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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 main piece of legislation in the pharmaceutical sector is the Medicinal Products and Medical Devices Act (MPA) of 15 December 2000 and its accompanying regulations, which together contain the main provisions relevant to the marketing and authorisation of pharmaceutical products.

In addition, there is a wealth of further legislation concerning the marketing and pricing of pharmaceutical products, such as the Health Insurance Act (directing that the maximum prices set for a range of pharmaceutical products are not to be exceeded), the Unfair Trade Practices Act and the Price Surveillance Act (which empowers the office of the price surveillance to monitor prices and to act against inflated prices). The Cartels and Other Restraints of Competition Act (Cartel Act), containing the main competition law provisions (similar to articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU)), is also generally applicable to pharmaceutical products, although it should be noted that the Cartel Act is not applicable to 'regulated markets'. Regulated markets are those in which legal provisions establish, for example, an official price system thus preventing free competition. There are no precedents and there is therefore considerable uncertainty whether the Swiss competition authorities would consider the pharmaceutical sector to be (price) regulated by the provisions mentioned above, since those provisions only establish maximum prices; lower prices and in particular the possibility to grant rebates are not prohibited by those provisions.

2 Which bodies are entrusted with enforcing these regulatory rules?

The central supervisory authority for therapeutic products in Switzerland is Swissmedic (www.swissmedic.ch). It is a public service organisation of the federal government headquartered in Berne.

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

Subject to what has been said in question 1 in relation to regulated markets, the pharmaceutical sector is fully subjected to the substantive provisions of the Cartel Act, namely:

- article 5, which prohibits anti-competitive agreements between competitors and between market participants operating at different levels of trade (vertical agreements);
- article 7, which prohibits the abuse of dominant market positions; and
- article 9 setting out the merger control regime.

The application of the Cartel Act to the pharmaceutical industry can lead to friction, especially in the area of patent law and protection (particularly relevant here are article 14(2) of the MPA regarding parallel imports of pharmaceuticals and article 3(2) of the Cartel Act, subjecting preventions of parallel imports based on the exercise of IP rights to the provisions of the Cartel Act). Thus, while the Swiss Federal Court in Kodak (RPW 2000|1 122) confirmed the principle of national exhaustion in relation to patents (thus largely allowing patent owners to prevent parallel imports), the revised Cartel Act explicitly applies to the abusive use of patents if such an abuse leads to the prevention of parallel imports.

Furthermore, in 2003 the Swiss Competition Commission (SCC) issued an advisory opinion on the admissibility of price agreements between producers of pharmaceuticals under the MPA. (Article 33 of the MPA makes it unlawful to grant, offer or promise material benefits to persons who prescribe or supply medicinal products. Manufacturers intended to invoke this article as justification for not granting any discounts to their customers.) In its advisory opinion, the SCC stated that article 33 of the MPA could not be relied on to justify unlawful price agreements under the Cartel Act.

Competition legislation and regulation

4 Which legislation sets out competition law?

Swiss competition law is set out in the Cartel Act of 6 October 1995, last revised in 2003.

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

There are no formal guidelines but in 2010 the SCC issued a revised notice on the competition law treatment of vertical agreements (Verticals Notice 2010) which, inter alia, provides guidance on the competition law assessment of price recommendations (see question 24). Price recommendations are of particular relevance to the pharmaceuticals industry as a result of the SCC's Hors Liste decision (RPW 2010|4 649). In that decision, the SCC held that Pfizer's, Eli Lilly's and Bayer's practice of issuing price recommendations regarding the non-reimbursable drugs Viagra, Cialis and Levitra constituted an illegal vertical agreement under article 5(4) Cartel Act, as the price recommendations were to a large extent adhered to by self-dispensing doctors and pharmacies (see question 20 for more information). In addition, in 2003 the SCC issued an advisory opinion on the relationship between the MPA and the Cartel Act in relation to agreements on price (see question 3).

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

The relevant Swiss authority is the Swiss Competition Commission (SCC) (www.weko.admin.ch), which is based in Berne. Its secretariat is the investigative authority for mergers, investigations of anti-competitive agreements and abuses of dominance.

