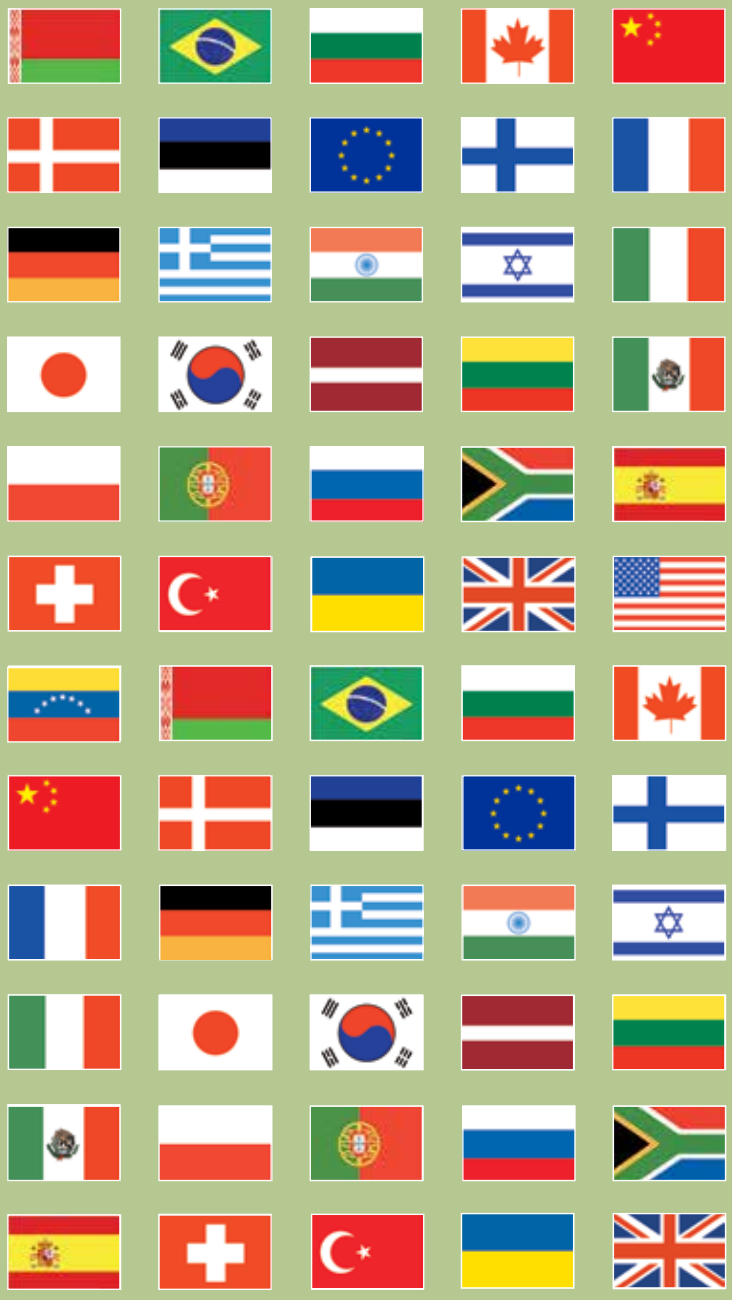
GETTING THE DEAL THROUGH

Pharmaceutical Antitrust

in 31 jurisdictions worldwide

2014

Contributing editor: Marleen Van Kerckhove



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Getting the Deal Through is delighted to publish the fully revised and updated seventh edition of *Pharmaceutical Antitrust*, a volume in our series of annual reports, which provide international analysis in key areas of law and policy for corporate counsel, cross-border legal practitioners and business people.

Following the format adopted throughout the series, the same key questions are answered by leading practitioners in each of the 31 jurisdictions featured. New jurisdictions this year include Israel, Poland and Spain.

Every effort has been made to ensure that matters of concern to readers are covered. However, specific legal advice should always be sought from experienced local advisers. *Getting the Deal Through* publications are updated annually in print. Please ensure you are always referring to the latest print edition or to the online version at www.GettingTheDealThrough.com.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. Getting the Deal Through would also like to extend special thanks to contributing editor Marleen Van Kerckhove at Arnold & Porter LLP for her continued assistance with this volume.

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France

Christophe Hénin and Anne Servoir

Intuity

Pharmaceutical regulatory law

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

The French Public Health Code (PHC) regulates the marketing authorisations (MA) of reference medicinal products for human use (articles L 5121-8 and R 5121-21 and following) and generic products (articles L 5121-10 and R 5121-5 and following).

Applications for MAs are submitted to the French National Agency for Medicines and Health Products Safety (ANSM). A simplified procedure exists for generics that have to prove the bioequivalence of their product with reference to the original medicine.

Any company marketing medicinal products without prior authorisation incurs two years' imprisonment and a fine of €30,000 (article L 5421-2 of the French PHC).

After having obtained an MA for its medicine, a pharmaceutical firm may decide on which market to place its product. A key distinction must be made between the hospital market for inpatients and the pharmacies market for outpatients:

- for the hospital market, pricing is free and prices are set through bids (except for medicines that can be purchased by outpatients and for most innovative medicines for which prices are set according to a procedure similar to the one applying to pharmacy reimbursable medicines as described below);
- for the pharmacy market, the firm can choose to enter the non-reimbursable market or the reimbursable market:
  - if it chooses the non-reimbursable market, pricing is totally free; or
  - if it chooses the reimbursable market, the price is then regulated and set by convention between the Economic Committee for Health Care Products (CEPS) and the firm.

