaluated under the rule of reason in the US (*State Oil Co. v Khan*, 522 US 3 (1997)) and the EU (*paragraphs 225-229, Notice providing guidelines on vertical restraints (OJ 2000 C291/1)*).

In both the US and the EU, manufacturers are free to suggest resale prices, advertise those prices, and provide dealers with suggested price lists, provided that the dealer can independently

determine whether it will adhere to the suggested prices. Manufacturers cannot coerce dealers into accepting resale prices, and unduly aggressive efforts to compel adherence (such as retaliatory wholesale price increases or other sanctions) can be considered to breach competition law.

Discounts and rebates

Companies should be aware of the competition risks associated with discounts and rebates. Under competition laws, a manufacturer cannot use rebates or dealer promotions to implement or police resale price maintenance. Rebates or discounts can occasionally be offered only on the condition that a customer agrees not to buy competing products from another manufacturer. Rebates tied to achieving a particular market share or exclusive sourcing are common in group purchasing organisations and should be analysed carefully to ensure that they do not unfairly restrict competition.

Price increases

While a price increase is not by definition a breach of competition law, increases in prices for particular drugs are attracting extensive competition scrutiny. Government enforcement agencies can assume or suspect that anti-competitive conduct caused the increase, and the increase can be used as evidence of consumer injury in competition proceedings.

In the US, state anti-trust enforcers focus on pharmaceutical pricing issues and, in 2002, the National Association of Attorneys General formed a Pharmaceutical Pricing Task Force to support these efforts. This is not surprising as states have traditionally focused on the consumer protection aspects of anti-trust law and are major purchasers of prescription drugs for Medicaid, prison and state employee healthcare purposes. In one example, attorneys general in at least two states recently launched an investigation into price increases associated with the drug Norvir (which is used as part of a cocktail containing drugs produced by other manufacturers). This investigation seems to focus, at least in part, on whether the manufacturer raised the price of Norvir to inhibit sales of the cocktail in favour of a newer drug it was producing in the same market.

Although charges of excessive pricing are rare in the European pharmaceutical sector because prices are generally subject to heavy governmental intervention, *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading (2002 CAT 1)* in the UK shows that there may be instances where dominant companies are challenged for imposing excessively high prices. In *Napp*, the UK's Office of Fair Trading held that Napp had abused its dominant position by charging excessively low prices in the hospital segment of the market with the intention of eliminating competition, and of charging excessively high prices in the community sector of the market.

COMPLIANCE ISSUES RELATING TO AGREEMENTS

Relevant competition compliance issues relate to:

- Licensing agreements.
- Research and development agreements.

- Co-marketing and co-promotion agreements.

Licensing agreements

Pharmaceutical manufacturers should be aware of the potential competition risks associated with licensing agreements related to intellectual property rights. The DOJ and FTC have issued joint guidelines on intellectual property licensing (*Antitrust Guidelines for the Licensing of Intellectual Property, 6 April 1995*). In the EU, licensing is governed by:

- Regulation (EC) No. 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements.
- Notice providing guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (*OJ 2004 C101/2*).

A licensing agreement increases anti-trust exposure if it can be seen to further the potential for any of the following:

- Price-fixing.
- Market allocation.
- Restricting output or competitive innovation.
- Containing ancillary restrictions going beyond the licensed product itself.

The particular risks often depend on whether the licensing agreement is vertical (that is, within the supply chain) or horizontal (that is, between competitors or potential competitors).

For vertical agreements, competition risks arise when the licensing agreement prevents the licensee from accessing competing intellectual property or developing its own competing products, or forecloses access to critical technologies or inputs. When the licensor has a dominant position or market power, it is much more likely that a restrictive agreement will be challenged. For example, a royalty payment structure imposed by a dominant licensor that essentially precludes the licensee from using competing products or technologies could have significant anti-competitive effects.

For horizontal agreements, the main concern is whether the licensing of the patented product or process will restrain actual or potential competition, not just for currently available products, but also for the manufacture or development of new products or processes. Although exclusive patent licenses are generally acceptable under US anti-trust law, such agreements can be considered anti-competitive if they eliminate incentives for competition, especially if the parties to the agreement are the major players in the market. Horizontal agreements can also increase the risk that one of the parties could use the licence to acquire or maintain significant market power. Finally, depending on the nature and likely economic significance of the agreement, it may also require a statutory filing with the US anti-trust agencies under pre-merger notification regimes.

