

1. Introduction

The pharmaceutical industry is an important sector of the Swiss economy. In 2014, the worldwide turnover realized by pharmaceutical companies headquartered in Switzerland represented more than USD 90 billion, while this sector contributed to one third of Swiss exports and employed more than 40'000 workers.¹ Comparatively, competition law enforcement has been rather moderate in this sector over the past 15 years. Merger review let aside, a handful of investigations carried out by the Competition Commission led to significant decisions. Among them was the well-known international vitamin price-fixing cartel. The others were cases related to the distribution of pharmaceutical products. It seems that Switzerland has not (yet) been caught by the wave of enforcement activity in this sector in the United States or, more recently in the European Union. The Competition Commission has notably not had yet to struggle with reverse payment settlements and other issues at the crossroad of intellectual property and competition law.

That being said, Switzerland is one of the countries with the highest prices for pharmaceuticals in the world and there has been considerable political pressure to curb ever-increasing drug prices (for both original preparations and generics). The mechanism through which maximum prices for pharmaceutical products are reimbursed by the mandatory health insurance has been reviewed several times over the past 10 years but is still heavily criticized.

The present report provides an overview of the way material competition law provisions are applied in the pharmaceutical sector in Switzerland (Section 2), the type of enforcement activities that took place over the past 15 years (Section 3), the interaction with intellectual property laws (Section 4), and public finance issues impacting the market (Section 5).

2. Competition law Context of the Pharmaceutical Industry

There is no competition law provision applying specifically to the pharmaceutical industry. This economic sector is governed by the general provisions enacted in the Cartel Act of 1995² and its execution ordinances.³ The Cartel Act features “standard” provisions on horizontal and vertical agreements, the abuse of a dominant position, as well as merger control. As such, all three sets of provisions could apply to infringements in the pharmaceutical sector, depending on the facts of the case.

Hence, the key provision governing horizontal and vertical agreements is Art. 5 CartA, which states the following:

Art. 5 Unlawful agreements affecting competition

¹ Source: Interpharma, Le marché suisse du médicament, 2015.

² Federal Act on Cartels and other Restraints of Competition of 6 October 1995, CartA, RS 251; unofficial English version accessible [here](#).

³ Essentially the Ordinance of 17 June 1996 on the Control of Concentrations of Undertakings (Merger Control Ordinance; RS 251.4) and the Ordinance of 12 March 2004 on Sanctions imposed for Unlawful Restraints of Competition (Cartel Sanctions Ordinance; RS 251.5, both accessible in unofficial English versions [here](#).

¹ Agreements that significantly restrict competition in a market for specific goods or services and are not justified on grounds of economic efficiency, and all agreements that eliminate effective competition are unlawful.

² Agreements affecting competition are deemed to be justified on grounds of economic efficiency if:

- a. they 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
- b. they will under no circumstances enable the parties involved to eliminate effective competition.

³ The following agreements between actual or potential competitors are presumed to lead to the elimination of effective competition:

- a. agreements to directly or indirectly fix prices;
- b. agreements to limit the quantities of goods or services to be produced, purchased or supplied;
- c. agreements to allocate markets geographically or according to trading partners.

⁴ The elimination of effective competition is also presumed in the case of agreements between undertakings at different levels of the production and distribution chain regarding fixed or minimum prices, and in the case of agreements contained in distribution contracts regarding the allocation of territories to the extent that sales by other distributors into these territories are not permitted.

The key provision governing the abuse of a dominant position is Art. 7 CartA:

Art. 7 Unlawful practices by dominant undertakings

¹ 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.

² The following behavior is in particular considered unlawful:

- a. any refusal to deal (e.g. refusal to supply or to purchase goods);
- b. any discrimination between trading partners in relation to prices or other conditions of trade;
- c. any imposition of unfair prices or other unfair conditions of trade;
- d. any under-cutting of prices or other conditions directed against a specific competitor;
- e. any limitation of production, supply or technical development;
- f. any conclusion of contracts on the condition that the other contracting party agrees to accept or deliver additional goods or services.

The main provision governing merger control is Art. 10 CartA:

Art. 10 Assessment of concentrations

¹ Concentrations that have to be notified shall be investigated by the Competition Commission if a preliminary assessment (Art. 32 para. 1) reveals that they create or strengthen a dominant position.

² The Competition Commission may prohibit a concentration or authorize it subject to conditions and obligations if the investigation indicates that the concentration:

- a. creates or strengthens a dominant position liable to eliminate effective competition; and
- b. does not improve the conditions of competition in another market such that the harmful effects of the dominant position can be outweighed.

³ If a concentration of banks within the meaning of the Banking Act¹ is deemed necessary by the Swiss Financial Market Supervisory Authority (FINMA) for reasons related to creditor protection, the interests of creditors may be given priority. In these cases, FINMA takes the place of the Competition Commission, which it shall invite to submit an opinion.

⁴ In assessing the effects of a concentration on the effectiveness of competition, the Competition Commission also takes account of any market developments and the position of the undertakings in relation to international competition.

Apart from the material provisions detailed above, two provisions governing the applicability of the Cartel Act generally have an increased importance for the assessment of conducts in the heavily regulated and innovation driven pharmaceutical sector. Art. 3 §§ 1 and 2 CartA stipulate that:

Art. 3 Relationship to other statutory provisions

¹ Statutory provisions that do not allow for competition in a market for certain goods or services take precedence over the provisions of this Act. Such statutory provisions include in particular:

- a. provisions that establish an official market or price system; and
- b. provisions that grant special rights to specific undertakings to enable them to fulfil public duties.

