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Contributing editor
Marleen Van Kerckhove
Arnold & Porter LLP

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Subscriptions@GettingTheDealThrough.com

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Editor-in-chief
Callum Campbell

Publisher
Richard Davey

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87 Lancaster Road
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Fax: +44 20 7229 6910

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Uría Menéndez

Pharmaceutical regulatory law

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

The main piece of Spanish legislation governing pharmaceutical products is Law 29/2006 on Guarantees and Rational Use of Medicines and Medical Devices (the 'Guarantees Law'), which regulates the authorisation, manufacturing, labelling, distribution, pharmacovigilance, promotion and dispensation of drugs (including generics), as well as their pricing and reimbursement. The Guarantees Law has been amended on a number of occasions, and most recently by three Royal Decree Laws (which were passed according to an urgent procedure that enables the government to approve rules with force of law that are subsequently sent to parliament for validation) approved in 2010 and 2011 that introduce additional cost-containment measures.

The marketing authorisation procedure is further regulated by Royal Decree 1345/2007 on the procedure for the authorisation, registration and dispensation of industrially manufactured human drugs.

The Guarantees Law also sets forth the main rules on the (selective) reimbursement of drugs. Although, as a matter of principle, the manufacturers of medicines are free to determine their prices, those medicines included in the public reimbursement regime and dispensed in Spain are subject to pricing intervention. Maximum ex-factory prices are set by the health authorities, on the basis of parameters similar to those applied to the reimbursement decision, and taking into account the prices applicable in other European Union countries. The procedure for the setting of the ex-factory price is further regulated by Royal Decree 271/1990 on the reorganisation of the intervention in prices of human medicines.

The price margins of wholesalers and pharmacies, and certain discounts and deductions, are fixed by Royal Decree 823/2008 on margins, deductions and discounts corresponding to the distribution and dispensation of human medicines.

Finally, concerning advertising and promotion, the Guarantees Law provisions are complemented by Royal Decree 1416/1994 on the promotion of medicines for human use.

2 Which bodies are entrusted with enforcing these regulatory rules?

The Spanish Medicines and Medical Devices Agency, a public entity attached to the Ministry of Health, is responsible for all matters connected with the quality, safety, efficacy and information regarding drugs including, particularly, the granting of marketing authorisations.

Prices are set by an Inter-Ministerial Commission composed primarily of representatives of several departments within the Ministry of Health and representatives of the Ministries of Industry and Economy. The General Directorate for the Basic Portfolio of National Health Service Benefits and Pharmacy, a department of the Ministry of Health, is responsible for deciding which medicines qualify for reimbursement and also, very importantly, for the management of the reference price system.

Spain is divided into 17 autonomous regions that exercise ample powers in health matters and are responsible for the provision of public health-care services. However, certain basic health-care conditions must be guaranteed for all Spanish citizens, and the main powers to establish reimbursement conditions and prices of medicines lie exclusively with the central authorities (though this is frequently questioned by the regions). Law 16/2003 on the Cohesion and Quality of the National Health System was enacted precisely for the purposes of guaranteeing such equal conditions. The autonomous regions are also the enforcement authorities as regards wholesale and supply, advertising and promotion, the establishment of pharmacies, etc.

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

Pharmaceutical companies operate in a very specific market environment, and the special features of this sector must be taken into account when assessing (unilateral or bilateral) conduct or transactions in this sector. Among other circumstances, the following should be pointed out:

- the level of regulation, combined with the purchasing power of the Social Security system, that leaves little room for abusive behaviour;
- the artificially low level at which medicine prices are set, which has traditionally created strong export flows (also causing shortages in the Spanish market);
- the obligation on pharmaceutical companies to keep the market duly supplied, and the restrictions on withdrawing a drug from the market (or from the reimbursement system);
- the imposition of INN prescription as a general rule and the reference price system, which imposes general reductions on prices of drugs when a generic medicine is authorised, even if it may not actually be marketed;
- the fact that pharmacies must be owned by individual pharmacists and are limited in number;
- the limits on discounts that may be offered to pharmacists, as well as the restrictions on advertising and promotion and the encouragement of self-regulation codes.

Competition legislation and regulation

4 Which legislation sets out competition law?

As Spain is a member state of the European Union, EU competition law is fully applicable by the Spanish authorities and courts under Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in articles 81 and 82 of the Treaty (now articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU))(Regulation 1/2003).

