

Pharmaceutical IP and competition law in Switzerland: overview

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PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

A patent is a registered proprietary right to an invention that is a new solution to a technological problem. Products and processes can be patented if the invention is:

- Novel (that is, not already part of the prior art).
- Not obvious to a person skilled in the art.
- Suitable for industrial application (commercially applicable, suitable for execution and reproducible).
- Not legally excluded from protection.

A patent gives its owner protection from another person commercially using the patented invention without permission.

Swiss patent law is codified in the Federal Patent Act and the related ordinance. The Patent Cooperation Treaty 1970 (PCT), the European Patent Convention 1973 (EPC) and related ordinances also apply to international or European patent applications.

Scope of protection

The Federal Patent Act allows patents for new inventions applicable in industry. However, anything that is obvious having regard to the state of the art (Article 7, paragraph 2) is not patentable as an invention. Whereas elements of the human body in their natural environment are not patentable, an element of the human body is patentable as an invention if it is produced by means of a technical process, a beneficial technical effect is indicated and the novelty and inventive step requirements are fulfilled. Also, a naturally occurring sequence or partial sequence of a gene is not patentable as such but sequences that are derived from a naturally occurring sequence or partial sequence of a gene can, however, be patented as an invention, if they are produced by means of a technical process, their function is specifically indicated, and the novelty and inventive step requirements are fulfilled. New processes for the production of existing products can also be protected by patent.

In any event, however, inventions whose exploitation is contrary to human dignity or that disregard the integrity of living organisms or that are in any other way contrary to public policy or morality are not patentable. Article 2 of the Patent Act includes a list of inventions for which no patent can be granted, including:

- Processes for cloning human beings and the clones obtained thereby.

- Processes for forming hybrid organisms by using human germ cells, human totipotent cells or human embryonic stem cells and the entities obtained thereby.
- Processes of parthenogenesis by using human germinal material and the parthenogenetic entities obtained thereby.
- Processes for modifying the germ line genetic identity of human beings and the germ line cells obtained thereby.
- Unmodified human embryonic stem cells and stem cell lines.
- The use of human embryos for non-medical purposes.
- Processes for modifying the genetic identity of animals which are likely to cause them suffering without being justified by overriding interests worthy of protection, and also animals resulting from such processes.

Also excluded from patentability are:

- Methods for treatment by surgery or therapy and diagnostic methods practised on the human or animal body.
- Plant varieties and animal varieties or essentially biological processes for the production of plants or animals; however, subject to the reservation of paragraph 1, microbiological or other technical processes and the products obtained thereby as well as inventions that concern plants or animals are patentable, provided that their application is not technically confined to a single plant or animal variety. A detailed list of exemptions is set out in Article 1a, 1b and 2 of the Federal Patent Act.

Under certain circumstances patent protection is limited by law. In particular, it is possible for third parties to claim a non-exclusive licence to produce and export pharmaceuticals to a country with insufficient pharmaceutical capacity and in need of the product for combating public health problems.

2. How is a patent obtained?

Application and guidance

A national application must be filed with the Swiss Federal Institute of Intellectual Property (SFIIP) (www.ige.ch/en.html). The application fee is CHF200 and the fee for the examination of the application by the SFIIP is CHF500. The fees for an optional search by the SFIIP are CHF500 and CHF200 for an expedited examination. An annual extension fee must be paid after the end of the third year following the date of registration. The fees are CHF100 to CHF960 annually, depending on the year (CHF100 for year four, increasing up to CHF900 for year 20).

Applicants can also file a:

- European patent application with the European Patent Office (EPO) (www.epo.org).

- Patent Cooperation Treaty application with the SFIIP if domiciled in Switzerland or a Swiss national, or with WIPO (www.wipo.int) or in some cases with the EPO.

All three websites provide application guidance.

The national application must be submitted on the official form. A patent application includes:

- Information on the patent holder (name, address, country of domicile).
- Mailing address in Switzerland or Liechtenstein if the patent holder is a foreign entity.
- Priority claim, if applicable, including the country and date of the prior application as well as the application number.
- A description of the invention.
- At least one formal patent claim.
- An abstract.
- If necessary, technical drawings. The technical documentation must be in German, French or Italian.

Process and timing

Once the application is submitted, the SFIIP checks whether the national application meets the formal requirements and whether the application fee has been paid. If this is the case, the applicant receives confirmation of receipt.

An invention will have a priority right in accordance with Article 4 of the Paris Convention where:

- The invention is the subject of a regular filing.
- The filing takes place in or with effect in a country that is a party to the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).

