Italy

Andrea De Matteis, Nicoletta Bosa, Simone Giordano

De Matteis Studio Legale

Pharmaceutical regulatory law

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

The regulatory framework for marketing and authorisation of pharmaceutical products, including generic drugs, is set out in Legislative Decree 219/2006 (as amended by Legislative Decree 274/2007). That Decree implements Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2003/94/EC which lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. The regulatory framework for the pricing of pharmaceutical products is set out in Law 326/2003. Current prices are contained in the updated Italian National Pharmaceutical Handbook.

2 Which bodies are entrusted with enforcing these regulatory rules?

Agenzia Italiana del Farmaco (AIFA) is the main body entrusted with enforcing the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products. AIFA is subject to the supervision of the Italian Ministries of Health and Finance.

AIFA is responsible for:

- issuing marketing authorisations (AICs) for pharmaceutical products, including generic drugs, for which a simplified procedure applies;
- classifying the medicinal product when a marketing authorisation is granted;
- issuing authorisations for the manufacture of medicinal products within the Italian territory and monitoring the manufacturing process;
- ensuring compliance with the provisions concerning product labelling and package leaflet inserts;
- negotiating with the pharmaceutical industry about the prices of medicinal products for which a reimbursement is granted by the Italian National Health Service;
- collecting information for medicinal product monitoring and evaluation; and
- promoting research and controlling the public pharmaceutical budget.

The regions and the autonomous provinces (Trento and Bolzano) grant marketing authorisations for wholesale distribution and storage of medicinal products.

The Italian Ministry of Health is entrusted with the granting of authorisations for the advertising of medicinal products.

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

Pharmaceutical legislation may be relevant to the application of competition law, in particular the provisions which favour generic drugs, regulate prices for reimbursed medicinal products, restrict the number of pharmacies and limit advertising.

Also relevant for parallel trade cases are the provisions on labelling and package inserts and the obligation for the holder of a marketing authorisation and the distributors to ensure appropriate and continued supplies.

Competition legislation and regulation

4 Which legislation sets out competition law?

Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) on, respectively, anti-competitive agreements and abuses of a dominant position, are fully and directly applicable in Italy to cases where trade between member states is affected.

Where trade between member states is not affected, Law 287/1990 (the Competition Act) is applicable. Articles 2 and 3 of the Competition Act essentially reproduce articles 101 and 102 of the TFEU:

- article 2 prohibits agreements that have as their object or effect the prevention, restriction or distortion of competition within the Italian market or within a substantial part of it. Prohibited agreements are null and void; and
- article 3 prohibits the abuse by one or more undertakings of a dominant position within the Italian market or in a substantial part of it.

Articles 5 and 6 of the Competition Act set out the regime for mandatory merger notifications.

The above-mentioned provisions of the Competition Act must be interpreted according to the principles of EU competition law.

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

There are no specific guidelines for the pharmaceutical sector. There are, however, a number of notices issued by the Italian Competition Authority which apply to all industries, including the pharmaceutical sector:

- Decision 16015/2006 on remedies;
- Decision 16218/2006 on interim measures; and
- Decision 16472/2007 on leniency.

In addition, the Block Exemption Regulations issued by the European Commission are directly applicable to the pharmaceutical sector in Italy, including:

- Regulation 330/2010/EU on vertical agreements and the Guidelines on Vertical Restraints, 2010/C 130/01;

- Regulation 1218/2010/EU on specialisation agreements;
- Regulation 1217/2010/EU on research and development agreements; and
- Regulation 772/2004/EC on technology transfer agreements.

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

The Italian Competition Authority is responsible for vetting pharmaceutical mergers that do not have a Community dimension and meet certain Italian turnover thresholds. Such thresholds are met if the combined aggregate domestic turnover of all the undertakings concerned exceeds €468 million or if the aggregate domestic turnover of the undertaking that is to be acquired exceeds €47 million. It is also responsible for investigating and sanctioning anti-competitive agreements and abuses of a dominant position in the pharmaceutical sector.

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

The Italian Competition Authority may impose a cease-and-desist order aimed at bringing an infringement to an end and a fine of up to 10 per cent of the infringing company's total turnover in the preceding business year.