Spain has its own national competition rules, which are applied consistently with article 3 of Regulation 1/2003. Spanish competition rules are set out in Law 15/2007 on the Defence of Competition (Spanish Competition Act) and further developed by the Competition Regulation, which was approved by Royal Decree 261/2008. The Spanish Competition Act sets out the main elements of national competition law (definitions of infringements, possible fines and sanctions, investigative powers of the competition authorities and conditions under which mergers are subject to prior authorisation), while the Competition Regulation establishes operational and procedural rules.

Under article 1.4 of the Spanish Competition Act, all EU block exemption regulations are also applicable to national cases. This would include, among others, Regulation 330/2010 of 20 April 2010 on the application of article 101(3) TFEU to categories of vertical agreements and concerted practices, Regulation 1217/2010 of 14 December 2010 on the application of article 101(3) TFEU to categories of research and development agreements, Regulation 1218/2010 of 14 December 2010 on the application of article 101(3) TFEU to categories of specialisation agreements, and Regulation 772/2004 of 27 April 2004 on the application of article 81(3) of the EC Treaty (now article 101(3) TFEU) to categories of technology transfer agreements. The Spanish Competition Act also enables the government to approve national block exemption regulations. So far, this possibility has only been used in relation to agreements on the exchange of information related to bad debtors (Royal Decree 602/2006).

Spanish law prohibits anti-competitive agreements and abuses of dominant positions in line with the EU rules (although with some minor differences). In addition, the Spanish Competition Act forbids acts of unfair competition that distort free competition (article 3 of the Spanish Competition Act). This prohibition is not aimed at fighting unfair competition itself (which is the task of Spanish judges) but rather its impact on the public interest when competition in the market is affected (see, for example, the decision of 16 July 1998 in Case R315/98, *Wellcome*).

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

There are no specific national guidelines on the application of competition law to the pharmaceutical sector.

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 sector-specific body in charge of applying competition law to the pharmaceutical sector.

In Spain, the main antitrust authority is the National Competition Commission (CNC), an independent body that is divided into an Investigation Directorate (in charge of the investigation and study of cases) and a Council (in charge of taking the decisions).

Article 13 of the Spanish Competition Act also gives regional competition authorities the power to investigate and decide on the infringement of competition rules when the scope and effects of the investigated behaviour does not go beyond the borders of a region (most Spanish regions have set up their own independent competition authorities).

Spanish civil courts are also empowered to directly apply EU and Spanish competition law to potentially restrictive agreements or alleged abuses of dominant positions. Private enforcement of competition law in Spain is still very limited.

In relation to mergers, the only body competent to investigate and decide on clearance is the CNC. The Council of Ministers retains a limited right to amend a prohibition or conditioned decision from the CNC on general interest grounds other than competition (eg, national security; public health and safety; free movement of goods and services within Spain; environmental protection; promotion of investigation and technological research; and preservation of sector objectives). As of 29 February 2012, this possibility has not been used.

On 25 February 2012, the government unveiled plans for an overhaul of the structure of competition and sector-specific regulators in Spain, involving the creation of a joint National Competition and Markets Commission. To date, nothing further has been announced regarding these plans.

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

The remedies that can be imposed on pharmaceutical companies for anti-competitive conduct or agreements do not differ from other sectors (ie, fines, punitive payments and structural remedies).

In relation to fines, article 62 of the Spanish Competition Act provides for three types of infringements:

- minor infringements (normally procedural infringements, such as the submission of incomplete, false or misleading information);
- serious infringements (which would cover the infringement of substantive competition law); and
- very serious infringements (including cartels and the abuse of a dominant position in a recently liberalised market by a company with a high market share or special rights).

This classification influences the amount of the potential fine, which would be up to 1 per cent of the company's annual turnover for minor infringements, up to 5 per cent for serious infringements, and up to 10 per cent for very serious infringements. Fines of up to €60,000 may also be imposed on the company's legal representatives taking part in the decision.

Spain has a leniency programme pursuant to which cooperating companies are exempted from or face reduced fines if they provide the competition authorities with substantive information about a cartel.

The competition authorities may also impose punitive or periodic fines of up to €12,000 per day of delay in complying with their decisions.