This right can be claimed for a patent application filed in Switzerland for the same invention within 12 months from the date of the first filing. The first filing in a country that grants reciprocity to Switzerland has the same effect as the first filing in a country that is party to the Paris Convention.

The effect of the priority right is that the application cannot be prejudiced by any circumstances that have arisen since the date of the first filing.

The patent application is published (at www.swissreg.ch) 18 months after filing. Following publication of the patent application, any person can inspect the dossier. The Federal Council can restrict the right of inspection only if required by manufacturing or trade secrets or other overriding interests. Third parties, however, do not have any right to participate in the application proceedings for a Swiss national patent. Therefore, unlike before the EPO, a third party cannot prevent a patent from being granted by filing third-party observations.

About three to five years after application, the SFIIP examines whether the invention is capable of industrial application. The novelty and inventive steps requirements are not checked. Accelerated examination can be requested. If the statutory requirements are met, the patent is issued, registered and published (at www.swissreg.ch).

Decisions of the SFIIP can be appealed before the Federal Administrative Court.

Patent approval is not conditional on any technology transfer from the owner to a third party.

The existence of a patent dispute does not prevent review of an application for a pharmaceutical's marketing authorisation.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Patent protection is valid for 20 years from the date when the application is submitted. The first term of protection is three years. Annual maintenance fees are due after then. Patent protection expires after 20 years and in principle cannot be renewed (see *below, Extending protection*).

Extending protection

Similarly to the EU, a supplementary protection certificate (SPC) can be issued. The option for extending a patent specifically applies to medicinal products and is intended to take into account the period between patent registration and grant of marketing authorisation, during which clinical trials must be carried out.

An application for an SPC must be submitted to the SFIIP no later than six months after the grant of marketing authorisation or within six months from obtaining the patent if it is obtained after marketing authorisation is obtained. The certificate is valid from the date of expiry of the normal patent protection, for a period equal to the time between the date of the patent application and the date marketing authorisation was granted, less five years. The certificate is valid for up to five years and the maximum period of protection from the date on which the marketing authorisation is issued is 15 years. The SFIIP fee for issuing the SPC is CHF2,500. The annual fee is between CHF1,060 and CHF1,560.

Together with the revision of the Law on Therapeutic Products (LTP) in 2016, the Federal Patent Act and related ordinances were revised and the revision came into effect on 1 January 2019. As at 1 January 2019 an extension of patent protection for six months is available on application if the approved product information reflects all studies performed according to the paediatric investigation plan. The extension can be in the form of an extension of the SPC (*Article 140n, Patent Act*) or, if there is no SPC, in the form of a paediatric supplementary protection certificate (*Article 140t, Patent Act*).

4. How can a patent be revoked?

Third parties have nine months from publication of the patent registration to oppose the patent registration with the SFIIP, on the grounds that its subject matter is excluded from the scope of protection. Further grounds of opposition are available in relation to European patents, such as:

- Lack of novelty, inventive step or industrial application.
- The patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- The subject-matter of the patent extends beyond the content of the application as filed.

Third parties can also submit a nullity claim to the Federal Patent Court, after registration, on the grounds that:

- The subject matter of the patent is not patentable. Lack of an inventive step or of novelty are often claimed in the pharmaceutical sector.
- The invention is not disclosed in the patent specification in such a way that a person skilled in the art could perform it.
- The subject-matter of the patent extends beyond the content of the application as filed.

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- The registered owner is not the inventor or his legal successor and has not acquired the right to the patent under another title.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The patent holder can take legal action under civil law or criminal law against any person who:

- Unlawfully uses the patented invention (imitation is deemed to be use).
- Refuses to indicate to the competent authorities the origin and volume of unlawfully manufactured products or of products that have been unlawfully put in circulation in his possession.
- Removes the patent marking from products or their packages without authorisation from the patentee or the licensee.
- Aids, abets, participates in or facilitates performance of any of the above acts.

Article 9 of the Federal Patent Act sets out exemptions from the effect of a patent. It includes among other things a research exemption, which states that the effects of the patent do not extend to acts undertaken for research or experimental purposes in order to obtain knowledge about the subject-matter of the invention including its uses, in particular any scientific research concerning the subject-matter of the invention is permitted.

Other exemptions covered by Article 9 of the Federal Patent Act are the private use exception and the educational use exception, stating that the effects of the patent do not extend to acts undertaken within the private sphere for non-commercial purposes or to the use of the invention for teaching purposes at educational institutions.

Applying for marketing authorisation for a medicinal product does not infringe a patent as such an application is not considered a commercial use of the patent. This is specifically mentioned in Article 9 para 1 let. c of the Federal Patent Act which states that the effects of the patent do not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control.