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

According to article 49a(1) of the Cartel Act, the SCC can impose fines on undertakings engaged in:

- hard-core horizontal cartels;
- vertical agreements providing for minimum or fixed resale prices (resale price maintenance) or the restriction of passive sales into an exclusive territory in distribution agreements; or
- abuses of a dominant position.

The fines may be as high as 10 per cent of the cumulative sales turnover achieved by any undertaking involved in such anti-competitive practices in Switzerland over the previous three business years. Horizontal or vertical restraints of competition other than those mentioned above can also be fined but only if the specific conduct has been held to be illegal by the SCC in the past and the company nevertheless engages in exactly the same conduct again. The SCC has issued detailed guidelines for the setting of fines. These are set out in the Ordinance regarding the Sanctions for Unlawful Restrictions of Competition (Ordinance on Sanctions) of 12 March 2004 and the explanatory Remarks on the Ordinance on Sanctions.

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, the Swiss courts can issue or award the following to private claimants for violations of Swiss competition law:

- orders to cease and desist anti-competitive conduct;
- damages; and
- seizure of unlawful profits based on anti-competitive conduct.

Under article 13 of the Cartel Act, a court may specifically declare anti-competitive agreements to be wholly or partially null and void. Under this provision, a court may also order an undertaking to conclude an agreement with a specific counterparty (specific performance).

In awarding damages for an infringement of Swiss competition law, the court will allow the claimant to choose between damages calculated in line with ordinary tort law (ie, putting the claimant in the position he would have been in but for the tort) and damages amounting to the profits achieved by the defendant as a result of the anti-competitive behaviour. So far, there has been only one case in which damages have been awarded to the claimant (see decision of the Commercial Court of Aargau in *General Undertakers, RPW* 2003|2 451). In that case, damages under tort law were said to be equal to the profits that could be expected to accrue had the claimant been able to capture a certain share of the market. The determination of how much market share the claimant could reasonably have captured was in turn based on an example in a neighbouring geographic market. The profits of the defendant were said to be equal to the savings achieved by the defendant as a result of the anti-competitive measure.

As for interim injunctions, the Swiss Civil Procedure Act (CPA) applies. According to article 261 CPA, the competent court may grant interim relief based on a prima facie case that a present or threatened competition law infringement will cause substantial harm which cannot easily be made good.

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 secretariat has in the past carried out market surveys, for example, in the telecom, energy and agriculture markets as well as in relation to, for example, gluten-free products. To date, however, no such surveys have concerned the pharmaceutical industry.

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

While Swissmedic has far-reaching regulatory powers, it has no mandate to devise sector-specific rules distinct from the general competition rules.

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

Under Swiss competition law, anti-competitive agreements fall into two categories. First, agreements relating to price fixing, output restrictions or market sharing (hard-core agreements). Those are presumed to eliminate competition altogether and they cannot be justified under any circumstances. In the case of all other anti-competitive agreements, as well as hard-core agreements for which the presumption of elimination of competition can be rebutted, article 5(2) of the Cartel Act contains an exhaustive list of 'grounds of economic efficiency' that can be adduced to justify an anti-competitive agreement. These are:

- reducing production or distribution costs;
- improving products or production processes;
- promoting research into or dissemination of technical or professional know-how; and
- exploiting resources more rationally.

While there is no case law on the matter, it is not impossible that the last of those grounds can be used to adduce industrial-policy type arguments.

In exceptional cases, anti-competitive behaviour and mergers can be authorised by the Swiss Federal Council upon request if necessary, in order to safeguard compelling public interests (see articles 8 and 11 of the Cartel Act).

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

There are numerous non-governmental associations that regularly lobby the government to effect changes to the national exhaustion doctrine of patents thus facilitating parallel imports, or to opt for the prescription of cheaper generics. Equally, there are pressure groups representing the pharmaceutical and chemical industries that lobby in favour of the retention of the national exhaustion rule.