As to the possibility of structural remedies, the Spanish Competition Act allows the competition authorities to impose certain conditions on companies involved in infringement proceedings in order to ensure that competition is properly restored. This power (that may lead to the imposition of compulsory licensing) has seldom been used. In its decision of 19 May 2009 in Case 646/08, *Axión/Abertis*, after deciding that certain contracts prevented new operators from entering the relevant market, the CNC imposed a heavy fine for an abuse of a dominant position and the mandatory modification of these agreements so that customers could switch to other suppliers.

In most cases, these remedies are imposed in settlement procedures, where the parties suggest remedies in order to avoid fines. Most settlements before the CNC involve the modification of contractual obligations in order to secure the commercial freedom of the parties or access to an otherwise limited resource.

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 are entitled to obtain competition-related remedies both before the competition authorities and the courts.

Any party harmed by potentially anti-competitive conduct may request the competition authorities to start infringement proceedings to prohibit the allegedly anti-competitive practices. The Spanish Competition Act also provides for the possibility of a claimant gaining interim relief before the case is formally decided. In its

decision of 7 May 2008, Case MC/0001/08 *Residuos sanitarios 2*, the CNC ordered the interim suspension of a non-compete obligation between a company and a former shareholder that prevented the latter from bidding in public tenders for the management of sanitary waste in hospitals.

As indicated in question 6, competition law is also directly applicable by the Spanish courts, where any party affected by anti-competitive behaviour can obtain redress. In general, the courts that are empowered to apply competition law are the commercial courts. To date, few actions of this type have been filed, but the number is steadily growing. These cases normally refer to the validity of contracts under competition law or actions for damages.

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 CNC is competent to conduct sector-wide inquires. In fact, it conducts periodic inquiries in the distribution sector. To date, no specific inquiries have been conducted into the pharmaceutical sector.

The CNC is also competent to analyse all legislation that may have an impact on competition before it is finally passed. In the pharmaceutical sector, the CNC has issued two reports in relation to future regulations as a result of the liberalisation of the services markets and, in particular, in relation to the distribution of medicines for humans and animals (Reports IPN 18/09 and IPN 32/09).

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

As indicated in question 4, in Spain there is no specific regime regulating competition in the pharmaceutical sector and, therefore, all issues affecting this sector are addressed under the ordinary regime. There is no regulatory body for the pharmaceutical sector responsible for sector-specific competition policy.

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

Industrial-policy type arguments may be used to counterbalance antitrust concerns. For example, evidencing efficiencies and general profits arising from R&D activities could overcome competition concerns raised by information sharing in an R&D agreement. So far, these arguments have only been identified in merger cases, as precedents in cases on anti-competitive behaviour are very limited.

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

Trade associations and patient groups have the right to be consulted on the approval of any regulation and to file complaints about alleged infringements, if the interests of their members are affected. The Pharmaceutical Industry Association (Farmaindustria), the Wholesaler's Association (Fedifar) and the Pharmaceutical Entrepreneur's Association (FEFE) have regularly made use of such powers and in the past few years the CNC has dealt with a number of cases brought by these associations. The European Association of Euro-Pharmaceutical Companies (EAEPC) has also been active in bringing actions based on alleged anti-competitive conduct (restriction of parallel exports and dual pricing).

On a different note, trade association meetings have become a target for antitrust investigation, as they are regarded as a likely forum for the exchange of commercially sensitive information and for reaching agreements between competitors. In the past few years, certain trade associations in the pharmaceutical sector (namely, Fedifar and FEFE) have been investigated and sanctioned for having induced their members to adopt concerted conduct.

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Mergers in the pharmaceutical industry are assessed according to the general merger control procedures. In view of the characteristics of the products, certain issues come up repeatedly in the decisions taken:

- Countervailing power from the demand-side. As Spanish public entities are the pharmaceutical companies' main customers, their bargaining power is generally acknowledged as heavily offsetting any market power the parties may hold.
- Strong public authority intervention, especially in prices. The fact that the pharmaceutical sector is highly regulated has also been a factor that the authorities have steadily taken into account in clearance decisions, as it limits the impact of the transactions.
- The importance of R&D expenses as a barrier to entry has also been referred to widely, although it has never been considered as a significant obstacle to competition.