It may accept undertakings offered by the parties and close the case without a finding of an infringement.

In addition, the Italian Competition Authority may impose interim measures where serious and irreparable harm to competition is likely to occur.

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 obtain competition-related remedies in civil courts. Civil courts may impose interim measures, cease-and-desist orders and compensation for damages. Damages claims are likely to be more successful following a finding of an infringement by the European Commission or by the Italian Competition Authority.

Private parties may lodge a complaint before the Italian Competition Authority. Even a private individual can bring an alleged infringement to the attention of the Italian Competition Authority (see for example Case A431 – *Ratiopharm/Pfizer*, described in question 26).

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

The Italian Competition Authority has the power to conduct sector-wide inquiries. In 1994, the Italian Competition Authority started a general sector-wide inquiry in the Italian pharmaceutical sector (Case IC14 – *Settore Farmaceutico*) and issued a final report in November 1997. The report recommended price deregulation and increased use of generic drugs.

The Italian Competition Authority thereafter carried out two sector-wide inquiries regarding pharmacists. The Authority started its first inquiry in 1994 and concluded it in 1997 (IC15 – *Settore degli Ordini e Collegi Professionali*). That final report highlighted the limited degree of competition among pharmacists. The second inquiry, which started in 2007 and was concluded in 2009 (IC34 – *Indagine Conoscitiva riguardante il settore degli Ordini Professionali*), verified the compliance of the Code of Conduct of the Pharmacists' Association with the Italian antitrust regulatory framework (in particular concerning the setting and publishing of prices, the advertising of products and the relationships between pharmacists and their clients).

In 2005 the Italian Competition Authority started a general inquiry on hospital services (IC30 – *Settore delle prestazioni sanitarie ospedaliere*), which is ongoing.

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

There is no sector-specific regulation of competition for the pharmaceutical sector. The Italian Competition Authority is exclusively entrusted with the application of the competition rules to the pharmaceutical sector.

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

Antitrust concerns may be addressed with industrial-policy considerations if they relate to efficiency gains within the framework of article 101(3) TFEU or article 4 of the Competition Act, which provide that anti-competitive agreements may be exempted if they:

- contribute to improving the efficiency of the production or distribution of goods or services or to promoting technical or economic progress;
- provide consumers with a fair share of the resulting benefits;
- do not impose on the undertakings restrictions that are not necessary to attain these objectives; and
- do not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products or services in question.

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

Consumer associations play an increasingly relevant role in the application of the competition rules to the pharmaceutical sector. They may submit complaints, intervene in the Italian Competition Authority's proceedings and lodge a class action before a civil court.

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?

In principle, all mergers in the pharmaceutical industry are reviewed and their respective impacts assessed against general competition law principles as well as sector-specific features and regulation. In particular, the necessity of obtaining marketing authorisation, price regulation and reimbursement mechanisms are sector-specific features that may be taken into account when reviewing mergers between pharmaceutical companies.

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

The approach of the Italian Competition Authority to market definition in the pharmaceutical sector is entirely consistent with that of the European Commission and other national competition authorities.

For product market definition, the Italian Competition Authority applies the Anatomical Therapeutic Chemical (ATC) classification adopted by the World Health Organisation. The third level, referred to as ATC3, allows medicines to be grouped according to their therapeutic indications (ie, their intended use) and is generally taken as the starting point for product market definition (see for example Case C11189 – *Biogén Idec International/Biogén-Dompé* of 25 August 2011). In certain cases, however, the Italian Competition Authority may carry out an analysis at other levels. For example

at ATC4 or ATC5 (based on the same main active pharmaceutical ingredient, as illustrated by Case C11073 *ACRAF/Ramo di Azienda del gruppo Novartis* of 8 June 2011), or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of market definition. In case of production and/or commercialisation of active principles that are used not exclusively in the pharmaceutical sector but also in the cosmetic, chemical and nutrition sectors, the Italian Competition Authority has defined the market generically without applying the ATC classification (C11488 – *Lauro Quarantotto/Prime European Therapeuticals (Euticals)* of 22 February 2012 and C11209 – *Novacap/Ramo Di Azienda Di Rhodia Opération* of 25 August 2011).