The price determination process takes into account various criteria set out in article L 162-16-4 of the French Social Security Code, including the improvement of clinical benefit evaluated by the Transparency Commission of the French National Authority for Health, the prices of other medicinal products with a similar therapeutic design, the expected or recorded sales' volume and the actual and foreseeable use of the medicinal product.

For generics, the price set out by the CEPS is 60 per cent lower than a reference medicinal product.

Major changes have recently been implemented in the French pharmaceutical sector regulation in the aftermath of the *Mediator* affair. On 29 December 2011, the parliament adopted a major reform, Law No. 2011-2012, that concerns some key aspects with respect to transparency of related interests, governance of health products, medicinal products and medical devices. Some of its provisions have been adjusted by Law No. 2012-1404 on Social Security System Financing dated 17 December 2012 or clarified by implementation decrees. More specifically, the transparency of related interests has been organised by Decree No. 2013-414 of 21 May 2013, which clarifies which kind of payment or transfer of value must be reported and sets out a threshold of €10, above which advantages provided by pharmaceutical firms to health-care professionals must be reported.

2 Which bodies are entrusted with enforcing these regulatory rules?

For many years the French Health Products Safety Agency (AFSSAPS) has been the competent administrative body to grant an MA and enforce the rules applicable to medicines and pharmaceutical firms. It was replaced by the ANSM on 1 May 2012 following the publication of Decree No. 2012-597 on 27 April 2012. As a public body under the supervision of the Ministry of Health, the ANSM has taken over the tasks of the AFSSAPS and has been entrusted with new responsibilities.

Pricing procedures and monitoring are still implemented by the CEPS.

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

Several aspects of the above legislation are relevant to the application of competition law to the pharmaceutical sector.

As prices are set out by public bodies, competition between pharmaceutical firms is limited in this field.

Article R 5124-59 of the French PHC, which was modified by Decree No. 2012-1096 of 28 September 2012 imposes public service obligations on wholesalers, the strictness of which may hinder free competition on all levels. For example, wholesalers must store at least 90 per cent of existing medicines. In the former version of the text, this obligation was, in itself, likely to prevent manufacturers from freely organising their own supply chain. The changes adopted in September 2012 now bar the possibility to implement, in France, some of the schemes that have been implemented in other European countries, in particular in the UK. The new text indeed imposes on the pharmaceutical firms the obligation to supply the French wholesalers so they are in a position to meet their own public service obligations.

Furthermore, the draft decree comprised provisions that would have hindered the wholesalers' parallel import activity. However, following the Competition Authority's opinion (Opinion No. 12-A-18 dated 20 July 2012), the government did not include such restrictions in the final decree.

Additionally, in the supply chain, wholesale and retail upper margins are set by the government, again eliminating competition.

Most importantly, within the past 10 years, French law has been designed to support the inclusion of generic products into the market. Initially, generics benefited from article L 5125-23 of the French PHC allowing pharmacists to replace prescribed brand-name medicines with their generic equivalent. Since 1 January 2009, general practitioners are required to write their prescriptions according to

the international non-proprietary names (INN), which assign a common name to each active substance. This mechanism is promoted through financial incentives to pharmacists. Indeed, their margins are set higher by the government when they sell generics to their patients. Furthermore, under the French Social Security Code, generic companies are allowed to grant much higher discounts than originator companies to pharmacists. Thus, where originator companies' discounts to pharmacists are limited to 2.5 per cent, generic companies were allowed to grant them discounts of up to 17 per cent. However, in practice, generic companies did not respect these thresholds and implemented various mechanisms in order to actually grant financial advantages that could, in fact, go up to almost 50 per cent. The government decided to take account of this situation and consequently proposed to modify the relevant provision. The maximum discount will from now on be set out by ministerial decree with a maximum of up to 50 per cent. At the time of writing, this rate was still under discussion between the government and the pharmacists. The new law provides that the generic companies will have to indicate to the CEPS the annual turnover they achieved for each medicine together with the global discounts and financial advantages granted to the pharmacists for each medicine. In case of absence of filing or false declaration, the generic company may incur a fine of up to 5 per cent of the concerned annual turnover.

Finally, on 4 May 2012, the Ministry of Labour, Employment and Health set a mandatory objective of national market penetration rate of generics at 85 per cent for the year 2012. With an actual rate of 83.7 per cent in 31 December 2012, this goal was almost achieved. The setting out of such rate also limits competition, even between generic and originator companies, since it restrains, in any case, the originator company's market share to a maximum of 15 per cent.

Competition legislation and regulation

4 Which legislation sets out competition law?

The competition legal framework is mainly codified in Book IV of the French Commercial Code, entitled 'Pricing freedom and competition' (article L 410-1 and following), lastly amended by Law No. 2008-776 on the Modernisation of the Economy (LME) and passed on 4 August 2008.

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 issued by official bodies. However, case law regarding this sector is rather abundant and sets out general principles on how the French competition authorities apply competition law to the pharmaceutical sector. Furthermore, the sector inquiry conducted by the Competition Authority in 2013 also gives interesting guidelines on the issues that could be deemed to be problematic and the way the different players may solve them in compliance with the Authority's view (see question 9).

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

There is no specific authority in charge of applying competition law in the pharmaceutical sector. Competition law is applied to this sector by the Competition Authority, which is also competent for all business sectors.

Since 2 March 2009, the former Competition Council has been transformed into a renewed Competition Authority.

The Authority is now solely responsible for making competition work on the markets by overseeing mergers as well as by enforcing rules prohibiting cartels, anti-competitive agreements and abuses of dominance in any economic sector.

In particular, the Authority is responsible for merger control. Filing is mandatory, when the conditions set out in article L 430-2 of the French Commercial Code are met (namely thresholds of total turnover).

