

Pharmaceutical Antitrust

in 31 jurisdictions worldwide

2014

Contributing editor: Marleen Van Kerckhove



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Pharmaceutical Antitrust 2014

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Marleen Van Kerckhove
Arnold & Porter LLP

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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Pharmaceutical regulatory law

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

The authorisation of a pharmaceutical product including generic drugs in Switzerland is governed by the Federal Law on Medicinal Products and Medical Devices of 15 December 2000 (TPA, SR 812.21) and its accompanying regulations. The pricing of pharmaceuticals is subject to the provisions of the Federal Health Insurance Act of 18 March 1994 (HIA, SR 832.10), the Ordinance on Health Insurance of 27 June 1995 (SR 832.102), and the Ordinance on Services in the Compulsory Health Insurance of 29 September 1995 (SR 832.112.31).

In addition, the Price Surveillance Act of 20 December 1985 (SR 942.20), which empowers the Federal Price Regulator to monitor prices and to act against inflated prices, and the Federal Act on Cartels and Other Restraints of Competition of 6 October 1995 (the Cartel Act, SR 251) might affect the pricing of pharmaceutical products as well.

- 2 Which bodies are entrusted with enforcing these regulatory rules?

The Swiss Agency for Therapeutic Products (Swissmedic), having its seat in Berne, is responsible for the authorisation and supervision of medicinal products. Swissmedic also issues licences for the manufacturing, wholesaling, and the import and export of medicinal products and determines the regulatory data protection of such products. Furthermore, Swissmedic can take all administrative measures necessary as set forth in article 66 to enforce the TPA with the support of the Swiss Cantons and the customs authorities.

The Federal Office of Public Health (FOPH) determines the prices of pharmaceutical products that are prescribed by a physician, employed in accordance with the approved indications, and included on the list of reimbursable pharmaceutical specialities (Specialities List). The FOPH regulates not only the ex-factory price but also the distribution margin to be shared between wholesalers and pharmacies in payment for logistic and capital costs of distribution.

The Federal Price Regulator executes the provisions of the Price Surveillance Act and the Federal Competition Commission (Comco) (and its Secretariat, respectively) executes the Cartel Act.

Finally, it is worth mentioning that the Swiss Federal Institute of Intellectual Property is the federal agency for matters concerning intellectual property in Switzerland. It is responsible for the grant of patents and supplementary protection certificates in the pharmaceutical sector.

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

The health sector is heavily regulated by provisions granting access to the market, by imposing prescription to the use of certain drugs

and by fixing prices and regulating reimbursement from compulsory health insurance. Tariffs applied by hospitals are also regulated through public law contracts.

The intersection between pharmaceutical sector regulation and the Cartel Act is regulated in article 3 of the Cartel Act, according to which sector regulation that does not allow for competition in a market for certain goods or services take precedence over the provisions of this Act. Such provisions include in particular provisions that establish an official market or price system, and provisions that grant special rights to specific undertakings to enable them to fulfil public duties. In addition, the Cartel Act does not apply to effects on competition that result exclusively from the legislation governing intellectual property, to the exclusion of import restrictions that are covered by the Cartel Act.

Consequently, clear regulations that exclude competition, such as price regulation, exclude also application of the Cartel Act. In 2008, the Comco found that approval of tariffs by cantonal authorities excluded the application of the Cartel Act. In general, the Comco has applied article 3 of the Cartel Act restrictively by considering that the Cartel Act applies whenever the sector regulation leaves some room for competition, be it through prices or quality (see *Markt für Hörgeräte*, 2011). Recently, the Federal Administrative Court held that the special provisions prohibiting advertisement for erectile dysfunction drugs and the need for discretion of their patients excluded competition among pharmacies and consequently the Cartel Act did not apply (article 3 of the Cartel Act, decision of 3 December 2013), which could open the way for excluding the application of the Cartel Act to prescription drugs not reimbursed by health insurance. The decision is highly controversial and the State Secretariat for Economic Affairs appealed against to the Federal Supreme Court.

Competition legislation and regulation

- 4 Which legislation sets out competition law?