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

The CNC generally defines the product market on the basis of the third level of the ATC Classification (ie, by therapeutic indication). However the CNC also analyses on a case-by-case basis whether such classification properly reflects exchangeability, not only in terms of use (indication) but also, for instance, in terms of price. Generally, the possibility of the market being defined at a lower level (in line with some EU precedents) may not be ruled out. In a recent decision dealing with alleged abuse based on the refusal by pharmaceutical companies to supply wholesalers, the CNC questioned whether exchangeability at dispensation level would be the proper parameter to define the product market at wholesale level, although no definitive conclusion was reached.

The geographic market for pharmaceutical products is national in scope and the medicines distribution market is regional in scope.

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

Geographical overlap will raise competition concerns when it can limit competition in the market. This potential limitation is assessed in view of each particular product. Thus, a significant degree of potential competition from third parties may be deemed to counterbalance possible competition concerns. In contrast, if the overlap between the parties is limited, but the merger reduces potential competition, the CNC will likely investigate further.

Potential competition is generally assessed from two perspectives: operators currently manufacturing the product in different geographic markets; and operators that do not manufacture the product, but are in a position to enter the market in the short term.

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

The CNC normally takes into account actual market shares to identify overlaps. As an exception, when the parties can evidence with some degree of certainty a future market share, this may be taken into account (see, for example, Report of 26 March 2002, Case *Iberdrola/Guadalcacín/Enron España*).

Future developments are seen as a source of potential competition, rather than a possible source of antitrust concerns. However, if

the transaction is seen as limiting such developments, the competition authorities may ask the parties to evidence further efficiencies.

In the Report of 27 December 2005, Case C93/05, *Telefónica/Iberbanda*, the Spanish competition authorities recommended Telefónica, a telecommunications operator, be prohibited from acquiring a small company that had the licence to operate internet over radio frequencies in Spain. Although this channel was still being developed and represented a negligible portion of Telefónica's business, the fact that the market had a potential for growth and that Telefónica had a significant position in all other channels led to a negative decision.

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

There is no precedent of conditions being imposed on a merger in the pharmaceutical sector. The merger control authorities tend to prefer structural remedies (ie, divestment of viable business units or divisions, including brands). Behavioural remedies are also accepted. Normally, behavioural remedies entail prohibitions on the resulting entity or commitments to ensure fair non-discriminatory access to resources or inputs. In our view, licensing agreements may be acceptable behavioural remedies to secure the fair and non-discriminatory behaviour of the resulting entity.

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Under Spanish law, an economic concentration is defined as a change of control over an undertaking. For these purposes, an undertaking includes any asset or corporate organisation that can be commercially operated independently. All pharmaceutical sector mergers in Spain have entailed the acquisition of a company or material assets, although the acquisition of a mere patent or licence could indeed be considered as a concentration for merger control purposes, provided that it can be commercially operated independently.

One of the clearest examples of this reasoning can be found in the report in Case N-05064, *L'Oréal/Delial*, concerning sun creams, where the competition authorities considered that the sale of all intangible assets and IP rights (brands), as well as all the contracts necessary for the daily operation of the business and the outstanding stocks, was an economic concentration.

Anti-competitive agreements

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

Article 1 of the Spanish Competition Act sets out the national legal framework on the assessment of the anti-competitiveness of an agreement or practice. The definition of 'agreement' for the purposes of this provision resembles that contained in article 101 TFEU, and includes not only legally binding contracts, but any kind of agreement, formal or informal, reached by two independent undertakings (ie, unilateral conduct is excluded).

The Spanish Competition Act differs slightly from article 101 TFEU in that it also forbids conscious parallelism, a situation where, without openly agreeing to do so, two competing undertakings engage in parallel commercial behaviour. In the Decision of 12 February 2001, Case R 437/00, *Pharmaceutical Laboratories*, this conduct was defined as a harmonised behaviour of various undertakings in the market, without an express or tacit agreement among them, but as the consequence of each undertaking acting with the aim of avoiding discordance.

For an agreement to be declared anti-competitive under the Spanish Competition Act, it must have the object or effect of restricting competition. Thus, if the agreement is restrictive 'by object', the Spanish competition authorities will have no need to evidence the existence of any effect in the market. However, in the case of agreements restrictive 'by effect', the CNC must evidence the actual negative effects on competition.