Pursuant to article L 430-7-1 of the French Commercial Code, the Minister of the Economy nonetheless retains certain powers such as opening an in-depth stage II investigation or reversing the Competition Authority's decision under certain circumstances.

Since the replacement of the Competition Council by the Competition Authority, competition investigations are mostly conducted by the investigators of the Competition Authority, under the sole supervision of the chief case-handler. However, the Ministry of the Economy holds some powers in this regard through its administration, which still has some investigators.

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

There are no particular remedies for the pharmaceutical sector that may be imposed by the Competition Authority.

The sanctions for infringements of French competition law are various: the Competition Authority may order interim measures, order the parties to change their conduct within a specified period or under special conditions, order publicity measures for its decisions or sentence parties to fines up to 10 per cent of their worldwide turnover.

French competition law also provides to companies suspected of infringement alternative means to resolve competition issues.

Firstly, before notifying an actual statement of objections, the Authority may indicate to a company it has 'competition concerns' regarding some of its behaviour. The said company may then propose commitments in order to resolve such concerns and thus avoid being fined.

Furthermore, even having received a statement of objections, companies may initiate a settlement procedure enabling them to obtain a fine reduction of between 10 and 25 per cent if they agree to waive their right to challenge the statement of objections and propose behavioural or structural commitments.

Finally, French law also provides a leniency programme under which companies may report anti-competitive practices to the Authority before or after the opening of a contentious procedure against them. They may thus obtain either full immunity or a reduction of the fine they would otherwise have incurred in consideration for handing over evidence to the Authority and for their cooperation during the investigation phase.

These solutions have been implemented in the pharmaceutical sector.

As regards financial sanctions, in Decision No. 07-D-09, the Competition Authority imposed a €10 million fine on GlaxoSmithKline as it ruled that the firm had abusively hindered the entry of generics into hospitals by implementing predatory prices as part of a global intimidation strategy aimed at discouraging generic medicine manufacturers from entering the hospital medicine market. However, this Decision was overruled by the Supreme Court in a Decision dated 17 March 2009.

More recently, in Decision No. 13-D-11, the Competition Authority imposed a €40.6 million fine on Sanofi-Aventis for having implemented a strategy which denigrated generics of Plavix, one of the top-selling medicinal products in the world. In three decisions (Nos. 07-D-22 (*Boehringer Ingelheim, Lilly France, Merck, Sanofi-Aventis*), 07-D-45 (*Pfizer*) and 07-D-46 (*GlaxoSmithKline*), the Competition Authority accepted the commitments submitted by pharmaceutical companies that amended their supply chain for medicinal products so as to increase its fluidity, flexibility and

transparency for wholesalers. These decisions were ultimately overruled by the Supreme Court on procedural grounds.

In Decision No. 13-D-21, Schering-Plough was fined €15.3 million for hindering the entry of generics of its originator, Subutex. Schering-Plough chose not to contest the objections brought forward by the Competition Authority and submitted several commitments in order to prevent such practices in the future, such as the control of commercial strategy before the entry of generics, and the sales staff training on the prohibition of denigration of generics. In this respect, the amount of the fine was reduced by 20 per cent.

Moreover, following the example of the European Commission of 2006, the Competition Authority published a Notice on the Method Relating to the Setting of Financial Penalties (16 May 2011), which provides a thorough analysis of the elements taken into consideration for the setting of the amount of the fine.

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 initiate proceedings before the Competition Authority by filing a complaint.

They usually request the Competition Authority to take interim measures to order the end of the practices they deem to be anti-competitive (see, for example, Decision No. 07-D-22 *Phoenix Pharma*, Decision No. 09-D-28 *Ratiopharm*, Decision No. 07-MC-06 *Arrow Génériques*). In the latter, based on a few pharmacist testimonies, the Competition Authority considered that Schering-Plough may have denigrated Arrow's generic. It thus adopted interim measures in order to restore the health-care professionals' confidence towards Arrow's generic and ordered Schering-Plough to publish a statement in this regard.

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?

Regarding competition inquiries, the powers of the Competition Authorities are very similar to the ones of the European Commission. Since the reform of competition investigations, the Competition Authority has its own investigators (see question 6) in order to conduct ordinary investigations (article L 450-3 of the French Commercial Code) or investigations under judicial control (article L 450-4 of the French Commercial Code).

On 25 February 2013, the Competition Authority launched a broad sector inquiry to investigate the distribution of human medicinal products 'in town'. After a first phase of discussions with all stakeholders (pharmaceutical companies, wholesalers and importers, trade unions, governments, councils of pharmacists and physicians, consumer groups, representatives of the retail sector, the Competition Authority issued in July a preliminary report that was extensively commented on by numerous stakeholders.

The final report was published on 19 December 2013 (opinion 13-A-24) and comprised various comments and proposals as regards each link of the supply chain, with the aim of 'enhancing competition within this highly regulated industry'.

As regards the originator companies, the main findings can be summarised as follows.

In 2013 the Competition Authority specifically punished the behaviour of originator companies denigrating generic medical products in the pharmaceutical sector (see question 7). In this regards, the final report insists that pharmaceutical companies adopt, beyond and within a compliance programme, a specific training programme for the whole staff of the company on the 'denigration issues and risks', in order to avoid 'denigration barriers' whenever generic products are about to enter the market.

In this respect, every originator company active on the French market should investigate and assess the possible necessity to finally adopt a competition compliance programme or amend its existing programme in this regard, if necessary.

The final report indirectly alludes to supply chain management schemes through the issue of supply shortages that arose in France in 2012 and 2013. The Authority implied that such shortages might have several and different causes but nevertheless noticed that these shortages might be the consequence of supply chain management schemes implemented by the pharmaceutical companies, as well as the activity of the wholesalers that export these products.