The Cartel Act sets out the rules applicable to agreements, abuse of dominance and merger control. The Cartel Act provides for administrative investigation and civil antitrust action against undertakings infringing the Cartel Act.

Claims against competition restrictions can also be based on article 28 of the Swiss Civil Code of 10 December 1907 RS 210 (CC). Article 28 CC protects personality rights, including economic rights. Besides the Cartel Act and the CC, the Swiss Federal Law against Unfair Competition of 19 December 1986 RS 241 (the Unfair Competition Act) is also pertinent for private antitrust actions.

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

There are no guidelines on the application of competition law that are specifically applicable to the pharmaceutical sector. The notification

form and ordinance on merger control regulation applies also to the pharmaceutical sector. In addition, the Comco has issued guidelines on vertical restraints.

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

Mergers and the anti-competitive effect of conduct or agreements in the pharmaceutical sector are reviewed by the Comco, and the investigations are carried out by its Secretariat.

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

Comco can impose injunctions or agree on an amicable settlement with pharmaceutical companies. In merger control, the Comco may grant clearance subject to conditions or obligations. Injunctions include prohibition of an agreement or certain practices and may make certain behaviour obligatory in the future (eg, duty to furnish a certain amount of products). Remedies may include making certain behaviour obligatory in the future. In general, conditions and obligations imposed in the framework of merger control are of a structural nature, and may include divestments or the granting of licences (eg, *Glaxo Wellcome PLC/SmithKline Beecham PLC*, 2001).

- 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?

Under article 12 of the Cartel Act, any person hindered by an unlawful restraint of competition from entering or competing in a market is entitled to request from the courts:

- the elimination of hindrance of competition. Hindrances of competition include in particular the refusal to deal and discriminatory measures;
- damages in accordance with the Code of Obligations RS 220 (CO); or
- the surrender of unlawfully earned profits in accordance with the provisions on agency without authority.

- 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?

There is no comparable legal basis for sector-wide enquiries in the Cartel Act, as in the European Union. The Comco may, however, open an inquiry over a large number of undertakings encompassing a whole economic sector, and use investigation powers pertaining to individual investigations. The latest enquiry of this nature concerned the transmission of the exchange rate advantages of the Swiss Franc into end-consumer prices and involved 22 importers of branded products and three retailers. To date, the Comco has not conducted an inquiry in the pharmaceutical sector as such.

In addition, the Federal Price Regulator monitors the pricing in the pharmaceutical sector. The competences of the Price Regulator are controversial. He or she regularly publishes recommendations on how the legislation should be amended to reduce the costs in the pharmaceutical sector.

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

No. Neither Swissmedic nor the FOPH are competent in antitrust matters.

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

Sector regulation was designed to foster innovation in the pharmaceutical sector. As explained above (see question 3), the Cartel Act does not apply when the sectoral regulation does not leave room for competition. Switzerland sets comparatively higher prices for prescription and reimbursable drugs as compared to other countries in order to foster innovation. Competition law as applied by the Comco also takes into account arguments related to innovation, however, it does not put greater emphasis on regional research and development activities. The Comco adheres to concerns related to the high cost of research and development, and the need to recover the cost of innovation, by accepting also that innovation through patents and generics introduced after patent protection is the main driver of competition in the market (see *Hoechst/Rhône-Poulenc*, 1999).

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

In general, trade or consumer organisations possess legal standing provided they are undertakings under the Cartel Act, which means that they exercise a commercial activity and are hindered in the process of competition. Trade associations may always lodge a complaint before the Comco, and will have rights attached to complainants. The issue of their standing to protect members' interests as was the case under the former Cartel Act of 1962, however, remains disputed. In principal, trade or consumer organisations would have legal standing with regard to actions for injunctions to terminate a restriction of competition, but not with regard to actions for damages incurred by their members. The new Code of Civil Procedure recognises active standing to associations and other organisations of national and regional importance to bring action in their own name against violations of the personality rights under article 28 CC of their members. Personality rights also include in principle economic rights and thus, at least in theory, trade or consumer organisations may claim for the prohibition of an existing or threatened violation of personality rights (for instance prohibition of a boycott or a refusal to deal).