While the treatment of patent licensing agreements is broadly the same under US and EC competition laws, a global licensing

agreement should be analysed under both regulatory regimes to minimise the risk of problems. The key difference is that territorial restrictions are much more likely to result in competition concerns in Europe because they are viewed as going against the fundamental goal of achieving a common market. Other differences between the two regimes include the treatment of post-term royalties (which is more problematic in the US) and exclusive grant-back and assignment clauses (which are more problematic in the EU).

Research and development agreements

Research and development agreements, including joint ventures, are often considered pro-competitive, but should be carefully monitored. The assessment of a research and development agreement will depend on the market structure, the extent to which the agreement will promote greater advances than either party to the agreement could expect to achieve independently and the parties' market share. Agreements that are seen as restricting the development of new technologies are generally prohibited under both US and EC competition rules. In particular, parties to a joint research and development agreement must be free to carry out independent research and development after the research and development phase has been completed, and restrictions on each party's ability to carry out research outside the scope of the collaboration are considered anti-competitive. The provisions in the agreement governing access to the results of the joint research should also be analysed for competition concerns. In general, open access for all participants willing either to initially fund the joint research or to pay a reasonable royalty to recover the costs paid is preferable. Of course, if the collaboration is seen as increasing the likelihood of price-fixing or otherwise restraining trade, it can result in serious competition risks (see above, *Risks associated with pricing*).

Territorial and customer restrictions are particularly likely to raise problems in Europe. Territorial and customer restrictions between parties are generally permitted for a period of up to seven years from the time the products were first placed on the market (*Regulation (EC) No. 2659/2000 on research and development agreements*). Restrictions for longer periods of time must be assessed on a case-by-case basis.

Co-marketing and co-promotion agreements

Co-marketing and co-promotion are common forms of collaboration agreements in the pharmaceutical industry. These are particularly likely to result in competition concerns if the parties compete with respect to the products covered by the arrangement. Other aspects of these agreements (such as the co-ordination of pricing strategies, the exchange of sensitive information, and the allocation of territories and customers) can also result in competition issues.

RISKS ASSOCIATED WITH RESTRICTIONS ON PARALLEL TRADE

Companies operating in the EU should pay special attention to practices that have, as their object or effect, the restriction of parallel trade among EU member states. A guiding principle in the application of the EC competition rules is the need to achieve

a common market, so that, not surprisingly, efforts by pharmaceutical companies to limit parallel trade have traditionally been attacked by the European Commission. In general, the US anti-trust laws are more tolerant of non-price vertical restraints that restrict how and where a distributor can resell a manufacturer's product, but recent challenges to prohibitions on re-importation of pharmaceuticals from Canada demonstrate that such practices are not entirely risk-free.

In the EU, significant price differences between member states for pharmaceutical products caused by national price controls have resulted in a high volume of parallel trade. Efforts by pharmaceutical companies to stem the flow of parallel trade have resulted in a series of competition challenges. The key issue in these cases is the extent to which the EC competition rules apply to strategies aimed at combating parallel trade in the pharmaceutical sector. As the price differences at the root of the problem are caused by national price controls, the industry argues that manufacturers should remain free to take steps to counter parallel trade. Many had hoped that the European Court of Justice would resolve this issue in a case involving an attempt by GlaxoSmithKline to limit supplies of products in Greece, but the case was dismissed on jurisdictional grounds (*Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline AEVE, Case C-53/03 (judgment of 31 May 2005)*). However, another case, also involving GlaxoSmithKline, is pending before the European Court of First Instance (CFI), which raises many of the same issues in the context of a dual-pricing arrangement introduced by GlaxoSmithKline in Spain (*Glaxo Wellcome v European Commission, Case T-168/01*). The CFI's ruling in this case is expected soon and could provide valuable guidance on the legality of strategies aimed at restricting parallel trade.

HOW TO SUCCESSFULLY IMPLEMENT A COMPLIANCE PROGRAMME

The purpose of a compliance programme is to prevent competition issues from developing and to facilitate the early detection of breaches that may still occur. A robust compliance programme can also limit a company's exposure for breach of competition law. For example, the US authorities will consider a company's anti-trust compliance programme in determining whether to bring criminal charges against the company itself for any breaches committed by its executives. This section considers the following points for creating a successful compliance programme:

- Considerations for the initial design of a compliance programme.
- Clear procedures.
- Internal sanctions.
- Ongoing monitoring.
- Audits.
- Actions to take when discovering a breach of competition law.