In addition, it is to be noted that the report only addresses the issue of the direct to pharmacy (DtP) channel by mentioning that it 'remained a minority channel'.

Finally, the Competition Authority commented on the relationships between originator companies and wholesalers only in relation to non-reimbursable medicinal products (OTC medicinal products). The report noticed that, for these medicinal products (for which rebates are not limited by legal provisions, see question 9), in some cases, rebates granted to pharmacists through the DtP channel seem to be superior to the ones granted to the wholesalers. Such difference would 'illustrate the power struggle created by the pharmaceutical firms with the wholesalers'. The Authority ventured the hypothesis that the situation could result from the companies' willingness to maintain their margins in relation to the smaller pharmacies since they would nevertheless keep an interest in buying from the pharmaceutical company rather than through wholesalers.

Even if, in practice, such behaviour is not limited to non-reimbursable medicinal products, it is to be kept in mind that, in itself, such behaviour would not constitute an anti-competitive practice. The situation only depends on the context as well as differentiated and specific conditions applied to both channels.

Other possible anti-competitive aspects of the commercial policy of pharmaceutical companies are not directly addressed by the final report. Tied rebates are solely mentioned as part of the commercial policy of companies selling, on the one hand, generic products and, on the other hand, non-reimbursable medicinal products.

Nevertheless, pharmaceutical companies should audit their commercial policy in this respect in order to suppress any risk, even potential abuse of a dominant position.

As regards the wholesaler link, the Report does not raise actual competition concerns and simply indicates that a risk of coordination between these players cannot be excluded without giving any tangible element that could have led to such mention (except for the fact that the wholesalers have been fined by the Competition Authority some years ago on such ground, see question 20).

Finally, with respect to retail sales, the Report notes that despite the strong growth of the self-medication practice, competition between pharmacies in this sector is very weak. Thus, the Authority recommended that the government should adopt measures to implement a limited and regulated opening to competition for self-medication medicines and that certain products such as pregnancy tests and contact lens care solutions should be taken out of the scope of the pharmacists' monopoly in order to be distributed also in drugstores or supermarkets. For the last two categories, the laws have been changed accordingly whereas the distribution of self-medication products outside the pharmacies is still the subject of strong disputes.

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 (as specified in question 2) have no jurisdiction over competition issues.

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

Article L 420-4 of the French Commercial Code lays down a system of exemptions that states that provisions related to cartels and abuse of dominant position do not apply to practices that have the effect of promoting economic progress and reserve for consumers a fair share in the resulting profit, without giving to the undertakings involved the opportunity to eliminate competition for a substantial part of the products in question.

For example, in Decision No. 07-D-05, the Competition Authority admitted that the price method set out by a trade association to determine the price of non-reimbursable prosthesis did not infringe the provisions of article L 420-1 of the French Commercial Code, as the conditions of exemptions were fulfilled. The method allowed patients to benefit from rare devices under better conditions.

As regards mergers, the Ministry of the Economy may reverse the decision taken by the Competition Authority on the grounds of general interest other than the maintenance of competition, notably industrial development, the competitiveness of companies with regard to international competition or the preservation of employment.

In the pharmaceutical sector as in other sectors, arguments such as strengthening the local or regional research and development activities are almost never admitted by the competition authorities.

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

Article L 462-1, paragraph 2, of the French Commercial Code enables professional associations, labour unions or recognised consumer groups to petition the Competition Authority with regard to the interests for which these are responsible to obtain its opinion on 'any issue regarding competition'.

The possibility has been used mainly by health-care professional associations. For example, the national association of emergency practitioners requested the Competition Council's opinion on rules set out by the Council of the national medical association to organise emergency cares in France (Opinion No. 96-A-17 dated 5 November 1996).

This opportunity has recently been used by manufacturers' associations. Thus, the French National Association of Dental Prostheses Manufacturers (SNFPD) consulted the Competition Authority regarding the effects on competition of dental prostheses' exclusive sale by dental surgeons (Opinion No. 12-A-06 dated 29 February 2012).

The Association of Veterinary Medicinal Products Manufacturers also used this faculty to obtain the Competition Authority's opinion regarding the possible competition issues that would result in the creation of an association of veterinary surgeons whose goal was to negotiate prices with the manufacturers on behalf of their members. The Authority concluded that the appearance of this newcomer would not by itself raise issues from a competition law standpoint (Opinion No. 12-A-14 dated 19 June 2012).

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?

Due to the size of most pharmaceutical firms, the majority of mergers in this sector referred to the Commission as European thresholds are often exceeded.

French practice in this sector is thus limited. However, specific sector features are taken into account in the definition of the relevant markets.

For example, the Competition Authority authorised a merger between Boiron and Dolisos, two French companies manufacturing homeopathic products (Opinion No. 05-A-01).

In this case, the definition of the relevant markets was influenced by the regulations applicable to certain products. The Competition Authority distinguished within the homeopathic medicines, generic homeopathic medicines (MNC) from branded homeopathic medicines (MNM), based, in particular, on the facts that the MNM include, contrary to the MNC, a therapeutic indication and are not reimbursable by social security insurance, their marketing is thus subject to a marketing authorisation, and their prices and margins are not controlled.

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

Product market

In general, medicinal products may be subdivided into therapeutic classes by reference to the 'anatomical therapeutic chemical' classification (ATC), which classifies medicinal products into five different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

The third level (ATC-3) allows products to be grouped in terms of their therapeutic indications (ie, their intended use) and is therefore generally used as an operational market definition. However, market definition may also be based on other levels of the ATC classification.