The revision of the Federal Patent Act that came into effect on 1 January 2019 provides for two additional exemptions from the effect of a patent:

- Actions in the context of a medical activity, which relates to an individual person or animal and concerns medicinal products, in particular, the prescription, supply or use of medicinal products by persons legally entitled to do so.
- The direct individual preparation of medicinal products by pharmacies in execution of a medical prescription as well as actions concerning the medicinal products prepared in this way.

Claim and remedies

On 1 January 2012, the Federal Patent Court became active. This court replaced the 26 cantonal jurisdictions in patent matters. Its decisions can be appealed to the Federal Supreme Court.

Remedies for a patent infringement include:

- Injunctions (preliminary or final).
- Declaratory judgment.
- Assignment of the patent.
- Order to disclose the origin and quantity of the objects in the defendant's possession and to disclose the addressees and the extent of any transfer to commercial recipients.

- Rendering of accounts.
- Damages, redress or surrender of profits.
- Publication of the judgment.
- Destruction of infringing goods and their removal from the market.
- Criminal sanctions.
- Assistance from the customs authorities.

Decisions of the Federal Patent Court can be appealed to the Federal Supreme Court.

Dispute resolution and settlement

Infringement allegations not based on a contractual dispute are rarely resolved in alternative dispute resolution such as arbitration or mediation but instead by negotiations and settlements between the parties or in the civil courts.

There are no specific rules governing settlement agreements and the general rules for contracts apply. Contractual disputes in contrast are often settled in arbitration or mediation proceedings.

Relevant international patent instruments and processes

Based on the Treaty between the Swiss Confederation and the Principality of Liechtenstein on Patent Protection (Patent Treaty) of 22 December 1978, Switzerland and the Principality of Liechtenstein form a unified territory of protection for the purposes of patent law. Switzerland is also a party to the European Patent Convention 2000.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

Undisclosed data that has been submitted to the authorities for obtaining marketing authorisation, the origination of which involves a considerable effort, is protected against unfair commercial use (Article 39(3), WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS)). In line with this principle, the Law on Therapeutic Products (LTP) provides ten years of data exclusivity for original preparations.

Data exclusivity is granted for three years for data filed in support of an authorisation for a medicinal product (original or not) for a new:

- Indication.
- Way of administering.
- Galenic form.
- Dosage.

For new indications, Swissmedic can grant ten years of data protection on request when a significant clinical benefit can be expected over existing therapies and the indication is supported by extensive clinical trials.

For a medicinal product specifically and exclusively for paediatric use in accordance with the paediatric investigation plan, Swissmedic can grant data protection of ten years on request.

For an important medicinal product for rare diseases Swissmedic can grant data protection of 15 years on request.

Before expiry of the data protection period, Swissmedic cannot grant a marketing authorisation referring to the protected data.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property

transfers for inventions funded, or partially funded, by public investment restricted?

There are no patent-specific restrictions placed on licensing or transferring patents to foreign parties or for inventions funded by public investment. General trading restrictions (sanctions and embargos) as well as contractual restrictions, however, may apply.

TRADE MARKS

8. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Legislation and scope of protection

The legislation that applies to trade marks includes the Federal Law on the Protection of Trademarks and Indications of Source of 28 August 1992, and the related Ordinance of 23 December 1992.

A trade mark must be a graphically reproducible sign which is distinctive, that is, capable of distinguishing a person's or enterprise's goods or services from those of another, provided no absolute grounds for refusal are given.

Trade mark rights are enforceable from their date of application or their seniority date, provided they will be registered. Trade marks used abroad, and which are well-known in Switzerland within the meaning of Article 6bis of the Paris Convention ("notorious marks"), enjoy the same protection as a registered mark.

General conditions and specific rules for naming medicines

Medicinal brands can generally be registered and are examined independently by the SFIIIP (trade mark registration) and by Swissmedic (marketing authorisation).

However, registration can be refused if the mark:

- Lacks distinctiveness (for example, international non-proprietary names).
- Is misleading.
- Is contrary to public order, morality or applicable law.

Registration of a specific shape as a trade mark can also be refused if the shape constitutes the nature of the goods, or the shape of the goods or of their packaging is technically necessary.

9. How is a trade mark registered?

Application and guidance

The SFIIIP registers trade marks (www.ige.ch/en.html). Guidance is available on its website.

The application fee for a national application is CHF550 and covers up to three product/service classes. There is a supplementary fee of CHF100 for each additional class.