² This Act does not apply to effects on competition that result exclusively from the legislation governing intellectual property. However, import restrictions based on intellectual property rights shall be assessed under this Act.

In addition, the Competition Commission has also issued several Communications, providing some guidelines as to how the Commission is applying the law to certain types of agreements. Among those Communications, the one that is the most likely to apply to pharmaceutical cases is the Communication of 28 June 2010 on Vertical Restraints (ComVert; see below 3).⁴

Looking more in details at some important stages of a competition analysis, market definition in pharmaceutical cases for example is based on the general principles anchored in the Merger Control Ordinance (Art. 11 § 3): The product market comprises all those goods or services that are regarded as interchangeable by consumers on the one hand and by suppliers on the other hand with regard to their characteristics and intended use. The geographic market comprises the area in which on the one hand consumers purchase and on the other hand suppliers sell the

⁴ Accessible in French [here](#). The Communication is based on, and is very similar to, EU Commission Regulation 330/2010 of 20 April 2010 on the application of Art. 81(3) of the Treaty to vertical agreements and concerted practices, and the Commission Guidelines on Vertical Restraints of 19 May 2010.

goods or services that constitute the product market. As a matter of practice, at the manufacturing level the Competition Commission – like the EU Commission – defines the relevant product markets for pharmaceutical products with reference to the Anatomical Therapeutic Chemical Classification Index (“ATC Classification”), generally using the therapeutic classes of level 3 as drugs on this level are considered to be close substitutes.⁵ Further, additional criteria are generally taken into consideration at the distribution level, such as whether the product is available with or without prescription, or whether it is reimbursed by the mandatory health insurance or not.⁶ As far as geographic market definition is concerned, the Competition Commission generally takes into consideration the fact that parallel imports are most of the time not possible, especially for patented drugs, and that, like other daily consumption products, most drugs are bought locally by the patients who need them.⁷ Hence the Commission has consistently defined the market as national.⁸

While it has more or less consistently applied the above mentioned principles, the Commission nevertheless adapts its analysis to the specifics of the concerned products, as it did in its two main decisions involving pharmaceutical products: In a 2010 decision in a resale price maintenance case (the *Hors-liste* case), the Competition Commission considered that the product market only included oral drugs for erectile disorders essentially based on the specific characteristics of this new generation of treatment compared to other previously available treatments (efficiency, ease of use, little side effects, etc.).⁹ Further, the Commission considered that the relevant geographic market was Switzerland, essentially due to: (i) the fact that the concerned drugs require a prescription and can hence only be legally bought in a pharmacy or from a doctor (therefore ruling out illegal purchases through internet); (ii) parallel imports for such products are illegal for patent law reasons; and (iii) like other daily consumption products, these drugs tend to be bought locally by the patients who need them.¹⁰ In the *Sanphar* case, the Commission reviewed rebates and margin agreements along the whole distribution chain: Between manufacturers, between wholesalers and between distributors (pharmacies and doctors), however without further distinctions based on the products as the agreements applied across the board to most medicines.¹¹ The geographic market was found to be Switzerland.¹²

As far as evidence assessment is concerned, there is no true “*per se*” or “object” infringement rule, neither under Swiss competition law in general, nor for pharmaceutical cases in particular. Art. 5 § 3 CartA sets a presumption of elimination of competition for horizontal agreements on price-fixing, limitations of quantities and market allocations (see above). According to a well-established case law such presumption can be rebutted by showing that some internal (i.e. among parties to the agreement) or external (from third parties) competition subsists despite the agreement, which is often the case. A similar provision in Art. 5 § 4 CartA sets the same kind of presumption for vertical agreements on resale price maintenance and the prohibition of passive sales in distribution contracts allocating territories. Here, the presumption can be rebutted by showing the existence of sufficient intra-brand or inter-brand competition.¹³ In both cases, once the presumption has been rebutted and according to a recent ruling

⁵ See DPC 2010/4 p. 649 n. 165ss *Hors-liste*; DPC 2009/4 p. 349 *Pfizer/Wyeth*.

⁶ See DPC 2009/2 p. 173 *Sun Store SA/Aristea SA/Distripharma SA/Galenica*.

⁷ See DPC 2010/4 p. 649 n. 165ss *Hors-liste*.

⁸ DPC 2003/2 p. 316 n. 15ss *Pfizer/Pharmacia*; DPC 2009/4 p. 349 *Pfizer/Wyeth*.

⁹ See DPC 2010/4 p. 649 n. 165ss *Hors-liste*.

¹⁰ See DPC 2010/4 p. 649 n. 191, 192, 197, 199 *Hors-liste*.

¹¹ DPC 2000/3 p. 356-387 *Sanphar*.

¹² DPC 2000/3 p. 356-387 *Sanphar*.