As regards merger control, the French authorities' practice regarding the market definition is mainly guided by the European Commission case law related to pharmaceutical sector. Nevertheless, it should be noted that in antitrust cases, the French Competition Authority considers level 3 of ATC merely as a starting point and tends to narrow the market definition to level 5 of the ATC medicinal product classification, namely, the molecule (see Decisions No. 03-D-35, *Sandoz*, No. 07-D-09, *GlaxoSmithKline*, No. 09-D-28 *Ratiopharm*, Decision No. 07-MC-06 *Arrow Génériques*). This trend is also visible in merger controls. In a recent decision, the Competition Authority had to assess possible effects of a merger on the market of regulators of bone calcium (acquisition of sole control of Warner Chilcott Company by Actavis Inc, Decision No. 13-DCC-106), a market that has previously been examined four times by the Commission between 2008 and 2010 (No. COMP/M.5295, *Teva/Barr*, 19 December 2008, No. COMP/M.5253, *Sanofi-Aventis/Zentiva*, 4 February 2009 and No. COMP/M.5555, *Novartis/EBEWE*, 22 September 2009, No. COMP/M.5865 *Teva/Ratiopharm*, 3 August 2010. In each case, the European authority had left the issue open on whether the market should be defined at level 3 (regulators of bone calcium) or at level 4 (bisphosphonates) but clearly ruled out the idea to narrow the market at level 5, deeming that there was a high degree of substitutability between the molecule (risedronic acid) and the other bisphosphonates. The French Authority nevertheless checked the market shares of the parties to the concentration on the three levels.

On the other hand, the French Authority conforms to the Commission's practice as regards the definition of the different market products and distinguishes between prescribed medicines and non-prescribed medicines, reimbursable and non-reimbursable medicines, products already on the market and pipeline products, active pharmaceutical ingredients, contract manufacturing. In the *Boiron/Dolisos* case, the Competition Authority made its own distinction between MNC and MNM (see question 13).

Geographical market

The geographic market for pharmaceutical products is in general defined on a national scope (see Decisions No. 07-MC-06 and 07-D-09) but may sometimes be said to be local. It could be the case for the market related to the supply of medicinal products by wholesalers

to pharmacists (due to public services obligations – see question 3), contrary to the market supply of medicinal products by pharmaceutical firms to wholesalers, which is on a national scope (Opinion No. 02-A-15 on a merger between two pharmaceutical wholesalers).

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

Under French Law, overlaps may be considered problematic when a market is deemed to be 'affected', that is, if one of the following three conditions is met (annex 4-3 of article R 430-2 of the French Commercial Code):

- two or more concerned undertakings operate on this market and their cumulative shares amount to 25 per cent or more;
- at least one of the concerned undertakings operates on this market and another of these undertakings operates on an upstream, downstream or related market, as soon as, in one or the other of these markets, the market shares of all the parties amount to 25 per cent or more; or
- the transaction leads to the elimination of a potential competitor on one of the markets on which the parties operate.

These criteria are detailed in the new guidelines related to merger control issued by the French Competition Authority on 10 July 2013.

When assessing the merger *Boiron/Dolisos*, the Competition Authority considered that the operation would not only affect the market but would create a near monopoly in the market for MNC. Regarding potential competition, the Authority ruled that new entries would be unlikely due to several barriers such as: the regulatory framework, impossibility of competing on prices, range effect, low level of prices and substantial registration fees for new products.

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

The few mergers in the pharmaceutical sector controlled by the French authorities did not imply pipeline products. However, it is likely that, in such cases, they would apply general rules. Overlaps between pipeline products would be assessed regarding the competition situation on the relevant markets and possible effects of the merger on these markets. It cannot be excluded that in case of serious doubts, the Competition Authority could authorise the merger, provided that rights on one product would be licensed if finally launched.

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

The Competition Authority is likely to require commitments from the parties such as licensing or divestments (even if such remedies have not been required yet in the pharmaceutical sector).

In the *Boiron/Dolisos* case, the merger was authorised after the parties guaranteed that the new entity would continue to offer every homeopathic strain they offered separately before the merger, and that they would not grant financial incentives to pharmacists in exchange of exclusive purchasing commitments of generic homeopathic medicines (MNC), or grant financial incentives to pharmacists buying MNC in exchange for a commitment to also buy their branded homeopathic medicines.

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?

In this regard, French law and practice by the authorities are quite similar to EU law and practice. Acquisition of assets falls within the meaning of 'control'. As with EC Merger Regulation No. 139/2004, the French Commercial Code (articles L 430-1, I, 2° and L 430-1, III) provides that the object of control can be one or more, or also parts of, undertakings that constitute legal entities, the assets of such entities, or only some of these assets.

Thus, in its new guidelines related to merger control dated 10 July 2013, the Competition Authority states that the acquisition of control over assets (such as brands or patents) can only be considered as a merger if those assets constitute the whole or a part of an undertaking, namely a business with a market presence, to which a market turnover can be clearly attributed (see paragraph 22 of the guidelines).

Anti-competitive agreements

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

Agreements or concerted practices fall under the scope of article L 420-1 of the French Commercial Code which is similar to article 101 of the Treaty on the Functioning of the European Union (TFEU) (formerly article 81 of the EC Treaty). It specifies that such practices that have the aim or that are likely to have the effect of preventing, restricting or distorting competition in a market, shall be prohibited, even through the direct or indirect intermediation of a company in the group established outside France, and in particular those that:

- limit access to the market or the free exercise of competition by other undertakings;
- prevent price fixing;
- limit or control production, opportunities, investments or technical progress; or
- share out the markets or sources of supply.