For geographic market definition, the Italian Competition Authority has defined the markets for production and marketing of pharmaceutical products as national in scope due to the existence of different regulatory controls and differences in price regulation and reimbursement mechanisms between member states. The market of production and commercialisation of active principles for the pharmaceutical sector is considered European or even worldwide in scope due to the reduced incidence of transport costs and the absence of technical or administrative barriers.

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

Product and geographical overlaps may be considered problematic when the aggregate market share of the two merging parties exceeds 40 per cent, provided the incremental increase caused by the merger is not negligible. In certain cases, however, the Italian Competition Authority may raise concerns even where the aggregate market share exceeds 30 per cent. Below this threshold, competition concerns are unlikely to arise.

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

The Italian Competition Authority takes potential competition into consideration when assessing a merger, which means that an overlap with respect to pipeline products may be problematic if it is likely that these products will make it to the market and the overlap will create a dominant position.

More specifically, the Italian Competition Authority may take into consideration the impact of pipeline products in Phase III (and in some cases even Phase II) of clinical trials on competition in existing or future product markets (see Case C10665 – *Aptuit/Ramo di Azienda di Glaxosmithkline* of 21 July 2010 and Case C10539 – *Eli Lilly and Company-Eli Lilly Export/Ramo di Azienda di Boehringer Ingelheim International* of 22 April 2010).

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

The Italian Competition Authority may authorise a merger with remedies. Remedies are aimed at resolving any competition issues that have been identified during its investigation and, in particular, at preventing the creation or the strengthening of a dominant position. The parties may propose structural or behavioural remedies. The Authority typically requires structural remedies because it considers them more efficient and easier to monitor than behavioural measures. In vetting the remedies proposed, the Authority applies the Commission Notice on remedies acceptable under the Council Regulation (EC) No. 139/2004 and under Commission Regulation (EC) No. 802/2004 (Official Journal C 267 of 22 October 2008).

Where the merger has already been consummated, the Italian Competition Authority may impose remedies aimed at eliminating the competitive concerns.

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?

A transaction confined to intangible assets such as brands, patents or copyrights is subject to merger control requirements if those assets constitute the whole or a part of an undertaking, ie, a business with a market presence, to which a market turnover can be clearly attributed. The transfer of licences for brands, patents or copyrights, without additional assets, can only fulfil these criteria if the licences are exclusive for a certain territory and the transfer of such licences will transfer the turnover-generating activity. Non-exclusive licences do not normally constitute on their own a business to which a market turnover is attached.

Anti-competitive agreements

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

Article 101 TFEU on anti-competitive agreements is fully and directly applicable in Italy to cases where trade between member states is affected. Where trade between member states is not affected, article 2 of the Competition Act is applicable.

Pursuant to article 2 of the Competition Act, agreements, decisions or concerted practices are prohibited if their object or effect is that of preventing, restricting or distorting in an appreciable manner competition within the national market or within a substantial part of it. In particular, article 2 considers null and void all the agreements that:

- directly or indirectly fix purchase or selling prices or other contractual conditions;
- limit or restrict production, market outlets or market access, investment, technical development or technological progress;
- share markets or sources of supply;
- apply to certain trading partners dissimilar conditions for equivalent transactions, thereby placing them at an unjustifiable competitive disadvantage;
- make the conclusion of contracts subject to acceptance by the other party of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

Anti-competitive agreements that would normally be prohibited under article 101(1) TFEU or article 2 of the Competition Act may be exempted if they lead to efficiency gains, ie, if they:

- contribute to improving the efficiency of the production or distribution of goods or services or to promoting technical or economic progress;
- provide consumers with a fair share of the resulting benefits;
- do not impose on the undertakings restrictions that are not necessary to attain these objectives; and
- do not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products or services in question.

Article 13 of the Competition Act provides that undertakings may voluntarily notify agreements that appear to have anti-competitive effects to the Italian Competition Authority to obtain an exemption. Even though article 13 has not been formally repealed or amended by the Italian legislator, the Authority has practically adopted the self-assessment rule of Regulation (EC) No. 1/2003. Therefore, Italian undertakings no longer notify possible anti-competitive agreements to the Italian Competition Authority. They instead self-assess whether an agreement or practice may be considered anti-competitive. All the relevant EU Block Exemption Regulations and Guidelines apply in Italy and are part of the general framework for self-assessing whether an agreement or practice is anti-competitive.