¹³ ComVert n. 11; see also for instance DPC 2011/3 p. 364 n. 53; CR Concurrence – AMSTUTZ/CARRON/REINERT, Basel 2013, Art. 5 LCart N 652-658.

of the Swiss Supreme Court, the agreements at stake shall however be considered as significantly affecting competition and shall be found illegal unless they can be justified by economic efficiencies (see below).¹⁴

Turning back to the two above mentioned cases, in the *Hors-liste* case, the presumption could not be rebutted: The analysis of the intra-brand competition showed that the price recommendations of the manufacturers were heavily followed – and even required - by doctors and pharmacies (which also allowed the Commission to demonstrate the existence of a concerted practice), with very few discounts at the cash desk. There was very little inter-brand competition as the latter one actually does not play an important role for purchases in pharmacies once the prescription has been established by the doctor, the Commission found.¹⁵

In the *Sanphar* case, the presumption could not be rebutted for the agreement at the manufacturers' level: The external competition was too weak – only about 10% of manufacturers were not members of the cartel and most of them were applying the cartel-set rebates and margin anyway – and barriers to entry were considered very high (especially due to the impossibility to carry out parallel imports).¹⁶ Further, there was no internal competition, as the manufacturers were overwhelmingly applying the cartel's rebates and margin. At the distributors' level, the presumption could not be rebutted, neither with respect to doctors allowed to sell drugs, nor with respect to pharmacies, because of the lack of internal or external competition.¹⁷

Agreements affecting competition may be justified by economic efficiencies, provided they do not lead to the elimination of effective competition, if they 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 (Art. 5 § 2 CartA). This list of efficiencies provided by the law is exhaustive – although it certainly allows for some interpretation. The concerned agreements must additionally appear necessary to obtain the efficiency and must not trigger a total elimination of competition.¹⁸ As far as vertical agreements are concerned, the Communication on the Appreciation of Vertical Agreements - ComVert provides a list of efficiencies based on Art. 5 § 2 Cartel Act.¹⁹ Certain categories of vertical agreements further benefit from a kind of “presumption of efficiency”, under certain conditions, when the concerned suppliers do not show market shares exceeding 30%.²⁰ There is no legal limitation of the scope to argue justifications for hardcore conducts, provided of course they do not eliminate competition, that is provided the presumptions set by Art. 5 §§ 3 and 4 CartA could be rebutted. In practice, justifications for such conducts will however need to be all the more compelling to counter their negative impact in the balance of effects made by the authority. It shall further be mentioned that according to a well-established case law, abuses of a dominant position may also be justified by “legitimate business reasons” (objective justifications or efficiencies), even though no specific legal provision foresees it.²¹

As far as pricing practices are concerned, excessive or discriminatory pricing by pharmaceutical companies is not tackled by any specific competition law provision. The pricing of pharmaceutical products that are reimbursed

¹⁴ Decision 2C_180/2014 of 28 June 2016, not published yet.

¹⁵ DPC 2010/4 p. 649 n. 201-226 *Hors-liste*.

¹⁶ DPC 2000/3 p. 358-361 *Sanphar*.

¹⁷ DPC 2000/3 p. 380-387.

¹⁸ CR Concurrence - AMSTUTZ/CARRON/REINERT, Art. 5 N 262.

¹⁹ Communication on Vertical Agreements – ComVert (adopted on the base of Art. 6 CartA), Art. 15 §4.

²⁰ ComVert, Art. 15 §2.

²¹ See for instance ATF 129 II 497, n. 6.5.4; DPC 1997/4 p. 490, n. 4.2; DPC 2008/3 p. 385 n. 155, 166; DPC 2011/1 p. 116, n. 407-4829; See also CR Concurrence – CLERC, art. 7 I LCart N 99-108.

under the regime of the mandatory health insurance is regulated by the Federal Office for Public Health (FOPH). For these products, maximum prices are set. When reviewing the prices of such medicines, the FOPH proceeds to an assessment of their cost-effectiveness, which is supposed to alleviate any concern of excessive pricing.²² The FOPH has to cooperate with the “Price Supervisor”, who has otherwise the power to investigate and tackle such abusive pricing methods on the basis of the Federal Act on the Supervision of Prices.²³ As part of its review, the FOPH must tackle abusive pricing methods by undertakings which are parties to agreements having a restraint of competition as their object or effect, as well as by undertakings having a dominant position.²⁴ The Price Supervisor can provide its recommendation to the FOPH, which is not bound by it but has to explain the reasons for any divergent approach, as the case may be.²⁵ As a matter of fact, over the past 10 years the Price Supervisor has led numerous investigations on the price of pharmaceutical products and issued several recommendations to the government and the FOPH as to how the “cost-effectiveness” criteria should be more strictly applied.²⁶ In this context, there is not much room for an additional assessment by the Competition Commission under a theory of excessive or discriminatory pricing by an undertaking in dominant position, although such assessment remains possible in theory.²⁷

In short, the quite sophisticated regulatory environment in the field of pharmaceutical products clearly has an influence on the application of competition law, especially when it comes to patented or price regulated products (see also below 4 and 5). But when competition law applies, the same general rules and principles as for conducts in other areas of the economy apply. One specificity may be the product market definition though, which is based on generally applicable principles but relies then more on the ATC classification than on a “standard” SSNIP test analysis.