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 sector are reviewed as any other merger. Sector-specific features are taken into account likewise, such as the impact of regulation on the definition of the geographical market, the high barriers to entry, and high costs of innovation that are liable to drive companies in consolidation, or the impact of actual and potential competition. In general, mergers in the pharmaceutical sector do not raise specific issues, and those that have raised concerns have been cleared rapidly subject to conditions or obligations.

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

The Comco applies the SSNIP test in defining the relevant markets. In the pharmaceutical sector, the Comco defines the market by

reference to the anatomical therapeutic chemical (ATC) classification system (www.ephmra.org). The analysis starts from the pharmacological subgroup (third level) (see *Hoechst/Rhône-Poulenc*, 1999; *Pfizer/Wyeth*, 2009); the drugs of this level are considered to be close substitutes. The market can be broadened further to include drugs from the second level (therapeutic subgroup) depending on the circumstances, for instance if drugs from different subgroups are substitutes for the treatment of a single disease. A narrower market compounded by drugs in the fourth level is also defensible, according to circumstances.

Substitutes from the ATC third level are examined to test the competitive constraints. If the 30 per cent of the relevant market based on the third-level drugs, the merger would not raise concerns (see *BristolMyers Squibb Company/Astra Zeneca PLC/Amylin Pharmaceuticals Inc*, 2013).

The ATC classification is used to define relevant markets at manufacturing market level. For other levels of the market, for instance distribution, other criteria are relevant such as prescription or reimbursement from health insurance (*Sun Store SA/Aristea SA/Distripharm SA/Galenica AG*, 2009; *Galenica SA/Alliance Uni-Chem*, 2005).

The geographical market remains national in scope, due to regulatory legislation applicable to pharmaceuticals (see *Roche/Corange*, 1998); in general, existence of parallel imports does not affect this definition (*Pfizer Inc/Pharmacia Corp*, 2003).

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

An overlap in Switzerland will be considered as problematic if the merger creates a dominant position in the relevant market. Comco will conduct a careful assessment if the overlap exceeds 40–50 per cent of the market shares. Calculation of the Herfindal-Hirschman Index (HHI) is an additional test: a careful assessment will be conducted for values of HHI between 1,000 and 2,000 and in the event delta (Δ HHI) exceeds 150 (eg, *Pfizer/Wyeth*, 2009). HHI values between 2,700 (pre-merger) and 3,000 (post-merger), with a delta exceeding 700 indicate a concentrated market with a risk of collective dominance (*Pfizer/Wyeth*, 2009).

In *Glaxo Wellcome PLC/SmithKline Beecham PLC* (2001), the merger would have created a new entity with a 75–85 per cent market share on the market for antiviral drugs on the one hand, and with a market share of 85–95 per cent on the drugs for the treatment of herpes labialis, on the other. The commitment of the merging parties to grant a licence for one of the products removed that overlap. The entry of generics in the old generation segment was not sufficient to remove competition law concerns.

Both actual and potential competition is relevant for the competitive assessment of the merger. In *Pfizer/Wyeth* (2009), the Comco took into account the presence of five other competing drugs, the short remaining patent protection as well as entry of generics in the market for the treatment of depression. In addition, two competitors had three Phase III drugs in the pipeline for the same therapeutic indication. Accordingly, the merger did not raise concerns in this market.

The same analysis applies to overlap of actual and pipeline products. In *Pfizer/Pharmacia* (*Pfizer Inc/Pharmacia Corp*, 2003), the Comco required divestiture of a Phase III pipeline product developed by Pfizer (potential competition), given the strong market share of 55–65 per cent of Pharmacia in the substitute drug for incontinence already on the market (actual competition). The same analysis resulted in the divestment of a pipeline product by Pharmacia for the treatment of erectile dysfunction, given the strong position of Pfizer in the market with Viagra (around 90 per cent of the market in 2002). The Comco refused to define a stand-alone innovation market.

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

The Comco has analysed several times the overlap of existing and pipeline products, which may raise competition concerns and require remedies (see question 15 above).