In the decision of 14 July 2003, Case A 326/02, *Portal Proxfarma*, the Spanish competition authorities held that a horizontal agreement between three laboratories to create a joint internet portal to handle orders from pharmacies did not have effects on competition and, therefore, the agreement fell outside the scope of the former Spanish Competition Act.

The Spanish courts have confirmed the possibility of declaring antitrust infringements based on mere indicia. In its decision of 30 September 1998, Case 395/97, *Flu Vaccines*, the CNC held that some laboratories had concerted their behaviour in the setting of prices for flu vaccines based exclusively on indicia and economic evidence. The courts subsequently confirmed this assessment.

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

Cartel investigations in the pharmaceutical sector would not differ from those performed in any other sector. The investigations can be started by the CNC ex officio or following a complaint from an interested party (competitor, customer, supplier, etc). In recent years, leniency applications have played a significant role in starting cartel investigations in Spain.

The CNC has announced the start of a cartel investigation on its website and any interested third party may ask to participate in the proceedings (and have access to non-confidential information).

Once the CNC decides to start a cartel investigation, it may perform dawn raids and submit information requests to the parties. Parties must cooperate with these investigations and those that fail to do so can be fined. The CNC may use all the information gathered during this phase, and it may even start new proceedings, where evidence or indicia of different infringements are found.

The complete procedure should last 18 months. The first 12 months are taken up by the investigation phase, which ends with a proposed decision. The remaining six months are for the Council to study and decide on the case.

The CNC may impose fines and order the parties to stop a given conduct. CNC decisions can be appealed before the Spanish courts.

Cartel investigations may also result in damages actions. In Spain, damages actions have normally been follow-on rather than stand-alone actions.

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

Under Spanish competition law, technology licensing agreements are considered anti-competitive in line with Regulation 772/2004 of 27 April 2004 on the application of article 81(3) EC Treaty (now article 101(3) TFEU) to categories of technology transfer agreements. This Regulation determines the thresholds and time limits of the agreements covered by the exemption established at a European level, and there are no complementary regulations applicable in Spain to technology licensing agreements.

There are no major precedents in this regard in Spain. In its decision of 14 December 2011, Case C-0411/11, *Ferrer/Rovi*, the CNC found a set of technology transfer agreements between the resulting entity and a third party to be ancillary to the merger.

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

There are no precedents of co-promotion and co-marketing agreements being considered anti-competitive in Spain. Co-promotion and co-marketing agreements are characterised as encompassing a vertical element (manufacturer-distributor) and, in many cases,

a horizontal element (agreement between two competing pharmaceutical companies). Some of the matters that could raise specific antitrust concerns (and, most particularly, regarding co-marketing agreements) would be:

- exclusivity obligations;
- non-cannibalisation provisions;
- market sharing;
- direct or indirect restrictions to parallel trade;
- the exchange of sensitive commercial information (eg, by means of sales reports or in the framework of Joint Steering Committees); and
- price fixing – coordination of pricing and discount policies.

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

Confidentiality provisions limiting the impact on competition of commercial information shared by the parties can resolve antitrust concerns if the parties can evidence that such provisions are useful and effective. In practice, this evidence may be hard to produce, in particular if the competition authorities have indicia of co-ordination between the parties.

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

The aspects most likely to raise antitrust concerns in vertical relationships are basically those described in question 22 (except as regards non-cannibalisation). In Spain, pharmaceutical companies are entitled to sell their products directly to hospitals and pharmacies, and are therefore actual or, at least, potential competitors of wholesalers, so the horizontal aspects of the relationship must also be considered in vertical agreements.

Potential restrictions to parallel trade have attracted much attention in recent years. Specific reference should be made to free pricing policies implemented by some pharmaceutical companies. Under these policies, pharmaceutical companies set a free price for their products that is replaced by the government intervened price only in those cases where the application of such government-set price is mandatory under applicable law (ie, for medicines listed for financing with public funds and dispensed in Spain). So far, the CNC, the health authorities and the civil courts have consistently held that these policies are not contrary to the prohibition of anti-competitive agreements, and, more specifically, that they do not constitute 'dual pricing' and that they would benefit from the Block Exemption under Regulation 330/2010. Reference should be made to Cases S 2623/05, *Spain Pharma*, S/0017/07 *EAEPC v Pharmaceutical Companies* and S 0038/08 *FEFE v Pharmaceutical companies and wholesalers*. The ruling in the last case is final, while the others are pending appeal. In the first case (S 2623/05, *Spain Pharma*), the National Court (Audiencia Nacional) revoked the decision of the CNC to dismiss the case without opening infringement proceedings; the CNC and the applicant have appealed this resolution before the Supreme Court.