3. Enforcement Mechanisms, Remedies and Consumer Protection

So far, there have not been enough cases in Switzerland involving anti-competitive behaviors on the markets for pharmaceutical products to distinguish any kind of general enforcement pattern or trend. As a matter of fact, the cases that led to the main decisions of the Competition Commission were restrictive agreements.²⁸ One case involved the abuse of the dominant position of a company gathering and publishing legally required information on authorized drugs for healthcare professionals on one side and for patients on the other side.²⁹ Further, the Commission is currently investigating another case involving a possible abuse in the area of the storage of, and access to, electronic data about pharmaceutical products, partly involving the same undertakings. One case of

²² See below under 5.

²³ FSPR, RS 942.20. Art. 8-10 give the power to the Federal Supervisor, an administrative authority, to investigate, reach an amicable settlement, and ultimately forbid all or part of a price increase and require a price reduction. According to the law, a price is abusive “when the price level on the relevant market is not the result of efficient competition” (taking into consideration price evolution on similar markets, the necessity to make an equitable profit, costs evolution, any particular service or performance by the concerned undertakings and any particularity of the relevant market; see Art. 12-13 FSPR).

²⁴ Art. 15 § 2 FSPR states that, whichever specific authority is competent to review the abusive aspect of a price, it has to act according to the FSPR as long as this is compatible with its own particular supervisory regime.

²⁵ Art. 15 §2bis and ter FSPR.

²⁶ See below under 5.

²⁷ One investigation concerned allegedly excessive pricing of the thalidomide drug, but no abuse could be found (DPC 2006/3 p. 433). See also the developments below in relation with Art. 3 § 1 CartA under 5.

²⁸ See DPC 2000/2 p. 186 *Vitamin Cartel* ; DPC 2000/3 p. 320 *Sanphar*; DPC 2004/4 p. 1040; *Distribution of veterinary drugs*; DPC 2010/4 p. 649; *Hors-liste drugs*.

²⁹ DPC 2008/3 p. 385ss *Documed*. The case involved price discriminations to the detriment of manufacturers who de facto had to contract with the dominant position in order to satisfy their obligations to publish legally required information about their products.

excessive pricing was also investigated.³⁰ As far as merger review is concerned, several concentrations were reviewed, but most of them got clearance at the end of a phase 1 review.³¹

What is clear though, is that enforcement of competition law in the pharmaceutical products sector has been exclusively public so far, with no reported cases of private actions in the past 15 years (at least to our knowledge). This is however not a specific feature of this sector, as private enforcement activity has generally been very low in Switzerland so far.

Apart from the Competition Commission, no other agency has competition law competences in Switzerland with respect to pharmaceutical products. Indeed, the regulating agency Swissmedic has no particular competition law competence and the same is true for the FOPH.

Further, no consumer protection authority plays any significant role in Switzerland. As a matter of fact, consumer protection provisions are not unified in one piece of legislation, but are spread in numerous acts and ordinances. They are generally enforced by civil courts. The Federal Consumer Office and the Federal Commission for Consumption merely act at the legislative level and provide financial support for private consumer protection organizations. In the field of pharmaceutical products, certain consumer protection aspects are taken into consideration at the stage of the authorization to put a new drug on the market (first and foremost safety and effectiveness, see below 4). Although one might imagine that consumer protection interests could conflict with competition law principles during the approval procedure of a new drug – especially generics – there is no information available on such interactions.

As already stated, there are no competition law guidelines or the like with a specific emphasis on pharmaceutical products. That being said, the Communication of 28 June 2010 on Vertical Restraints applies to competition law issues within the distribution chain for pharmaceutical products. Similarly to EU Commission Regulation 330/2010 and the Commission Guidelines on Vertical Restraints of 19 May 2010, this non-binding Communication defines a set of principles applicable to the review of vertical agreements, including a list of “black” clauses and safe harbors. Further, even if the EU block exemption Regulation on technology transfer agreements (TTBER) and its Guidelines do of course not apply in Switzerland, they would likely be taken into consideration by the Competition Commission when reviewing a case involving intellectual property rights.³²

Possible remedies under Swiss law include injunctions (prohibition of a certain agreement or conduct, obligation to adopt a certain behavior, such as supplying a third party, and/or an amicable settlement). In the event of hardcore agreements (price fixing, quantity setting, market/product allocations, resale price maintenance, walling-off of the market) or the abuse of a dominant position, the concerned undertakings can be, and generally are, sanctioned with a fine. Disgorgement orders are not possible under the Cartel Act. In merger cases, divestments are typically

³⁰ DPC 2006/3 p. 433 *Price for pharmaceutical thalidomide* (excessive pricing denied).

³¹ Notably DPC 2003/2 p. 316 *Pfizer/Pharmacia*, with commitments; DPC 2009/4 p. 349 *Pfizer/Wyeth*, with commitments; DPC 2011/4 p. 653 *Galenica / Fresenius* (joint-venture); DPC 1998/1 p. 62 *Roche/Corange*.

³² Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements (TTBER; OJ L93, 28.03.2014, p.17-23), and Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (OJ C89, 28.03.2014, p.3-50).

required if necessary to avoid the creation or strengthening of a dominant position.³³ Compulsory licensing could also be required.

With respect to patent settlements, it shall be underline that there is no mechanism for their monitoring in Switzerland. This might be one of the explanations why there has not been any reversed payment case reviewed by the Competition Commission so far. Compulsory licensing is possible as a matter of law,³⁴ however there has not been any such case so far.