To date, it has not considered overlap between two or more pipeline products in the absence of an existing market for drugs with the same therapeutic indication problematic. Phase III pipeline products risk attracting further enquiry if there is already a therapeutic indication for such products, and a high likelihood of successful market entry.

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

Both divestments and licensing arrangements may resolve competition law concerns raised by the merger. Divestment of a business was used in *Pfizer/Pharmacia* (*Pfizer Inc/Pharmacia Corp*, 2003), where each merging party divested their respective pipeline product. Licensing for Switzerland was used in *Glaxo Wellcome PLC/SmithKline Beecham PLC* (2001).

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?

Acquisition of patents or licences is subject to prior notification if such patents or licences constitute a business to which a turnover in the market can be clearly allocated.

Anti-competitive agreements

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

The Cartel Act states that agreements that significantly restrict competition in a market for specific goods or services and are not justified on the grounds of economic efficiency, and all agreements that eliminate effective competition are unlawful (article 5, paragraph 1 of the Cartel Act). Agreements that simply restrict competition are not subject to fines.

Justification on the grounds of economic efficiency is granted if:

- the agreements are necessary in order to reduce production or distribution costs, improve products or production processes, promote research into or dissemination of technical or professional know-how, or exploit resources more rationally; and
- the agreements will under no circumstances enable the parties involved to eliminate effective competition.

A second group of agreements is prohibited and subject to fines of up to 10 per cent of the aggregate turnover in the three preceding financial years. This group comprises horizontal agreements that directly or indirectly fix prices; limit the quantity of goods or services to be produced, purchased or supplied; or allocate markets geographically or according to trading partners (article 5, paragraph 3 of the Cartel Act) on the one hand, as well as vertical agreements that set fixed or minimum resale prices, or allocate territories (article 5, paragraph 4 of the Cartel Act). These agreements are presumed to lead to the elimination of effective competition. The presumption is rebuttable, although it is hard in practice to rebut.

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

Agreements fixing prices between competitors are prohibited; one of the first decisions of the Comco was the prohibition of the cartel in the vitamin sector (*Vitamin Cartel*, 2000).

Investigation of resale price maintenance and vertical price recommendations are an important part of Comco's enforcement in this sector. Setting of margins and limitation of rebates among pharmacies was held illegal by the Comco (see *Vertrieb von Arzneimitteln: Sanphar*, 2000).

Price recommendations issued by hearing aid producers were held to restrict competition since most acousticians actually observed these recommendations (see *Markt für Hörgeräte*, 2011). In an investigation in the market for erectile dysfunction drugs, the Comco held that price recommendations issued by three pharmaceutical companies restricted competition, given that such recommendations were followed by more than 80 per cent of pharmacies (*Hors-Liste Medikamente: Preise von Cialis, Levitra und Viagra*, 2010), and fined the three drug manufacturers over 5 million Swiss francs. Over 800 pharmacies, physicians and distributors were involved in the investigation. The Federal Administrative Court quashed the three decisions, by holding that the special provisions prohibiting advertisement for these drugs and the need for discretion of patients excluded competition among pharmacies and consequently the Cartel Act did not apply (article 3 of the Cartel Act; decision of 3 December 2013).

Prohibition of parallel imports would also fall under the prohibition, even though such restriction were to be included in a licensing agreement may also fall under the prohibition of article 5 of the Cartel Act; in *Gebro Pharma* (GABA, 2009, the decision concerned toothpaste), the Comco fined restrictions to parallel imports included in a licence manufacturing agreement, the decision was upheld by the Federal Administrative Court in February 2014).

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

Technology licensing agreements are considered in the framework of article 5 of the Cartel Act. There has been no decision to date (see response to question 29). Technology licensing agreements may be considered anti-competitive if they contain hard-core provisions, such as provisions allocating markets and prohibiting passive sales or parallel imports.

Swiss law does not provide statutory rules specifically concerning technology transfer agreements similar to the Commission Regulation No. 772/2004 of April 2004 on the application of article 3 of the Treaty to categories of technology transfer agreements.