Those consumer associations and pressure groups are usually consulted in relation to secondary legislation and they could, theoretically, also get involved in civil antitrust proceedings (Switzerland does not, however, allow class or representative actions in relation to antitrust offences). In practice, the role of consumer groups and other associations in antitrust proceedings has been very limited, save for their role in tipping off the regulator about alleged infringements of the Cartel Act.

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?

To the extent that any sector-specific features are relevant for the economic analysis of a merger, they can be taken into account, but there are no special rules applicable to mergers in the pharmaceutical industry.

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

The definition of product markets under Swiss merger control follows the approach of the European Commission. According to the past practice of the SCC, the starting point for a product market definition for human pharmaceutical products is the Anatomical Therapeutic Chemical (ATC) classification. As the third level of the ATC classification allows medicines to be grouped in terms of their therapeutic indications, it can therefore be used as an operational starting point for a market definition. In certain cases it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC level 3 classes on the basis of demand-related criteria (see *Pfizer/Pharmacia*, RPW 2003|2 314). Further distinctions (eg, into 'prescription-only' medicines versus 'non-prescription' medicines or 'reimbursable medicine' versus 'non-reimbursable medicines') have been left open by the SCC in *Roche/Corange* (RPW 1998|1 61).

It is unclear, however, to which ATC classification system the SCC refers. In *Pfizer/Pharmacia* or *Price for pharmaceutical 'thalidomide'* (RPW 2006|3 433) the SCC referred to the five-level ATC classification system of the World Health Organization (WHO), whereas in other cases reference was made to the four-level ATC classification system of the European Pharmaceutical Marketing Research Association (EphMRA) (for recent cases see *Pfizer/Wyeth*, RPW 2009|4 349; and *Merck & Co/Schering Plough*, RPW 2009|4 442). It appears that the SCC is not aware of the differences between the two ATC classifications. In Hors Liste (RPW 2010|4 649), the SCC refers to the four-level EphMRA classification but proceeds to explain that it consists of five levels (as if it were the WHO classification). In any event, it is unlikely that the SCC seeks any disparity with the European Commission's practice (which primarily uses the EphMRA classification; see COMP/M.1846 *Glaxo Wellcome/SmithKline Beecham* in 2000 or COMP/M.4367 *APW/APSA/Nordic Capital/Capio*), as the SCC in all decisions referred to the European Commission's practice without mentioning any discrepancy.

The relevant geographical market has consistently been defined to be national.

As regards the market definition for veterinary pharmaceuticals, the geographical market is also defined on a national basis. The product market for veterinary pharmaceuticals has been held to consist of the main product categories food additives, hygiene products, vaccines and veterinary medicines. The latter can be divided into anti-microbial, anti-infectious, anti-inflammatories and parasiticides products. If necessary, these can be further subdivided depending on the respective animal, the dosage form, the period of effectiveness, the mandatory waiting period, the active ingredient and the status of the reproductive cycle of the animal that is to be treated (see *Pfizer/Wyeth*).

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

In a merger situation, the market will be considered 'affected' if one party of the transaction has a market share of more than 30 per cent or if at least two of the parties of the transaction have a combined market share of more than 20 per cent. Below these thresholds, competition concerns are very unlikely to arise.

Even an individual market share of almost 100 per cent was held to not raise any concerns where the mergers did not lead to an addition of market shares and were carried out in markets with marginal turnover or where competition was ensured by the presence of other major players or several smaller undertakings (see *Pfizer/Pharmacia* and *Sanofi-Synthélabo/Aventis*). Competition concerns were assumed, however, at a combined market share level of more than 75 per cent where the merger would have led to the disappearance of a competing product or where a major change in market shares (eg, due to the entry of new competing products or generic drugs) could not be expected in the near future (*Glaxo Wellcome/SmithKline Beecham*, RPW 2001|2 338). In *Pfizer/Wyeth* and *Sanofi-Synthélabo/Aventis*, even a combined market share level of more than 50 per cent was considered problematic.

According to the SCC's assessment, major changes of market shares due to high market dynamics are likely to occur in a market where a patent expires or new innovative products and generic drugs are introduced (see *Pfizer/Pharmacia*).