Except for the studies realized by the Price Supervisor (see below under Section 5), there has been no general, sector wide, official competition law review in Switzerland so far. However, the Secretariat of the Competition Commission has been closely monitoring the distribution of pharmaceutical products on a more or less permanent basis.

As already mentioned above, several issues in the distribution of pharmaceutical products gave rise to the two main competition law cases investigated and sanctioned by the Competition Commission over the past 15 years. In the *Sanphar* case, the Competition Commission ruled that agreements between the manufacturers of pharmaceutical products, setting rebates and profit margins applicable to manufacturers, wholesalers and distributors were unlawful, at all three levels.³⁵ The *Hors-liste* case was a sort of resurgence of the *Sanphar* case, as the vertical agreements at stake – concerted practices between each of the three manufacturers and the distributors (pharmacies, doctors) – consisted in the recommendations of end prices for the concerned drugs (Viagra, Cialis and Levitra).³⁶ The distribution of pharmaceutical products in Switzerland is strongly influenced by two features: (i) the fact that parallel imports are (almost) impossible (see below under Section 4), and (ii) an increasing vertical integration.³⁷ In this context, the Competition Commission also led a pre-investigation on a possible abuse of dominance of a pre-wholesaler who had started to demand substantial collaterals to continue to supply a particular wholesaler.³⁸ In its final report, the authority confirmed it had strong evidence to support the existence of a dominant position, notably because of the very limited alternative constituted by foreign pre-wholesalers due to the current regulatory environment.³⁹

We shall add that in our opinion, good and extended cooperation between the various regulatory bodies and the competition authority is key for a coherent and efficient enforcement of the various applicable legal provisions, including competition law provisions. In Switzerland, there is no specific provision governing the relationship between the Competition Commission and Swissmedic or the FOPH. As a matter of facts, it seems very much that – like in other jurisdictions – each agency is working in its own corner, with limited understanding of what the other is doing and without taking into consideration their mutual goals. On other occasions, it seems that agencies are passing the buck, considering that a particular issue is a competition law issue when it is more a regulatory/approval issue, and vice versa. Thus, regular exchanges between the agencies would certainly increase

³³ See for example DPC 2003/2 p. 356 n. 127 *Pfizer/Pharmacia*.

³⁴ See Art. 40 Federal Act on Patents for Inventions (PatA; RS 232.14).

³⁵ DPC 2000/3 p. 320

³⁶ We shall mention here that an appeal against the ruling of the Competition Commission is still pending. One of the challenged questions that will need to be reviewed is the existence of a concerted practice in itself, between each of the three manufacturers and several hundreds of pharmacies and doctors across Switzerland.

³⁷ See Annual report 2014 of the Competition Commission, DPC 2015/1 p. 1, n. 3.2.3.

³⁸ DPC 2015/3, p. 363 *Alloga*.

³⁹ *Ibidem*, n. 73-75. The report also states that the collaterals required (bank guarantees) were likely to be a case of imposition of unfair conditions of trade (art. 7 § 2 c CartA), but the agency closed the investigations after *Alloga* adapted its requirements.

their understanding of each other's activity and provide for a better and more efficient enforcement of the various legal provisions at stake.

4. Innovation – Interaction with Patent law

According to the Federal Law on Medicinal Products and Medical Devices, authorizations from Swissmedic, the regulatory agency, are necessary to manufacture pharmaceutical products, put them on the market and import them in Switzerland.⁴⁰ An authorization to market a particular drug is granted if the product is of high quality, safe and effective.⁴¹ The applicant has to provide all the necessary clinical data to show that these criteria are met.⁴² With respect to generics, the application for a marketing authorization for a medicinal product which is essentially the same as an already authorized medicinal product (original preparation) and is intended for the same use, may be based on the results of the pharmacological, toxicological and clinical tests of the already authorized medicinal product, provided however that the ten years protection period for the clinical data of the original preparation has expired.⁴³ As in the EU, and unlike in the U.S., the first generic to be marketed does not enjoy an exclusivity period before other generics can be authorized. And the application for a marketing authorization does not yet constitute a possible infringement of the patent (unlike the « Paragraph IV certification » in the U.S.). In the event the original preparation is still patent protected, Swiss patent law however specifies that the effects of the patent do not extend to actions required to obtain a marketing authorization (so called “Bolar exception”).⁴⁴

As far as the relationship between patent law and competition law is concerned, the Cartel Act foresees that it does not apply to effects on competition that result exclusively from the legislation governing intellectual property.⁴⁵ According to case law and most scholars, this provision does not have a proper normative scope and shall simply ensure that the competition law analysis takes into account the objectives of intellectual property laws.⁴⁶ Hence, it is only when it comes to the application of the material provisions of the law that the question whether a particular competition restraint results exclusively from an intellectual property right or not shall be reviewed.⁴⁷ There are no guidelines about the application of competition law when intellectual property rights are concerned, unlike in the E.U. or in the U.S. The core principles are however the same: Identity of the objectives of the two legislations, no difference between material and immaterial property, and an intellectual property right does not automatically grant market power.⁴⁸

In this context, the main factors that are likely to be taken into consideration by the Swiss Competition Commission or a court are the ones considered in the EU regulation (TTBER) and case law. Hence the authority is likely to start from a “scope of the patent” approach (Art. 3 §2 CartA), but without considering that the mere existence of the patent automatically shields any action of the patent holder from the application of competition law. In a reverse payment case for example, the effects of the agreement would have to be analyzed based on Art. 5 CartA. The question would arise whether the restraint of competition that is the object or the result of the conduct is the

⁴⁰ Therapeutic Products Act (TPA ; RS 812.21), Art. 5, 9, 18.