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

French competition authorities have investigated situations where they suspected that pharmaceutical firms may have implemented concerted practices:

- agreements between wholesalers (OCP Répartition, Alliance Santé, CERP Rouen) with the aim of freezing market shares (see Decision No. 01-D-07);
- concerted refusal to supply pharmacists and implementation of discriminatory conditions (see Decision No. 05-D-52);
- the parallel increase of prices of medical devices sold to hospitals by two manufacturers (see Decision No. 09-D-38); and
- the alleged boycott, by manufacturers, of a bid launched by a group of public hospitals for the supply of defibrillators (see Decision No. 07-D-49).

In some of these cases, the pharmaceutical firms were not found guilty of the suspected practices (see Decisions No. 05-D-52 and 09-D-38).

In its inquiry sector findings, the Competition Authority insinuated, without providing solid evidence, that the originator companies marketing medicines belonging to the same therapeutic areas could agree on the scope of their respective MA applications in order to avoid competing with one another or exchanging information as regards the costs they submit to the CEPS in order to inflate such costs and thus ensure that their medicine prices are set out at a higher level.

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

The French Commercial Code does not contain provisions applicable to technology licensing agreements. Thus, such agreements are assessed in accordance with the rules laid down in EC Regulation

No. 772/2004 on technology transfer (see the Competition Council's Annual Report, 2004, p. 125).

Licensing agreements would consequently not be deemed as anti-competitive, subject to the conditions that the parties' market shares meet the thresholds set out by the Regulation and that they do not contain hard-core restrictions as listed by the Regulation.

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

French legislation does not contain specific provisions applicable to co-promotion and co-marketing agreements. Thus, the Competition Authority's review of such agreements follows European legislation and practice.

The Commission defined co-promotion and co-marketing agreements in its Final Report on the pharmaceutical sector inquiry (8 July 2009) as being:

- co-promotion agreements: (joint) commercialisation of a specific medicinal product by both parties under one single trademark; and
- co-marketing agreements: commercialisation of a specific medicinal product by both parties under different trademarks.

Such definitions may appear to be clear in first instance. However, assessment of such contracts under competition law is often problematic as the relationships they create between the parties may fall under the scope of various regulations and guidelines (vertical and horizontal agreements, R&D, transfer of technology agreements).

The content and nature of the relationships created between the parties have to be carefully scrutinised in order to determine under which set of competition rules a particular agreement may fall into and, consequently, assess its validity under competition law, in particular if they imply exchanges of information between the parties.

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 focusing on R&D create a collaborative relationship between two companies in which they contribute to the overall discovery process by using the parties' combined expertise to deliver outcomes. R&D agreements often contain a transfer of technology (see question 21).

Other agreements (as listed in the final report of the European Commission, such as consignment stock agreements, agreements focusing on the transfer of a market authorisation or the underlying documentation) could contain direct or indirect restrictions such as price fixing or territorial restrictions.

All these agreements often contain confidentiality provisions related to information exchanged between parties. However, these provisions should not and cannot obstruct the application of competition rules so that they may not be upheld in case of antitrust infringements.

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

The Competition Authority uses the principles set out in EC Regulation No. 2790/1999 (now EC Regulation No. 330/2010 of 20 April 2010) to apply French competition law to vertical agreements, if the relevant market share does not exceed the 30 per cent threshold. In this regard, the negative effects on the market that may result from vertical agreements are as follows:

- foreclosure of other suppliers or other buyers by raising barriers to entry;
- price fixing (see Decision No. 07-D-35, *Sirona Dental Systems*);
- reduction of inter-brand competition; and
- limitations to the freedom of consumers to purchase goods or services in a member state.

In this respect, the Authority had the opportunity to assess vertical agreements in many decisions. It deemed that, under certain circumstances, in particular when having small market shares, approval of its wholesalers by a pharmaceutical firm shall not be prohibited (see Decision No. 03-D-53, *Biotherm*).

Furthermore, the Authority ruled that the prohibition of mail-order selling imposed by a prosthesis to its wholesalers did not restrict competition law (see Decision No. 03-D-69, *Ivoclar*). However, this case law would no longer apply since, according to the Court of Justice's decision in the *Pierre Fabre* case (Case C-439/09, *Pierre Fabre Dermo-Cosmétique SAS*), the Paris Court of Appeal ruled, on 31 January 2013, that prohibition to sell on the internet constitutes a per se restriction to competition when the clause contains no objective justification with respect to product properties.

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

There is no French case law concerning the settlement of a patent dispute in the pharmaceutical sector in relation to an antitrust violation.

The Commission's final report on sector inquiry suggested that, under certain circumstances, settlement agreements between originator and generic companies could be deemed to be anti-competitive. Following such statement, the Commission sent several statements of objection to pharmaceutical firms and fined Lunbeck, and most recently Johnson &Johnson and Novartis.

In the *Lundbeck* case, the agreements went further than other settlements of patent disputes as the originator company, not only paid significant lump sums to generic companies, but also purchased their stocks for the sole purpose of destroying them, and guaranteed them profits through a distribution agreement. Therefore Lundbeck maintained the generic producers out of the market for the duration of the agreements without promising the generic companies any guarantee of market entry thereafter.

In the second case, Johnson & Johnson provided Novartis, through the conclusion of a co-promotion agreement, monthly payments exceeding the profit that the company would have expected to obtain from selling its generic on the market.

However, it appears that potential antitrust violation by such settlements may only be discussed in the cases where the settlements would contain provisions preventing the generic company to enter the market and providing for a kind of value transfer.