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

There is not much case law in Spain on the settlement of patent disputes, but under certain circumstances it is possible that the settlement of a patent dispute may amount to an anti-competitive agreement.

The decision of the CNC of 25 April 2011, Case S/0228/10, *Novartis*, is especially relevant. In that case, Novartis was accused by a competitor of abusive litigation. A few days after the complaint was lodged, Novartis abandoned all judicial proceedings against the claimant, and the claimant accepted this abandonment. However, the claimant did not waive the complaint before the CNC. The allegation of abuse was dismissed on the grounds that the claimant had not evidenced that Novartis actually held a dominant position in the relevant market. The CNC noted that Novartis' decision to start judicial proceedings seemed reasonable, as the claimant itself had acknowledged Novartis' initial right to market the products. In relation to the existence of an anti-competitive agreement in abandoning the claim, the CNC remarked that no such agreement could have existed, as Novartis' decision to abandon the proceedings was unilateral and had not arisen from an agreement with the claimant. A contrario, the existence of a settlement agreement could have justified an investigation into a possible anti-competitive agreement.

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 2 of the Spanish Competition Act basically mirrors article 102 TFEU. The types of abusive conduct defined under this provision can be classified as exploitative abuses (discrimination between customers or suppliers, excessive pricing, tying practices), or exclusionary abuses (refusal to deal, predatory pricing, exclusivity clauses or loyalty discounts with a market foreclosure effect). Only conduct that lacks objective justification can be abusive. If it responds to an objective economic rationale (other than the obstruction of competition), it could not be qualified as such.

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

It is generally understood, as under EU case law, that an undertaking is dominant when it enjoys a position of economic strength which affords it the power to behave independently of its competitors, suppliers, and customers. The first parameter that is assessed is the undertaking's market share, but other factors must be taken into account, such as the historical volatility of such market shares, the number and market power of competitors, the degree of vertical integration in the market, the barriers to entry, and, very importantly in the pharmaceutical sector, the level of regulation.

So far, no pharmaceutical company in Spain has been found to have a dominant position, mainly due to the high degree of regulation (which prevents them from behaving independently in key matters such as pricing) and the purchasing power of the National Health System (see decisions in Cases R 611/04, *Spain Pharma/Glaxo* and R 643/05, *Pharmaceutical Companies*). However, this possibility has not been ruled out. For instance, in a case regarding the refusal to supply wholesalers (S/0176/09, *Sedifa-Grufarma*), the CNC mentioned that the specific characteristics of the pharmaceutical sector did not necessarily exclude the possibility of a company being dominant.

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

Merely holding a patent would not per se imply holding a dominant position. A dominant position would be found to exist if the circumstances outlined in question 27 exist.

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

The mere application for the grant of a patent could not be considered per se abusive. This would require not only holding a dominant position, but also actually engaging in abusive practices.

There are no precedents in Spain where the mere application for a patent or patents was considered as an abuse. In this respect, the CNC would be likely to follow the Conclusions of the European Commission on the Pharmaceutical Sector Inquiry.

Update and trends

One particular phenomenon in the pharmaceutical sector in Spain that has attracted and continues to attract much attention is the reorganisation by pharmaceutical companies of their traditional supply systems. This reorganisation has generally been based on the implementation of free price policies (see question 24) and the optimisation of the distribution network through a reduction of wholesalers.

Both aspects have been systematically challenged by wholesalers and their associations before every authority, including the antitrust authorities. In general terms, the outcome of these challenges has so far proved to be favourable to the pharmaceutical companies, but the debate remains open, not only before the courts, but also before the government, which has repeatedly been asked by wholesalers to issue regulations to guarantee their alleged rights.