⁴¹ Art. 10 § 1 a TPA.

⁴² For more details on the procedure, see T. GÄCHTER / B. RÜTSCHÉ, *Gesundheitsrecht*, Basel 2013, p. 216-217.

⁴³ Art. 12 TPA; Art. 17 of the Ordinance on Medicines (OMed ; RS 812.212.21).

⁴⁴ Art. 9 § 1 Patent Act.

⁴⁵ Art. 3 § 2 Cartel Act.

⁴⁶ See DPC 2011/1, p. 96, n. 107 ss. CR Concurrence - ALBERINI, art. 3 § 2 LCart N 4.

⁴⁷ CR Concurrence-ALBERINI, art. 3 § 2 LCart N 59 ss.

⁴⁸ CR Concurrence-ALBERINI, art. 3 § 2 LCart N 19 ss.

consequence of the agreement or whether it is the consequence of the exclusivity right attached to the patent of the originator. In such case, one may expect the Competition Commission to base its analysis on EU case law, hence checking the true nature, value and justification for the payment in favor of the generic manufacturer.

The regulatory barriers to entry typically faced by a generic drug maker are more or less the same in Switzerland than in most jurisdictions: Ten years clinical data protection, extensions for new therapeutic use and existence of blocking patents, among other, can render the marketing authorization process very cumbersome. To our knowledge, there has been no case of “sham litigation” introduced by original manufacturers to slow up the authorization process of a generic. An additional barrier to entry specific to the Swiss market may be language requirements for packaging and instructions to professionals and patients (three languages). Once the marketing authorization has been obtained, the registration of the generic on the Specialty List so that it can be reimbursed by mandatory health insurance is also necessary and can take several additional months.

In conclusion, while one may think that Switzerland would handle cases at the crossroad of IP rights and competition law similarly to the EU Commission and Courts, it remains to be seen how the Competition Commission would react in a concrete case.

5. Public Finance Considerations

As already mentioned, enforcement of competition law in Switzerland has almost exclusively been public so far and there is no divergent trend in the health care sector, irrespective whether third party payers such as insurers or public funding bodies are involved.

Further, Swiss competition law does not generally exempt certain bodies in the healthcare industry. The Cartel Act applies to “undertakings”, that is “all consumers or suppliers of goods or services active in commerce regardless of their legal or organizational form” (Art. 2 § 1bis CartA). This includes the State (and State entities) as long as it is active on the supply or demand side on a market.⁴⁹ In theory, there is no differentiated treatment of healthcare purchasers and providers for the purpose of applying competition law.

However, as already stated above, the Cartel Act stipulates that « Statutory provisions that do not allow for competition in a market for certain goods or services take precedence over the provisions of this Act. Such statutory provisions include in particular : a) provisions that establish an official market or price system, and b) provisions that grant special rights to specific undertakings to enable them to fulfill public duties” (Art. 3 §1 CartA). According to case law, a provision establishes an official market or price system when several essential economic parameters are restrained in such a way that there remains only an insignificant place for free competition.⁵⁰

Being heavily regulated, the healthcare sector traditionally provides for a significant number of statutory provisions that might have an impact on competition. An example from recent case law is the advertizing ban for pharmaceutical products available on prescription only. In the *Hors-liste* case, the Federal Administrative Court struck down an infringement decision of the Competition Commission, arguing that the advertizing ban for such drugs, coupled with a “shame factor” allegedly preventing patients from asking about the prices in pharmacies,

⁴⁹ See for example R. JACOBS, *Gesundheitswesen und Kartellrecht*, in: *Gesundheitsrecht im wettbewerblichen Umfeld*, Zurich 2010, p. 3.

⁵⁰ ATF 129 II 497, c. 3.3.3. CR Concurrency-MARTENET/CARRON, art. 3 § 2 LCart N 35-37.

did not leave any room for the application of competition law.⁵¹ In a key decision regarding the application of Art. 3 §1 CartA, the Swiss Supreme Court reversed that finding.⁵² In a nutshell, the Court ruled that Art. 3 §1 applies only when a competition law provision and another legal provision collide because they regulate the same facts from the same point of view. In other words, there is no such collision – and no room for the application of Art. 3 §1 – if one of the provision is pursuing a competition law objective while the other one is pursuing a healthcare policy or public safety objective.⁵³ In the case at stake, the Court ruled that the advertizing ban had only a healthcare policy goal (allowing doctors to prescribe drugs only based on their medical know-how without being influenced by the advertizing messages conveyed by their patients) and thus that it did not prevent the application of the Cartel Act (even though it admitted that competition might be a bit limited under such circumstances as advertizing is normally an important way for producers to inform about their products and for customers to obtain that information).⁵⁴

As the Federal Office for Public Health (FOPH) fixes maximum prices for all pharmaceutical products that are reimbursed within the framework of the mandatory health insurance coverage,⁵⁵ the question also arises whether such products fall under the scope of the Cartel Act or not. Based on the general principles set in the above mentioned ruling of the Swiss Supreme Court, the answer is most probably yes. By fixing a maximum price, the State is clearly pursuing a healthcare policy goal (public finance interest as well as guarantee of reasonable healthcare insurance premiums). The objective of this price control is certainly not to restrain price competition on pharmaceutical products, quite the contrary. In fact, price regulation is supposed to come mainly from efficient competition, especially between originators and generic drug manufacturers.