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

The Italian Competition Authority has opened several cartel investigations in the pharmaceutical sector, resulting in the imposition of fines (Case I701 – *Vendita al Dettaglio di Prodotti Cosmetici* of 15 December 2010, Case I623 – *Prezzi del Latte per L'Infanzia* of 12 October 2005, Case I337 – *Bracco-BYK Gulden Italia-Farmades-Nycomed Amersham Sorin-Schering* of 23 November 2000; Case I331 – *Servier Italia-Istituto Farmaco Biologico Stroder* of 1 July 1999; Case I332 – *BYK Gulden Italia-Istituto Gentili* of 25 February 1999; Case I333 – *Istituto Gentili-Merck Sharp & Dohme – Neopharmed-Sigma-Tau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici* of 25 February 1999). The most recent cartel investigation (Case I701 – *Vendita al Dettaglio di Prodotti Cosmetici*), concerning cosmetic products, involved 19 parties including several pharmaceutical companies and resulted in a total fine of €81 million. In a judgment of 13 March 2012, the Regional Administrative Court of Lazio partially annulled the decision of the Italian Competition Authority ordering the Authority to re-determine the fine.

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

Technology licensing agreements are covered by the EU Block Exemption Regulation 772/2004 on the application of article 81(3) of the EC Treaty to certain categories of technology transfer agreements, provided that the market shares of the parties to such an agreement do not exceed certain thresholds (20 per cent combined if the licensor and licensee are competitors, or 30 per cent each if they are not competitors), and that the agreement does not include hardcore restrictions. This regulation is directly applicable in Italy.

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

Co-promotion agreements have been formally regulated in Italy by Legislative Decree 219/2006 (as amended by Legislative Decree 274/2007 and Law 88/2009). Pursuant to article 119 of Legislative Decree 219/2006, pharmaceutical companies may conclude co-promotion agreements whereby a company uses another company's sales force to promote the same brand or range of brands.

Co-promotion and co-marketing agreements may be considered anti-competitive if they lead to price fixing, market sharing or the exchange of sensitive commercial information. The Italian Competition Authority has in two instances fined the parties of a co-marketing agreement because the agreement led to price coordination (Case I331 – *Servier Italia-Istituto Farmaco Biologico Stroder* of 1 July 1999 and Case I333 – *Istituto Gentili-Merck Sharp & Dohme-Neopharmed-Sigma-Tau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici* of 25 February 1999).

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 between actual or potential competitors are in principle illegal when their object or effect is to fix prices, limit output, share markets or customers or exchange sensitive commercial information. Other horizontal agreements, such as R&D or specialisation agreements must be assessed on a case-by-case basis taking into consideration their market effect. Under certain circumstances, for example in relation to the creation of a joint venture, the antitrust concerns raised by these agreements may be resolved by confidentiality measures preventing the exchange of sensitive commercial information (eg, ring-fencing provisions).

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

The aspects of vertical agreements that are most likely to raise antitrust concerns are the so-called hard-core restrictions, such as price-fixing, limitation of output, resale price-maintenance and market and customer allocation. Exclusionary rebates by dominant undertakings and non-compete clauses, the duration of which is indefinite or exceeds five years, are also likely to raise antitrust concerns.

Article 4 of Commission Regulation 330/2010 on the application of article 101(3) TFEU to categories of vertical agreements and concerted practices lists a number of hard-core restrictions that remove the benefit of the block exemption and that are relevant in the pharmaceutical sector.

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

Settlements of patent disputes may expose the parties concerned to liability for antitrust violation if the settlements have as their object or effect the prevention or restriction of competition. This may be the case for example where a manufacturer of generic pharmaceuticals agrees to keep its product off the market and delays its entrance purposely against remuneration from the manufacturer of an original pharmaceutical.

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?

Article 102 TFEU on abuses of a dominant position is fully and directly applicable in Italy to cases where trade between member states is affected.