Considerations for the initial design of a compliance programme

To be effective, a compliance programme should be user-friendly. 15 years ago, a competition compliance programme consisted of simply handing out a compliance brochure drafted in dry legal prose by the company's competition counsel, which was rarely implemented. Later, plain English, and sometimes even humour, were introduced along with pictures added to the brochure. However, when it became obvious that many were only looking at the pictures, mandatory training programmes were introduced. Today, compliance programmes take a variety of forms and generally include some element of interactive training. Some companies have gone so far as to hire professionals to produce training videos and others use internet-based training modules.

A good compliance programme should be tailored to the company's business and the kinds of competition risk associated with that business. For example, it is a waste of time to train managers about the competition dos and don'ts of retail distribution agreements when the company supplies products to just a few large wholesalers. Similarly, there is no reason to train managers about the various pitfalls that dominant companies must avoid if the company has a small market share in a highly competitive market. Therefore, when designing a compliance programme, the initial effort should be focused on identifying where the competition risks lie.

The competition risks specific to a given jurisdiction should also be identified. For example, territorial restrictions imposed on commercial arrangements represent significant competition risks in Europe, while they pose virtually no problem in the US.

Finally, a compliance programme should be properly implemented over time. Many companies introduce excellent compliance programmes, but then fail to follow them up later on with refresher training for long-term employees and initial training for new or reassigned employees. A compliance programme should include ongoing training for all personnel with commercial responsibilities, especially those involved in pricing or interactions with competitors. The main goal should be to ensure that all participants can identify situations likely to raise competition problems and that they are instructed to seek legal advice before acting. These training courses should also identify markets where the company has a potentially dominant position and explain the increased competition risks in these markets.

Clear procedures

The company should set up a clear procedure to report possible breaches of competition law. To promote disclosure of unlawful practices, disclosing parties may be offered a guarantee that they will not be punished. In addition, the company may decide to keep the report confidential.

Participation of the company's representatives in industry associations should be closely monitored by the legal department, which should:

- Approve the company's participation in the industry association.

- Require employees attending industry meetings to:
 - inform the legal department of the meetings' agendas before they take place;
 - supply a copy of the minutes once they are available.
- Remind attendees not to engage in price or other improper discussions with competitors.

The company should set up a document retention policy. This should take into account requirements imposed by local jurisdictions but, in general, it should ensure that only documents that are necessary for commercial or legal reasons are kept. Similarly, the company should have procedures in place to quickly and effectively implement a document hold if it learns of an investigation or a claim that requires document retention.

Employees should be instructed to bear in mind competition rules when drafting their day-to-day communications. For example, they should avoid producing e-mails that could suggest the existence of a cartel or that over-emphasise the company's economic strength in the market. Inopportune comments in e-mails have been at the heart of several recent competition cases. Employees should also ensure that potentially privileged or protected communications are clearly identified as such. The rules on privilege tend to be much more restrictive in Europe than in the US, so that it cannot be assumed that a lawyer's advice is privileged in Europe. For example, in the EU, competition advice from in-house counsel who are not admitted to an EU bar is not privileged and can be seized in an investigation. In some jurisdictions, such as Germany and Switzerland, even advice by outside counsel is generally not privileged.

Internal sanctions

An internal system of sanctions on individuals who breach the procedures is necessary to convey the message that compliance is important. In addition, the credibility of the sanctions is an important part of the success of a compliance programme. Sanctions can vary from being mild (for example, censure or denial of bonuses) when an employee fails to comply with procedures (such as not clearing the agenda of an industry meeting with the legal department) to resulting in dismissal if an employee participates in a cartel. However, a company must balance the need for sanctions with the need to minimise its competition exposure, which could mean that dismissal for cartel activity should not be immediate (*see below, Actions to take when discovering a breach of competition law*).

Ongoing monitoring

A senior executive should be given responsibility for monitoring the company's compliance with competition rules. This can be done by setting an annual date on which the responsible person must report on the compatibility of the agreements and policies under his supervision.

Ongoing monitoring is particularly important with products for which the company experiences an increase in market share. Practices that were lawful when they were initially implemented may become unlawful with an increase in market share.

Therefore, companies should regularly check the list of products for which they may have a dominant position and review their policies accordingly.

In addition, a review of agreements and practices is crucial when there are significant changes in the relevant competition rules.

Audits

Periodic internal audits are designed to identify unlawful practices. They should be conducted to ensure that the compliance programme is being effectively implemented. In particular, they should be carried out when the company suspects that there is ongoing cartel activity and at regular intervals in those markets where competition exposure is higher.

There are several tools that can be used to conduct an audit, from interviews to mock dawn raids. Audits should not be too frequent and mock dawn raids are not advisable unless there are clear suspicions of a specific violation. Conducting a mock dawn raid merely to search for possible infringements may be counter-productive because of the risks that documents will be destroyed and business will be disrupted.