The 'selected price system', envisaged by the government but still not in operation, is also likely to raise concerns from an antitrust perspective, as it foresees that medicines which are not selected (mainly based on price criteria) will be excluded from the reimbursed market for a given period of time. Some regions (eg, Andalucía) have already begun to launch similar systems, and this decision has been heavily contested.

More generally, cartel prosecution continues to be the main priority of the CNC. It is the opinion of this authority that the leniency programme introduced in 2008 is proving and will continue to be a key element in cartel prosecution.

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

No enforcement of patent rights has yet been considered as an abuse of dominant position in Spain, but this does not necessarily mean that it could not be deemed so under certain circumstances. As previously mentioned, the Spanish Competition Authority would be likely to follow the Conclusions of the European Commission on the Pharmaceutical Sector Inquiry.

That said, article 3 of the Spanish Competition Act prohibits unfair competition acts with a significant impact on competition. The enforcement of a patent may be considered as contrary to article 3 in certain cases. In the decision of 16 July 1998, Case R 315/98, *Wellcome*, the Spanish competition authorities confirmed the closing of a case where a laboratory was charged with an alleged violation of antitrust law because it had tried to enforce a patent before the courts. In this case, Wellcome's action was filed against a laboratory that manufactured a product for Combino Pharm, a Wellcome competitor. Combino Pharm alleged that the action was unfair (and thus in breach of current article 3 of the Spanish Competition Act) as it was aimed at inducing the laboratory to breach its manufacturing agreement with Combino Pharm. The competition authorities concluded that the defendant had legally lodged an action to protect its rights under Spanish patent law. If the defendant considers that its rights have been damaged, it could submit a claim before the courts in order to protect such rights.

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

To the extent that life-cycle management strategies are objectively justified for purposes other than merely delaying or blocking generic entry after the expiration of a patent, they should not raise antitrust concerns. While there are no precedents in Spain, some examples of cases where these strategies could be regarded as abusive have been identified by the European Commission and are likely to be similarly assessed by the Spanish competition authorities (eg, questioning the safety or efficacy of generics).

32 Do authorised generics raise issues under the competition law?

Due to the regulatory system in Spain (which imposes INN prescription and dispensation of the lowest-priced medicine) it is not likely that the originator company would market or license its drug as a generic before the expiry of the patent, because such generic would be reimbursed at a significantly lower price than the originator drug, and would immediately cause the originator drug itself to equal such price or be excluded (upon prior authorisation) from the public financing regime. Unlike other jurisdictions, there are no regulatory advantages in Spain to being the first generic entrant.

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

General objective justifications are admissible for the pharmaceutical sector (for example, meeting competition would justify aggressive commercial policies, and the default of the customer would justify a refusal to supply).

For the pharmaceutical sector in particular, rather than to provide an objective justification for conduct that would otherwise be abusive, the specific features of the pharmaceutical sector in Spain have been taken into account by the competition authorities to discard dominant positions in cases involving pharmaceutical companies (see question 30). However, the Spanish competition authorities

Uría Menéndez

Teresa Paz-Ares **teresa.paz-ares@uria.com**
Beatriz Cocina **beatriz.cocina@uria.com**
Borja Martínez **borja.martinez@uria.com**

C/ Príncipe de Vergara 187, Plaza de Rodrigo Uría
28002 Madrid
Spain

Tel: +34 915 860 400
Fax: +34 915 860 403
www.uria.com

have not ruled out the possibility that, for certain purposes – such as in relationships with wholesalers – a pharmaceutical company could be found dominant (see, for instance, Case S/0176/09, *Sedifa-Grufarma*).

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.

Generally, competition enforcement in Spain has remained steady in the past few years in terms of the number of cases opened. On the other hand, a significant effort has been made as regards the investigation activity, and has resulted in the doubling of the number of cases where a proposal is submitted for final resolution (when the proposal was to penalise conduct – 15 cases in 2010 versus 31 cases in 2011). The number of investigations launched has also slightly increased (37 in 2011).

The manufacturing industry is the sector where most cases have been opened in the last year, followed by the logistics industry (transport and storage), IT services and commercial distribution. There is no particular data on the pharmaceutical sector.

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.

Traditionally, follow-on litigation has not been relevant in Spain and there have only been a handful of cases. These cases have normally referred to cartel (or at least article 1 cases), although there are some decisions on dominant position. See also questions 8 and 20.

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