As regards potential competition, according to the SCC's assessment in *Roche/Corange*, competition at manufacturing level consists of international competition for innovations (patents) and international competition for imitations (generic drugs). Even though there are significant barriers to market entry at the level of the 'global players' due to the high costs for research and development of new products, competition is likely to be ensured by the existence of small but highly specialised players or start-ups launching new promising pharmaceuticals.

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

Pipeline products will likely only be taken into account if they are in the last phase of development and where their ATC classification is sufficiently foreseeable. In *Pfizer/Pharmacia*, the SCC voiced competition concerns at a market share level of 55 per cent of one of the parties with the other party having a pipeline product in the same market.

However, the SCC has held that there is not a separate market for innovations as the final ATC of a pipeline product cannot be established until shortly before authorisation is obtained.

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

According to article 10(2) of the Cartel Act, a merger can be made subject to conditions or obligations if there is a risk that it would otherwise eliminate effective competition. The SCC has accepted both the divestment of a product or product line (see *Pfizer/Wyeth*, *Sanofi-Synthélabo/Aventis* and *Pfizer/Pharmacia*) and the conclusion of a licensing agreement with a third party (*Glaxo Wellcome/SmithKline Beecham*) as possible remedies to meet competition law 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?

Under Swiss law, a transaction is subject to statutory merger control if it inter alia involves the acquisition of control over one or more previously independent enterprises or part(s) thereof, irrespective of whether that part has previously been operating on the market as a separate company or unit within a company or a group of companies. It is, however, necessary for that part of an enterprise to be transferred to have a certain 'market strategic autonomy', usually evidenced by assets, employees, customers, a clear attribution of turnover, etc. If a patent or licence transfer fulfils those criteria, Swiss merger control provisions generally apply and the transaction may have to be notified to the SCC if the relevant jurisdictional thresholds are exceeded.

Anti-competitive agreements

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

Under the Cartel Act, 'agreements affecting competition' comprise binding or non-binding agreements and concerted practices between enterprises operating at the same or at different levels of the market,

the purpose or effect of which is to restrain competition.

According to article 5(1) of the Cartel Act, agreements that significantly affect competition in the market for certain goods or services and all agreements that lead to the suppression of effective competition are unlawful, but may exceptionally be justified on grounds of economic efficiency according to article 5(2) of the Cartel Act if they are necessary and do not in any way whatsoever allow the enterprises concerned to eliminate effective competition.

However, according to article 5(3), horizontal agreements relating to price fixing, output restrictions or market sharing (hard-core agreements) are presumed to eliminate competition altogether; those cannot be justified unless the presumption is rebutted first. The same is true for vertical agreements regarding fixed or minimum prices and the allocation of territories coupled with a prohibition on passive sales (article 5(4) of the Cartel Act).

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

Since June 2006, the secretariat of the SCC has been conducting an in-depth investigation concerning vertical price-fixing allegations in relation to Viagra, Cialis and Levitra (manufactured by Pfizer, Eli Lilly and Bayer respectively). In November 2009, the investigation was closed and the SCC held that the public price recommendations issued by the manufacturers to pharmacies and self-dispensing doctors constituted an illegal vertical agreement (more specifically: resale price maintenance). Pfizer, Eli Lilly and Bayer were consequently fined a total of 5.7 million Swiss francs; appeals against the decision have been lodged with the Swiss Federal Administrative Court where they are currently still pending.

In addition, there have been several investigations regarding the distribution of human and veterinary pharmaceuticals. In *Sanphar* (RPW 2000|3 320), the SCC held that an agreement between the manufacturers of human pharmaceuticals relating to the profit margin of wholesale merchants was unlawful. In the *Distribution of veterinary pharmaceuticals* case of 2004, the SCC questioned the coordinated behaviour between manufacturers and wholesale merchants excluding pharmacies from the supply of veterinary pharmaceuticals. In both cases the 'grounds of economic efficiency' provided for in article 5(2) of the Cartel Act were invoked by the parties but rejected by the SCC. It should be noted, however, that until the most recent revision of the Cartel Act entered into force in April 2004, proceedings suffered from the fact that unlawful agreements were not punishable under the Cartel Act. In the *Sanphar* case, the SCC could therefore only issue a prohibition decision, whereas the *Distribution of veterinary pharmaceuticals* case was settled by an amicable agreement between the SCC and the parties to the proceedings.