Auditing files of key individuals and conducting interviews with sales managers on a regular basis are usually more appropriate regular first steps. E-mail audits can be a very effective tool to discover possible breaches of law, but may be constrained by data protection rules or the volume of e-mails generated. The most effective means for conducting an e-mail audit are to focus on key individuals or to search for keywords that can indicate the existence of an unlawful practice, such as the words "parallel sales", "grey traders" (which take advantage of cheaper prices for goods in one country and make a profit by selling those goods in another country where they are generally sold at higher prices) or "price" in the same sentence as the names of major competitors.

Actions to take when discovering a breach of competition law

If a company becomes aware of a problem as a result of an audit, an employee coming forward, or otherwise, it should immediately take steps to uncover the full extent of the problem. If competi-

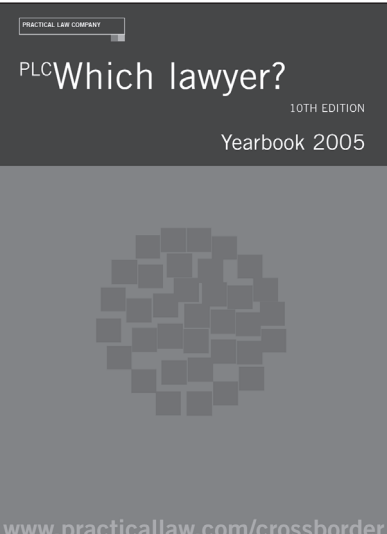
tion law is breached, the company should immediately consider what (if any) document retention procedures should be implemented or modified as a result of the discovery. The destruction of documents will, in most cases, be useless as other companies (in the case of cartel activity) or distributors (in the case of parallel trade-related breaches) will probably have a copy of the incriminating documents. Destruction could also deprive the company of the option to apply for leniency, or may result in charges of, for example, spoiling legal documents, or inferences that the destroyed documents contained damaging evidence.

The legal department must assess the seriousness of the breach of law and the appropriate course of conduct, taking account of the following:

- The type of breach.
- The products involved.
- The countries affected.
- The duration of the breach.

In particular, if the audit reveals that the company is participating in a cartel, a decision must be made quickly as to whether to apply for leniency. If it delays and one of its competitors applies to the relevant competition authority first, the difference can be between no fine at all and one running into tens of millions of dollars. When considering a leniency application, a careful decision must be made with regard to the employees involved in the cartel. It is advisable that they are removed from their positions, but an immediate dismissal can be counterproductive, as it can indicate the company's actions to other companies party to the cartel which, in turn, could make their own internal investigations and disclose the cartel to the authorities. In addition, the co-operation of the employees involved in the cartel is generally crucial to providing the necessary evidence to support a leniency application.

**The authors would like to thank Derek Ludwin and Rocío Salvador Roldán for their assistance in preparing this chapter.*



PLC Which lawyer?
10TH EDITION
Yearbook 2005

www.practicallaw.com/crossborder

PRACTICAL LAW COMPANY

PLC Which lawyer?
Yearbook 2005

This publication (formerly known as ^{PLC}Global Counsel 3000) analyses the legal market in over 75 jurisdictions worldwide, providing on a country-by-country basis:

- An overview of the legal market and recent developments
- Analysis and rankings of the leading firms and lawyers in all major practice areas
- Checklists of issues to address when appointing counsel including fees, approach to conflicts, professional indemnity insurance, legal privilege and the holding of client funds
- Profiles of leading firms

It also identifies the 50 law firms which received the greatest depth of recommendations across the research for the 2005 Yearbook - the Global 50 - and profiles their practices.

^{PLC}Which lawyer? is updated on a continuous basis at www.practicallaw.com/crossborder



Covington & Burling Life Sciences

Integration

Corporate
Collaboration
Regulatory
Intellectual Property
Commercial
Competition
Litigation

Worldwide

Key Contacts in Our
Life Sciences Group

Richard F. Kingham

London
+44 (0)20 7067 2018
202.662-5268
rkingham@cov.com

Peter W.L. Bogaert

Brussels
32.2.549.5243
pbogaert@cov.com

John A. Hurvitz

Washington
202.662.5319
jhurvitz@cov.com

James C. Snipes

San Francisco
415.591.7071
jsnipes@cov.com

Scott F. Smith

New York
212.841.1056
ssmith@cov.com

COVINGTON & BURLING

London • Brussels • Washington • San Francisco • New York
www.cov.com