Even in such case, this kind of settlement cannot be deemed to be anti-competitive per se but only on a case-by-case analysis of each particular settlement.

In the US, some circuit courts first ruled that patent settlements that would not go further than the potential exclusionary effect that is the essence of the rights conferred to the holder by the patent itself (the patent test) did not infringe competition law, even when providing for a transfer of value from the originator company to the generic firm in compensation for the latter not entering or delaying its entry on the market.

However, in a decision dated 17 June 2013 (*Federal Trade Commission v Actavis, Inc,*), the Supreme Court dismissed the patent test and ruled that the probability for a reverse payment to be deemed anti-competitive depends on the size of the reverse payment, its relationship to projected litigation costs, the existence of convincing justification, and the predicted magnitude of the harm.

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?

Any conduct aimed at limiting access to the market or competition on the merits by other undertakings is likely to be considered abusive if it is carried out by an undertaking holding a dominant position (article L 420-2 of the French Commercial Code).

Abusive behaviour by a dominant firm may consist of a refusal to sell, tying, discriminatory conditions of selling and breach of commercial relationships, or denigration of generic medicinal products.

For example, in Decision No. 03-D-35, the Competition Authority imposed a €7.8 million fine on Sandoz for abuse of dominant position by offering tied discount. The firm proposed the hospitals discounts on its global sales to the hospitals (especially sales of medicines that were deemed to be in a dominant position) on the condition that the hospitals undertook to buy other products for which the firm was competing with other pharmaceutical firms. The Authority considered that such a scheme resulted in increasing customer loyalty towards Sandoz.

More recently, the Competition Authority fined both Sanofi-Aventis (in Decision No. 13-D-11) and Schering-Plough (in Decision No. 13-D-21), for abusing their dominant position notably by denigrating generic medicinal products. The Competition Authority ruled that such practices had the object and effect of restricting the generic companies' access to market (See question 7).

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

The French Commercial Code does not define dominant position. Under such circumstances, the Competition Authority applies the definition set out by the European Court of Justice in the *United Brands* case (27/76), that is, the faculty for an undertaking to detach itself from the competition of other undertakings from its customers and ultimately from consumers.

The main indicator of dominance is, of course, a large market share; other factors include the economic weakness of competitors, the absence of latent competition and control of resources and technology.

In the assessment of these situations, the Competition Authority follows the European case law. However, in a decision dated 14 January 2010, although it left the question open, the Competition Authority surprisingly seemed to consider that, despite important market shares of 55/60 per cent in 2000 to 70/75 per cent in 2004, Sanofi-Aventis may not have held a dominant position in the hospital medicines market (see Decision No. 10-D-02).

Regarding joint domination, the Competition Authority applies the conditions set out by the Court of First Instance (now the General Court) in the *Irish Sugar* case (T-228/97), that is, factors connecting the undertakings that give them the power to adopt a common market policy.

The Competition Authority never found a joint domination in the pharmaceutical sector (see Decision No. 07-D-42, *Nestlé, Danone-Blédina, Milupa-Nutricia, Sodilac*). The issue was again addressed recently by the Ministry of the Economy when seizing the Authority for the alleged concerted practices and abuse of a joint dominant position by Ethicon and Tyco Healthcare. However, the Authority did not rule on the issue of joint domination as it deemed that the practices of the undertakings concerned were not anti-competitive (see Decision No. 09-D-38).

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

Under French Competition Law, in theory, ownership of a patent does not systematically confer a dominant position to the holder, but under certain circumstances, the Authority deems that it may create or reinforce the dominant position of a company, in particular because this intellectual property right has 'itself an economic force'. Such position was reasserted by the Competition Authority in its Annual Report for 2004.

As mentioned above (see answer to question 14), it is worth noting that, in antitrust cases, the French Competition Authority tends to narrow the market definition to level 5 of the ATC medicinal product classification, namely, the molecule.

In its Decision No. 96-D-12, confirmed by the Supreme Court, the Competition Authority deemed that from 1987 to 1991, Lilly France held a dominant position on the Dobutrex market. The firm had an exclusive right of distribution of Dobutrex as it held a patent on the medicine.

Since then, French competition authorities have almost always defined the relevant market as being the one of the molecule without real verification of the therapeutic use of the medicines on the market, thus establishing an almost automatic link between patent and dominant position.

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

In 2001, the Competition Authority ruled that the mere application for the grant of a patent was not abusive, since such conduct would not be capable of harming competition (see Decision No. 01-D-57).

However, it is to be kept in mind that, in the *AstraZeneca* case, the General Court (judgment dated 1 July 2010, case T-321/05), upheld the Commission's decision which ruled that the mere application for a SPC (supplementary protection certificate) could amount to an abuse (see Decision dated 15 June 2005). On 6 December 2012, the ECJ confirmed the General Court's decision (case C-457/10P). Furthermore, in its final report on the pharmaceutical sector inquiry, the European Commission identified practices, called 'patent filing strategies', suggesting that filing numerous patent applications for the same medicine (forming the 'patent clusters') could, in itself, delay or block the market entry of generic medicines.

Under such circumstances, one could wonder whether, the Competition Authority would hold to its former ruling regarding patent application or would evolve in the direction set out by the European authorities.

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

Prima facie, enforcing one's patents against parties infringing them is a legitimate procedural dimension of the material right granted to the patent holder.

In its final report, the European Commission alleged that in certain instances, originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

However, for the time being, European case law considers that court proceedings may constitute an abuse only in exceptional circumstances (see criteria set out by the Court of First Instance (now the General Court) in its *ITT Promedia NV* case). This case law is also applied in France. The Competition Council ruled that the mere fact of a dominant undertaking to defend its intellectual property rights before the competent courts may not be seen per se as an abuse (see Decision No. 01-D-57).