It is also worth to be noted that in 2003 the Competition Commission issued an advisory opinion stating that legal provisions banning the grant of material benefits to persons who prescribe or dispense medicinal products, or to the organizations which employ them (Art. 33 TPA), do not bar the application of the Cartel Act on the basis of Art. 3 § 1 CartA and could not be used to justify agreements between manufacturers to eliminate or limit commercial rebates and discounts.⁵⁶

Coming back to the price-fixing activity of the FOPH,⁵⁷ the three criteria determining the inclusion of a particular drug in the List of Specialties are its effectiveness, appropriateness and cost-effectiveness.⁵⁸ While the FOPH relies on the findings of Swissmedic for the two first criteria, it determines whether the cost-effectiveness criteria is fulfilled by carrying out price comparisons with (i) other similar medicines and (ii) prices for the same medicine in foreign countries.⁵⁹ For original drugs, a surcharge for research and developments costs is admitted for fifteen

⁵¹ DPC 2010/4 p. 649 (Commission decision); DPC 2013/4, p. 704 (Federal Administrative Court decision).

⁵² See Ruling 2_C80/2014 of 28 January 2015, DPC 2005/1, p. 131.

⁵³ Ibidem, n. 2.4.

⁵⁴ Ibidem, n. 3.

⁵⁵ These products are mentioned on the List of pharmaceutical specialties reimbursed by the mandatory health insurance, according to Art. 52 §1 b and § 3 of the Federal Act on Health Insurance (FAHI; RS 832.10). See also Ordinance on Health Insurance (OHI; RS 832.102), Art. 64-77.

⁵⁶ DPC 2003/3 p. 623-638

⁵⁷ List of Pharmaceutical Specialties reimbursed by the mandatory health insurance, according to Art. 52 §1 b FAHI, with the indication of the maximum price allowed for sale to pharmacists, doctors, hospitals and home care facilities (Art. 67 OHI). The maximum price includes the ex-factory price plus the costs related to the distribution of the medicine (distribution premiums, see Art. 67 § 1bis-quarter OHI) plus VAT.

⁵⁸ Art. 32 FAHI, Art. 65 § 3 OHI.

⁵⁹ Art. 34-35 FAHI; Art. 65b §§ 1-4 OHI; Art. 34a bis – 37e of the Ordinance on the Benefits of the Health Insurance (OBHI; RS 832.112.31). T. GÄCHTER / B. RÜTSCHÉ, op.cit., n. 937 ss. The average price in the other countries weights 2/3 and the price of other similar medicine weights 1/3, see OHI Art. 65b § 5. The countries currently taken into consideration are Germany, Denmark, Great-Britain, the Netherlands, France, Austria, Belgium, Finland and Sweden (Art. 34a bis OBHI). Wholesalers' margin and imposed discounts in the various

years,⁶⁰ while the evaluation of the cost-effectiveness of generics has to take into consideration their lower development costs compared to the original product.⁶¹ According to the law, the price of a generic is presumed to be cost-effective provided it is between 10% - 60% lower than the price of the original product with which it is interchangeable.⁶² The use of generics is supposed to be encouraged through a higher self-payment requirement (20% instead of 10%) when an original drug is purchased while generics with an average price at least 20% lower are also available.⁶³

As previously mentioned, prices of pharmaceutical products are also closely monitored by the Federal Price Supervisor, based on the law on Price supervision. Over the past few years, the Price Supervisor has strongly engaged for more price competition on these markets, reduced prices and an increased use of generics. Indeed, the Price Supervisor has repeatedly asked that prices be reviewed by the FOPH on an annual basis (if not more frequently) instead of every three years and pleaded for an extension of the countries taken into consideration for the price comparison.⁶⁴ Further, he has criticized the margin for distribution costs admitted by the FOPH as too high.⁶⁵ In order to increase the use of generics and reduce their prices, which are often perceived as much higher in Switzerland than in neighboring countries, the Price Supervisor is also advocating for a change in the way the cost-effectiveness of drugs with expired patent protection and their generics is assessed: The idea would be to switch to a so called “reference price” system, that is to put all original products out of patent protection and the generics that have the same active principle in the same group and set a maximum price for the whole group, based on the price of the cheapest products.⁶⁶

In jurisdictions where drug prices are somehow controlled by the State, parallel imports tend to be restricted as well, even for non-patented products. Switzerland is no exception, even if there has been a considerable effort to harmonize the Federal Act on Medicinal Products and Medical Devices with international and EU standards, there remains important practical differences. Besides, the “Cassis de Dijon” principle does not apply to pharmaceutical products, which still require an authorization before they can be imported.⁶⁷ Imports are subject to a mandatory specific authorization (Art. 18-19 TPA),⁶⁸ and a marketing authorization (Art. 20 § 1 TPA). The process to obtain such authorization is somehow simplified in the case of an application from another person responsible for the placing on the market of a medicinal product which is already authorized in Switzerland and which is imported from a country with an equivalent authorization system (Art. 14 § 2 TPA).⁶⁹ However, divergences as to which kind of information must be provided to professionals and patients remain, as well as specific languages requirements. Last but not least, once the marketing authorization is obtained, the importer additionally needs to

countries are also taken into consideration (Art. 65b § 3-4 OHI, 34b OBHI). The prices are to be checked again for their cost-effectiveness every three years, as well as upon expiration of the relevant patent (Art. 65d and e OHI; Art. 34d-h, 36-37 OBHI), as well as in the event of the extension or reduction of the use of an original medicine by Swissmedic (Art. 65f and g OHI; Art. 37a and b OBHI).