Where trade between member states is not affected, article 3 of the Competition Act is applicable. Article 3 of the Competition Act prohibits any abuse by one or more undertaking of a dominant position within the national market or in a substantial part of it. An abuse of dominant position exists when a dominant undertaking:

- directly or indirectly imposes unfair purchase or selling prices or other unfair contractual conditions;
- limits or restricts production, access to the market or market output, technical development or technological progress to the detriment of consumers;
- discriminates between undertakings applying dissimilar conditions for equivalent transactions, thereby placing them at an unjustifiable competitive disadvantage; and
- makes the conclusion of contracts subject to the acceptance by the other party of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

This list of examples is not exhaustive. The Italian Competition Authority has investigated in several instances unilateral conduct by dominant undertakings in the pharmaceutical sector. In its recent decision of 11 January 2012 (Case A431 – *Ratiopharm/Pfizer*), the Italian Competition Authority fined Pfizer Italia Srl €10.6 million for alleged abusive conduct aimed at preventing or delaying competitors' production and commercialisation of the generic version of prostglandins after patent coverage had expired.

In its decision of 28 June 2011 (Case A415 – *Sapec Afro/Bayer-Helm*), the Italian Competition Authority fined Bayer Cropscience Srl €5.12 million for alleged abusive conduct aimed at preventing other companies from accessing the results of two toxicological studies concerning the active principle Fosetil.

In Case A364 – *Merck-Principi Attivi* of 21 March 2007, the Italian Competition Authority accepted the remedies offered by Merck (after the imposition of interim measures pursuant to article 14-bis of the Competition Act) and closed the case without a finding of an infringement. Merck undertook to grant royalty-free non-exclusive

Update and trends

On 5 January 2012 the Italian Competition Authority published a report to the Italian Parliament advocating for the liberalisation of the sale of medicines that are subject to medical prescription but are not reimbursed by the Italian National Health Service and the removal of existing obstacles to the opening of new pharmacies.

Following the Authority's report, the Italian government adopted Law Decree No. 1/2012, which provides for a partial liberalisation in the pharmaceutical sector and favours the use of generics. Pursuant to the Decree, doctors, when prescribing a medicine, must now also indicate the corresponding generic version. Pharmacists, unless the prescription indicates otherwise or the client requests the non-generic version, are obliged to sell the generic version if this is cheaper.

The Decree allows the opening of about 5,000 new pharmacies. It also provides that by 31 December 2012 AIFA will identify optimal packaging requirements and introduce single doses for certain products.

In relation to life cycle management, in Case A431 – *Ratiopharm/Pfizer* of 11 January 2012 the Italian Competition Authority fined Pfizer for having delayed the market entry of equivalent generic drugs after patent coverage had expired.

In relation to class actions, the first class action by a consumer association in the pharmaceutical sector has been directed against a pharmaceutical producer of tests for the H1N1 influenza virus in January 2010. In its judgment of 13 March 2012 the Court of Milan rejected the class action because of the absence of sufficient evidence of the damage suffered by the claimant. Until recently, Italian law set a high standard for bringing class actions: consumers had to show that their rights were identical in terms of title of claim and type of damage suffered. Accordingly, the courts refused to accept class actions where the claimants' rights were not deemed identical. Law Decree 1/2012 now provides for a less stringent standard whereby consumers' rights must be of the same kind in terms of title of claim, but the claimants need not have suffered the same damage. For this reason, there may be an increase in class actions in the pharmaceutical sector.

licences to allow the importation, manufacture and marketing in Italy of the active principle Finasteride.

In Case A363 – *Glaxo-Principi Attivi* of 8 February 2006, the Italian Competition Authority found that Glaxo had infringed article 82 of the EC Treaty by having refused to grant a licence to produce the active ingredient Sumatriptan Succinato to a competitor, which intended to export it to a different member state where the product was not patented.

The Italian Competition Authority applies the Guidance on the Commission's enforcement priorities in applying article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (2009/C 45/02).

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

The existence of a dominant position is assessed in the context of the relevant product and geographical market where the undertaking is active. The main indicator of a dominant position is the undertaking's market share. A market share above 40 per cent provides an indication of the existence of a dominant position. Dominance is not likely if the undertaking's market share is below 40 per cent in the relevant market. The Italian Competition Authority will interpret market shares in light of the relevant market conditions.