The well-known vitamin cartel case between Hoffmann-La Roche, Rhône-Poulenc and BASF was also investigated in Switzerland and was subject to an adverse decision by the SCC in 2000.

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

There is no specific case law regarding licensing agreements in the pharmaceutical sector, nor a notice comparable to the European Technology Transfer Block Exemption Regulation. Therefore, the general provisions of the Cartel Act set out above (see question 19) as well as the provisions of the Verticals Notice 2010 (see questions 5 and 24) apply. In addition, when faced with a novel situation involving technology licensing in the future, the SCC will most likely look to the European Technology Transfer Block Exemption Regulation for general guidance.

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

There is no specific case law regarding co-promotion or co-marketing agreements in the pharmaceutical sector. However, distribution co-operations to reach economies of scale are deemed admissible (see *Virtuelle Kalenderfabrik Schweiz*, RPW 1998|1 19) as long as they fulfil the requirements of article 5(2) of the Cartel Act (see question 11).

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

There is a statutory presumption that horizontal agreements between actual or potential competitors lead to the elimination of effective competition if they directly or indirectly fix prices between competitors, restrict the quantities of goods or services to be produced, bought or supplied or allocate markets geographically or according to trading partners (article 5(3) of the Cartel Act). Those agreements cannot be justified unless the presumption can be rebutted. Other agreements between competitors can also give rise to competition law concerns but may be justified on grounds of economic efficiency (see question 19).

Although there is no case law on the matter, it is not impossible that appropriate confidentiality provisions between the parties to, for example, a co-promotion or a co-marketing agreement can alleviate any competition law concerns of coordination.

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

In 2010, the SCC published the updated Verticals Notice 2010 (not available in English). Cipher 12 sets out the practices that the SCC considers to be 'qualitatively serious'. The following may be relevant for the pharmaceuticals industry:

- restricting downstream customers' ability to set their own prices;
- restricting the area or customer group (in) to which downstream customers can sell their goods or services;
- restricting active or passive sales to end customers by resellers active at the retail level of trade;
- restricting cross-supplies between authorised distributors of a selective distribution system;
- non-compete clauses that are agreed for a duration of more than five years or for an indefinite period of time;
- post-contractual non-compete clauses, unless the clause refers to goods or services that compete with the contractual goods or services; refers to the area or building from which the purchaser carried out his contractual obligations; is necessary to protect the purchaser's know-how (assigned by the supplier or seller); and is limited to one year after the end of the contractual relationship. The unlimited restriction of the use and publication of secret know-how remains possible; and
- restricting multi-brand distribution within a selective distribution system where the focus is on brands of specific competitors.

Other vertical agreements are generally unlikely to give rise to competition law concerns if no party to the agreement has a market share of more than 15 per cent in the relevant market (cipher 13 of the Notice). If competition on the market is restricted by the cumulative effect of numerous parallel vertical distribution systems, the market share threshold mentioned in the previous sentence is reduced to 5 per cent. As a general rule, if less than 30 per cent of the relevant market is covered by similar parallel vertical distribution systems, no foreclosure concerns should arise.

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

There is no Swiss case law on the matter but since the SCC often looks to EC competition law for guidance, the position is likely to be similar to the position under EC competition law.

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?

Practices of enterprises having a dominant position are deemed unlawful when such enterprises, through an abuse of their dominant position, prevent other enterprises from entering or competing in the market or when they harm trading partners. According to the Cartel Act unlawful practices are in particular:

- refusal to maintain business relations (eg, refusal to supply or buy goods);
- discrimination between trading partners with regard to prices or other conditions of trade;
- the imposition of unfair prices or other unfair conditions of trade;
- the undercutting of prices or other conditions directed against a specific competitor;
- restrictions on production, outlets or technical development; and
- the conclusion of contracts only on condition that partners agree to supply additional goods or services.