⁶⁰ Art. 65b § 6 OHI.

⁶¹ Art. 65c OHI.

⁶² Depending on the market volume in Switzerland of the original product and its co-marketing drug, see Art. 65c § 2 OHI.

⁶³ Art. 104a OHI and 38a OBHI. Provided there is no medical reason for the prescription and use of the original medicine instead of a generic.

⁶⁴ DPC 2014/5, p. 908; DPC 2012/5, p. 936-939 (more frequent adaptation of the exchange rate applied for the comparison with neighboring countries).

⁶⁵ See DPC 2010/5, p. 863-864; DPC 2009/5, p. 519.

⁶⁶ See DPC 2015/5 p. 970-972; DPC 2014/5, p. 905-909; DPC 2013/5, p. 923; DPC 2009/5, p. 519-510.

⁶⁷ Art. 16a § 2 of the Federal Act on Technical Barriers to Commerce (FATBC; RS 946.51); Art. 20 § 1 TPA.

⁶⁸ See also T. GÄCHTER / B. RÜTSCHÉ, op. cit., p. 220.

⁶⁹ For more details on the conditions that must nevertheless be fulfilled, see the Ordinance of the Swiss Therapeutic Products Institutes on the Simplified Authorization of Medicinal Products (RS 812.212.23).

have the product added to the Specialties List that guarantees its reimbursement by the mandatory healthcare insurance – and regulate its pricing.

As per the Patent Act, parallel imports of patented drugs are in principle not possible in Switzerland. Indeed, if Art. 9a of the Federal Act on Patents for Inventions allows the parallel import of patent-protected goods whose proprietor has already placed on the market in Switzerland or within the European Economic Area, or has consented to such placing (so called “regional exhaustion” principle), this provision does not apply when the price of the concerned goods is fixed by the state (in Switzerland or in the country in which they are placed), meaning that the express consent of the proprietor would be necessary.⁷⁰ The main type of goods affected by this exception are naturally the pharmaceutical products.

That being said, import restrictions based on intellectual property rights can nevertheless be assessed under the Cartel Act. Article 3 § 2 *in fine* CartA enacts *de facto* a decision of the Swiss Supreme Court of 1999, according to which the Cartel Act shall remain applicable to competition restraints induced by the principle of national exhaustion of patent rights.⁷¹ There is considerable uncertainty however as to the exact meaning and scope of this provision: Does it nevertheless introduce through a backdoor the regional exhaustion principle also for price regulated products? Does it apply only in the event of an abusive use of intellectual property rights? There is no case law yet on this provision and no unity among scholars.⁷²

In short, regulatory provisions governing the price and import of pharmaceutical products generally do not rule out the application of competition law, leaving it to the Competition Commission (or the courts as the case may be) to draw the boundaries on a case by case basis, at the risk of considerable uncertainty.

6. Conclusion

In Switzerland pharmaceutical products are governed by the same competition law provisions as any other product or service. There are no specific legal provisions, guidelines or the like that provide guidance as to how the material provisions of the law about agreements and abuse of dominance are to be applied in this sector. Of course, Switzerland has long acknowledged the specific characteristics of pharmaceutical products and the resulting needs for consumer protection, promotion of innovation and protection of public budgets, by enacting an abundant legislation. Hence, in this heavily regulated framework, the major difficulty in applying competition law to pharmaceutical products is the potential for conflicts with other regulations. Conflict rules were enacted in Article 3 of the Cartel Act, in theory giving precedence to other pieces of legislation, especially provisions on price control and intellectual property rights. Although we have seen that these provisions tend to be construed narrowly, on a case by case basis there is always considerable uncertainty as to whether the Cartel Act will be applicable or not. Further, since the Cartel Act and other regulatory provisions will often apply simultaneously, the lack of coordination between the different pieces of legislation may be problematic. Given the importance of this sector for the Swiss economy and compared to investigations led in other countries, there have been very few competition

⁷⁰ Patents Act of 25 June 1954 (PatA; RS 232.14), Art. 9a §1 and 5.

⁷¹ ATF 126 III 129, c. 9 *Kodak*.

⁷² CR Concurrence - ALBERINI, Art. 3 § 2 LCart N 93-107; see also T. EICHENBERGER / PH. ZURKINDEN, Der Parallelimport von Arzneimitteln in die Schweiz, in SZW/RSDA 3/2008 p. 313, § 2.3.

law cases involving pharmaceuticals so far, but this may change in the future. It would be interesting to see how conflicts between competition law and provisions governing market authorization would be dealt with in sham litigation or product hopping cases for example, or how a reverse payment agreement would be handled. While health and safety issues, as well as the need to promote innovation, or pricing control, are key legitimate concerns, competition law can certainly contribute to reaching these objectives.