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

No, the patent holder cannot be considered dominant simply on account of the patent that it holds. A patent holder may be considered dominant in the relevant product and geographic market if the conditions mentioned in question 27 above are met and, in particular, if there are no proprietary or non-proprietary substitutes in the markets. If this is the case, a refusal to license intellectual property rights by a patent holder, which enjoys a dominant position for the patented product, may be considered abusive.

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

An application for the grant of a patent would not normally expose the patent owner to liability for an antitrust violation.

However, there may be anti-competitive concerns if there is proof that a dominant undertaking has misused the patent application system (including the rules for the grant of supplementary patent certificates) with the purpose of preventing the entrance of generic drugs onto the market and there is no other objective justification (see also Case A431 – *Ratiopharm/Pfizer*, Italian Competition Authority Decision of 11 January 2012; Case COMP/A. 37.507/F3 – *AstraZeneca*, Commission Decision of 15 June 2005).

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

The enforcement of a patent is in principle legal when it is aimed only at protecting the patent itself. However, there may be anti-competitive concerns if there is proof that a dominant undertaking has misused the enforcement system with the purpose of excluding potential competitors or restricting competition and there is no other objective justification.

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

Life-cycle management strategies do not normally expose the patent holder to liability for an antitrust violation. However, there may be competitive concerns if a dominant patent holder uses these strategies with the purpose of excluding potential competitors or restricting competition and there is no other objective justification. For example, in Case A431 – *Ratiopharm/Pfizer* of 11 January 2012 the Italian Competition Authority fined Pfizer for delaying the market entry of equivalent generic drugs after patent coverage had expired.

32 Do authorised generics raise issues under the competition law?

Generics, including authorised generics, cannot be marketed before the expiry of the relevant patent. A patent holder may launch its own generic following patent expiry in competition with the new entrant generic producers. While this practice would generally be considered pro-competitive, in certain cases, where the patent holder is a dominant undertaking there may be anti-competitive concerns, for example if the patent holder engages in predatory pricing or other abusive practices to exclude the new entrant generic producers.

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

The specific features of the pharmaceutical sector may under certain circumstances provide an objective justification for conduct that would otherwise infringe antitrust rules. In making this assessment, the Italian Competition Authority will consider whether the conduct concerned is objectively necessary and, based on weighing-up any apparent anti-competitive effects against any advanced and substantiated efficiencies, is likely to result in consumer harm.

For example, even though it is not normally the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product, exclusionary conduct may, in certain cases, be considered objectively necessary for health reasons related to the nature of the product in question. In addition, a dominant pharmaceutical undertaking may also justify conduct leading to foreclosure of competitors on the ground of efficiencies that are sufficient to guarantee that no net harm to consumers is likely to arise.

In making this assessment of objective justification, the Italian Competition Authority will rely on the relevant European Court judgments in the pharmaceutical sector, for example those concerning dual pricing and quota allocation systems, where the condition of objective necessity has been analysed by the court (*GlaxoSmithKline Service Unlimited v Commission*; *Bayer Adalat*; *Syfait and others v GlaxoSmithKline, Lélos*).

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.

Antitrust enforcement in the pharmaceutical sector has continued steadily in 2011. In 2011 and until March 2012 the Italian Competition Authority imposed fines on pharmaceutical producers for alleged antitrust violations in two cases (Case A415 – *Sapec Agro/Bayer-Helm* of 28 June 2011 and Case A431 – *Ratiopharm/Pfizer* of 11 January 2012). In addition, the scope of the intervention of the Italian Competition Authority has widened. The Italian Competition Authority recently found that life-cycle management strategies may be anti-competitive when they delay the market entry of equivalent generic drugs after patent coverage had expired (Case A431 – *Ratiopharm/Pfizer* of 11 January 2012).

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

Follow-on damage litigation is increasingly frequent. Damage litigation is governed by general civil law and procedure. Law Decree 1/2012, as amended by Law 27/2012, will increase the likelihood of class actions in the pharmaceutical sector (see 'Update and trends').

De Matteis STUDIO LEGALE

Andrea De Matteis **ademattei s@dematteislex.com**

Via Ventiquattro Maggio 46
00187 Rome
Italy

Tel: +39 06 98378411
Fax: +39 06 69921235
www.dematteislex.com