Update and trends

As mentioned in question 9, the Competition Authority's final report on the inquiry sector specifically developed on the possible denigration behaviour adopted by originator companies, on the generic medicinal products all the more that both decisions rendered by the Competition Authority in 2013 in the pharmaceutical sector sanctioned more specifically this type of behaviour implemented by the originator companies (see question 7). In this regards, the final report insists on the opportunity for pharmaceutical companies to adopt, beyond and within a compliance programme, a specific training programme for the whole staff of the company on the 'denigration issues and risks', in order to avoid 'denigration barriers' whenever generic products are about to enter the market.

Originator companies should then pay particular attention to possible denigration when generics enter the market. In this respect, every originator company, active on the French market, should investigate and assess the possible necessity of finally adopting a competition compliance programme or amending its existing programme in this regard, if necessary.

For more details, see question 9.

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

Such strategies may consist, for the originator companies, in the launch of second generation products or the follow-on of medicinal products shortly before the loss of exclusivity of the first generation product, sometimes combined with the withdrawal of the initial product from the market and withdrawal of the MA. The European Commission considered that AstraZeneca abused of its dominant position for having implemented such practices with its medicine Losec (see also question 29). This decision was upheld by the General Court (judgment dated 1 July 2010, case T-321/05) and then confirmed by the ECJ (judgment dated 6 December 2012, case C-457/10P). In its final report, the Commission stated that as a result of such strategies, generic companies may encounter some difficulties to sell their generic products.

The ECJ has already had the occasion of ruling on such practices from a regulatory and parallel import point of view (ECJ, C-94/98 *Rhone Poulenc Rorer*). It acknowledged the possibility for a pharmaceutical company to withdraw its MA 'at any point in time without being obliged to give any reasons', setting out the principle that 'the concept of compulsory licensing is unknown in any Community pharmaceutical legislation'.

Furthermore, the Court of First Instance (now the General Court) has set out the limits within which 'an undertaking in a dominant position enjoys an exclusive right with an entitlement to agree to waive that right', considering that such undertaking 'is under a duty to make reasonable use of the right of veto conferred on it by agreement in respect of third parties' access to the market' (CFI T-24/93, *Compagnie maritime Belge Transport SA v Commission*).

Thus, life-cycle management strategies may be deemed anti-competitive to access the market only if they result in hindering other undertakings, in particular generic companies. For example, such a decision was recently rendered on 3 September 2012 by the Regional Administrative Tribunal for Latium that reversed the Italian Competition Authority's decision fining Pfizer Group €10.6 million for having implemented a multifaceted strategy to prevent the entry of generic producers.

However, for the time being, the French Competition Authority did not have the occasion to rule on the conformity of such practices with competition law, whereas the English Office of Fair Trading issued a statement of objections against Reckitt Benckiser for having withdrawn Gaviscon from the market before generic entry and promoted the second generation medicine. Reckitt Benckiser agreed to pay a £10.2 million penalty for abuse of dominance in October 2010.

32 Do authorised generics raise issues under the competition law?

The launch by an originator company of a generic of its own medicine or to grant a licence shortly before the expiry of the protection of a patent with the intention to allow an 'early entry' has been a common practice in the pharmaceutical market for many years. In its final report, the European Commission states that early entry agreements are used to control market launch of a generic product.

In France, there is no case law yet regarding the practice of authorised generics.

In principle, it is not possible to consider such practices as anti-competitive per se. Such statement would only be justified after an in-depth analysis of each contractual provision and of the possible effects on competition and consumers. In this regard, it is worth noticing that, in its interim report on authorised generics, the FTC noticed that such early entry could have a positive impact on consumers and health-care system.

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

In France, public health issues may be taken into account. Thus, in Decision No. 07-D-22, the Competition Authority admitted that quota systems adopted by some originator companies had the legitimate aim to rationalise production and optimise medicine distribution with regard to the country's needs, even if specificity of the sector has not been deemed sufficient to be considered as an objective justification that would allow, in itself, some practices to benefit from exemptions provided for by articles L 420-1 and L 420-2 of the French Commercial Code. While analysing the quota systems,

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the Competition Authority noticed that the restrictions imposed by the pharmaceutical firms to the wholesalers were limited to what was strictly necessary for a reliable and optimal supply of the French market, while maintaining real competition possibilities between wholesale distributors.

However, it should be noticed that the French decision practice could evolve based on more recent European case law. Thus, in the *Spanish GSK* case (ECJ, October 2009, *GlaxoSmithKline Services Unlimited*, C-501/06, C-213/06, C-515/06 and C-519/06), when examining the dual pricing schemes, the ECJ has confirmed that the specific legal and economic context of the pharmaceutical sector could be relevant in the application of article 101(3).

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.

Two decisions were rendered by the Competition Authority in 2013 in the *Plavix* and *Subutex* cases (see question 7), whereas several cases are still being instructed by the Authority. In one of these cases, a solution could be found in 2014.

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.

In theory, follow-on litigation could be a tool to be used in pharmaceutical antitrust enforcement in France. In practice, up until now, there are no examples of such cases in the pharmaceutical sector. A new law was adopted on 17 March 2014, which implements a form of class action into French law, as it will, from now on, enable an association whose specific purpose is consumer protection to bring an action against an undertaking in order to obtain compensation for damages suffered by individual consumers due to a competition law infringement. However, the implementation of the law is subject to the adoption of government decrees and no action will be possible in cases in which an irrevocable decision has been made by a competition authority (at national or European level) at the date of the adoption of the law.

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