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

Co-promotion and co-marketing agreements are assessed in the light of article 5 of the Cartel Act. Regarding horizontal effects, these agreements would trigger antitrust liability if they allow for exchange of sensible information, such as prices, margins, customers, terms and conditions of trade, current and estimates of promotion expenses, as well as coordination of commercial activities having an impact on the above-mentioned components. Down the distribution supply chain, these agreement raise issues related to customers, territorial allocation and price fixing. Any such agreement should avoid coordination on such elements.

Cost reduction may be considered as a justification for agreements not having an impact on prices, production or market allocation. The analysis will aim to balance negative effects with efficiency gains (see response to question 19).

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

The more the agreement will regulate issues pertaining to the supply chain, for instance the commercialisation of products, the more

these forms of agreements are liable to raise numerous competition law issues. Exchange of sensible information cannot always be resolved by appropriate confidentiality agreements.

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

The most delicate issues under Swiss law are prohibitions of parallel imports, territorial allocations and minimum resale pricing. Price recommendations may also be considered as hard-core restrictions if they are followed by retailers.

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

There have been no competition law cases on settlements of patent disputes under Swiss law. Patent disputes would be liable to trigger antitrust liability in view of the circumstances of the case, such as a sham litigation in order to block any entry into the market of a competitor and without any basis, or other litigation that would exclude competition on the market without objective justification.

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?

The Swiss Cartel Act applies to unilateral practices of dominant undertakings. According to article 7 of the Cartel Act, dominant undertakings behave unlawfully if they, by abusing their position in the market, hinder other undertakings from starting or continuing to compete, or disadvantage trading partners.

The Swiss Cartel Act is construed independently from EU competition law (judgment of the Federal Supreme Court of 11 April 2011, joint cases 2C_343/2010 and 2C_344/2010, pt 4.3). Therefore, the legislation and individual solutions diverge from EU case law and the European Commission's decision-making practice.

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

Article 4 paragraph 2 of the Cartel Act defines dominant undertakings as 'one or more undertakings in a specific market that are able, as suppliers or consumers, to behave to an appreciable extent independently of the other participants (competitors, suppliers or consumers) in the market'.

Neither the law nor case law refers to any threshold above which a company would be considered dominant. A market share between 45 and 80 per cent is considered high. However, such a market share constitutes only an indication, and is not sufficient to prove dominance. The Comco goes through an in-depth analysis of the market characteristics even though the market definition reveals a market share of 100 per cent (*Terminierungsgebühren beim SMS-Versand via Large Account* 2008). In particular, when barriers to entry are low and potential competition is strong, high market share does not justify the qualification of a dominant position.

On the one hand, the Comco has denied dominance in the case of a market share of 69 per cent, where the company had lost market share due to the entry of new competitors (*Mobilfunkmarkt (Swisscom)* 2002). In another case, a market share of 50 to 70 per cent was not sufficient to qualify for dominance because of the strong competition that was facing the company from the two other (actual) competitors. The market test had shown that the larger company was unable to raise its prices and thus to ignore competition on the market (*Johnson & Johnson* 2003).

On the other hand, public hospitals were found to be dominant with a market share of 45 per cent. In this case, the absence

of potential competition and the existence of particular dependency relationships between public hospitals and insurers in the private insurance field justified the qualification of dominance (*Zusatzversicherung Kanton Luzern*, 2008). A market share of 50 per cent coupled with weak potential competition and high barriers to entry justified the qualification of dominance in the market for poster advertising (*Plakatierung in der Stadt Luzern*, 2003).

Other factors contribute to finding dominance when the undertaking under investigation possesses a high market share: stable or increasing market share, weak counterparties or competitors in financial difficulty, existence of switching costs or existence of must-in-stock products.

Dominance is defined as a position held by 'one or more undertakings', and therefore collective dominance is covered by the law. There is, however, no specific definition of collective dominance, whose characteristics are developed by the practice of the Comco.

The first case that dealt with collective dominance was the merger between Price Waterhouse and STG-Coopers & Lybrand (1998). According to the Comco, the criteria to qualify for a collective dominance are similar to that of collusion (horizontal agreement) (*Konsumkredit*, 2007, where the Commission denied both the finding of collective dominance and the existence of an agreement).