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

According to the statutory definition contained in article 4(2) of the Cartel Act, the term 'enterprises having a dominant position in the market' means 'one or more enterprises being able, as regards supply or demand, to behave in a substantially independent manner with regard to the other participants (competitors, suppliers or customers) in the market'. Relevant factors are the degree of dependence on the supply or demand side and the market structure of the relevant market. In the academic literature, it is commonly assumed that a dominant position is unlikely to arise with a market share lower than 20 per cent. Where an enterprise has a market share between 20 and 40 per cent, further elements are generally required to establish a dominant position, whereas a market share of more than 50 per cent is a strong indicator for a dominant position, which can, however, be rebutted if mitigating factors can be proven (see, for example, *Borer, Kommentar Kartellgesetz, 2011*).

As regards the existence of joint dominance, the SCC assumes that there is an incentive for collusive behaviour if the following conditions are met: high barriers to market entry, transparent market conditions, mature or stable markets, homogeneity of products, high concentration on the supply side, and stagnation or lack of price elasticity on the demand side. In the pharmaceutical sector, market transparency, stable market conditions and the concentration on the supply side are particularly relevant (see *Pfizer/Pharmacia*).

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

Generally speaking, according to the Swiss Federal Court's decision in *Kodak* (RPW 2000|1 122), the Cartel Act applies to prevent any fraudulent use of patents. Therefore, using a patent to block new technological developments of competitors could be classified as an unlawful practice unless it can be objectively justified.

There is, however, no specific case law on whether a patent holder is per se dominant. In *Price for pharmaceutical 'thalidomide'* (RPW 2006|3 433), the SCC considered whether the licence holder of a patented product held a dominant position, but the question was eventually left open as there was no evidence of abuse. The reasoning of the SCC does, however, indicate that a dominant position does not exist if the market introduction of a new product treating the same disease as the patented one can be expected in the near future. According to the Swiss academic literature, there should be no presumption that a patent necessarily confers market power on its holder.

Update and trends

The MPA is currently being revised. In November 2012 the Swiss Federal Council (the government) submitted its suggested amendments and a bill to the Swiss Federal Assembly (the parliament).The revised MPA contains inter alia a provision pursuant to which the acceptance of monetary benefits by persons who prescribe or dispense medicinal products (as well as the organisations which employ them) shall be punishable. Currently, pursuant to a judgment by the Swiss Federal Court in December 2012, accepting monetary benefits is prohibited but cannot be punished. The new law will probably enter into force in 2016.

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

The acquisition of a patent might be seen as an unlawful practice if the sole purpose of the acquirer is to block new technological developments of its competitors ('blocking patent'). Also, the creation of a patent pool or the conclusion of cross-licensing agreements might be unlawful, if the sole purpose is to create barriers to market entry or to hinder competitors in any other way.

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

In principle, preventing new developments on the basis of an existing patent is not contrary to Swiss competition law unless the sole purpose of the patent holder is to block the technological development of his competitors ('blocking patent'). Following the revision of the Cartel Act in 2003 introducing article 3(2), the holder of a patent cannot prevent parallel imports if the enforcement of his patent constitutes an unlawful behaviour under the Cartel Act (see question 3). The results of the concurrent application of the Cartel Act and intellectual property law can therefore be difficult to predict with any degree of certainty.

The question of whether a patent holder who is considered dominant might be obliged to grant a compulsory licence to a competitor has not yet been answered for Swiss competition law, but Swiss courts might follow the jurisprudence of the Court of Justice of the European Union. In any event, refusing to grant a licence is unlikely to be considered unlawful if the decision can be objectively justified.

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

See question 25.

32 Do authorised generics raise issues under the competition law?

See question 25.

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

There is no case law on the matter but arguments relating to mandatory product safety standards or official price regulation are likely to be taken into consideration as an objective justification for anti-competitive conduct.

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 not been an increase in antitrust enforcement in the pharmaceutical sector in Switzerland. The investigation directed against Pfizer, Eli Lilly and Bayer (see question 20) must be considered the biggest investigation in the sector 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.

There has been no follow-on litigation in the aftermath of any pharmaceutical antitrust enforcement in Switzerland. See also question 8.

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