One of the most in-depth analyses with regard to collective dominance was carried out in the pork meat market (decision of 15 March 2004, *Migros* (Micarna) and *Coop* (Bell Holding)). The following criteria were considered relevant for the finding of collective dominance:

- small number of competitors;
- existence or non-existence of fringe competitors;
- an aggregate market share of undertakings under investigation of more than 50 or 60 per cent;
- high transparency on the market, in particular in relation to price;
- mature and stagnant market;
- high barriers to entry and low probability of potential competition;
- symmetry with regard to interests, products and costs;
- weak position of commercial counterparties;
- existence of cross-shareholdings; and
- existence of a credible sanction mechanism.

The assessment of the Comco was completed with an empirical economic analysis of price margin development in the industry, which allowed the Commission to reject the existence of collective dominance.

The revision of the Cartel Act of 2003 extended the concept of dominance to cover the vertical economically dependent relationship between a supplier and its customer, respectively between a buyer and its customers. Articles 4 and 7 of the Cartel Act apply therefore to the conduct of non-dominant firms. However, the Cartel Act does not contain any specific behavioural provision in relation to the abuse of economic dependence.

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

No. The relevant market would be defined by reference to the competing patents and products having the same functionality and satisfying the same demand from consumers. A patent holder would be found to be dominant only in the event there are no or only a few substitute technologies (patents) or substitute products, the barriers to entry are high and potential competition is weak.

Update and trends

The costs of pharmaceutical products that are reimbursed by the compulsory health-care system are an abiding theme in Switzerland. While the national enforcement of life cycle management and settlement agreements does not seem to have significantly increased, the provisions concerning the pricing of pharmaceutical products that are listed on the list of specialties have been amended several times during the last few years and the federal government plans to introduce completely revised provisions this year.

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

In general, dominant undertakings are considered to behave unlawfully 'if they, by abusing their position in the market, hinder other undertakings from starting or continuing to compete, or disadvantage trading partners' (article 7, paragraph 1 of the Cartel Act). Article 7, paragraph 2 lists examples of conduct that may be considered abusive.

The Cartel Act contains no per se prohibitions. The unlawful (or abusive) character of a conduct should be determined on a case-by-case basis, taking into account market conditions.

To date there have been no cases of abuse related to patent applications. A patent application may trigger liability under article 7 of the Cartel Act in the event such application unduly hinders other undertakings from starting or continuing to compete, or disadvantage trading partners. The Cartel Act allows for cases similar to *AstraZeneca*, in the EU, to be caught.

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

Enforcement of patent as such would not expose the patent owner to antitrust liability. Depending on the circumstances of the case, enforcement of invalid patents to exclude a competitor from the market may be caught by provisions on the abuse of dominance, provided the owner of the patent is found to be dominant.

To date, no such cases have occurred in Switzerland.

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

See question 29.

32 Do authorised generics raise issues under the competition law?

A patent holder is allowed to market or license its drug as a generic (co-marketing product), or to allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition. Originator companies often offer their co-marketing pharmaceuticals at a lower price than their original preparation. However, as soon as there are at least three similar products (including original products, co-marketing products and generic products) listed on the list of specialties the price of the original product must either be lowered so that it does no more exceed the average price of the cheapest third of the relevant product category for more than 20 per cent or the deductibly that is not paid by the social health care but by the patient himself will increase from 10 to 20 per cent for the concerned original product.

Pay-for-delay agreements or other practices aiming at excluding generic competition may be considered as anti-competitive agreements, or abuse of dominant position, provided the owner of the patent is found to be dominant.

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

Innovation and other specific characteristics may be considered as an objective justification. In addition, the same circumstances that were used by the Federal Administrative Court to exclude the application of the Cartel Act, could be used to justify a restriction of competition (eg, special provisions prohibiting advertisement and the need for discretion of patients, see decision of 3 December 2013).

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.

There has been no increase in antitrust enforcement in recent years.

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

Follow-on litigation is possible, although not frequently used in Switzerland. To our knowledge, there have been no follow-on litigation cases in the pharmaceutical sector.

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