International trade mark registrations are also protected in Switzerland if they have a Swiss designation.

Swissmedic does not review proposed trade marks in the trade mark registration proceedings. Proposed product names are reviewed by Swissmedic as part of the marketing authorisation proceeding.

Process and timing

An application for a national trade mark is made on an official form. Provided it is admitted for trade mark protection, the mark is

protected as from the application date. The application is examined generally within either:

- Four to six months after payment of the application fees.
- Six working days after its filing, if both:
 - the electronic application is clearly registrable;
 - the list of goods and services only covers those contained in the SFIIIP's electronic database of accepted goods and services (preponed examination).

A fast-track method with a maximum processing time of one month for the first examination (registration or provisional refusal) and of two months for each further step in the application process is available for all kinds of applications for an additional fee of CHF400. If trade mark registration is refused, it is possible to file an opposition against the refusal. The SFIIIP's decision can be appealed. Once registered, the trade mark is published on www.swissreg.ch. Publication triggers a three-month opposition period. Third parties cannot participate in the application process and therefore cannot challenge the trade mark when it is still in the application stage.

Where a trade mark is first duly filed in another member state of the Paris Convention or with effect in such a member state, the applicant or successor in title can claim the date of the first filing for the filing of the same trade mark in Switzerland, provided the filing in Switzerland takes place within six months of the date of the first filing. The first filing in a state that grants reciprocity to Switzerland has the same effect as the first filing in a member state of the Paris Convention.

Further, any person who exhibits goods or services bearing a trade mark at an official or officially recognised exhibition under the Convention of 22 November 1928 Relating to International Exhibitions in a Member State of the Paris Convention, can claim the opening date of the exhibition for filing the application provided that the trade mark is filed within six months of this date.

Any person who claims priority under the Paris Convention or an exhibition priority must file a declaration of priority with the SFIIIP. The SFIIIP may require the submission of a priority document.

10. How long does trade mark protection typically last?

The registration is valid for ten years from the date of application.

The registration of a trade mark can be renewed indefinitely for further ten-year periods. The renewal fee for a national trade mark is CHF700 (plus an additional fee of CHF50 if the renewal is filed within the six-month grace period following the expiration of the renewal date).

11. How can a trade mark be revoked?

If the trade mark is not being used for a continual period of five years without important reasons, it becomes vulnerable to cancellation. Third parties can file a cancellation request directly with the SFIIIP or a cancellation action for non-use with the competent civil court.

Third parties can also file a nullity court action if they believe that the mark should not have been registered due to absolute grounds of refusal, or because it has become generic.

A collective trade mark or guarantee mark is cancelled if either:

- The regulations do not satisfy or no longer satisfy the legal requirements, and the owner does not remedy this within the deadline set by the court.

- The owner tolerates repeated use that infringes essential provisions of the regulations and does not remedy this within the deadline set by the court.

Finally, the Swiss designation of an international registration is revoked following a successful central attack on the foreign basic registration.

12. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

A trade mark is infringed if both:

- The earlier (senior) trade mark is identical or confusingly similar to the later (junior) sign (mark, company name or domain name).
- The senior trade mark claims protection for goods and/or services which are identical or of the same kind as the goods and/or service for which the junior sign is registered or used in the course of trade.

Other grounds of infringement include using a guarantee or collective mark in a manner contrary to the applicable regulations.

Claim and remedies

The owner of the senior trade mark can file an opposition with the SFIP against the registration of the junior trade mark, within three months of the date on which the junior trade mark is published. Opposition proceedings are inexpensive and quick. The SFIP's decision can be appealed to the Federal Administrative Court.

Provided that there is no forfeiture of claim, a civil or criminal action can be filed in court against a trade mark infringer.

Remedies for trade mark infringement include:

- Injunctions (preliminary or final).
- Declaratory judgment.
- Assignment of the trade mark.
- Order to disclose the origin and quantity of the objects in the defendant's possession and to disclose the addressees and the extent of any transfer to commercial recipients.
- Rendering of accounts.
- Damages, redress or surrender of profits.
- Publication of the judgment.
- Destruction of infringing goods and their removal from the market.
- Criminal sanctions.
- Assistance from the customs authorities.

Dispute resolution and settlement

See *Question 5, Dispute resolution and settlement*. The same applies for trade marks.

Relevant international trade mark instruments and processes

Switzerland is member of the WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement) and the Protocol Relating to that Agreement 2004 (Madrid Protocol), as well as the Paris Convention.

13. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

Swiss legislation provides for several means to combat counterfeiting and illegal distribution of medicines. The Law on Therapeutic Products (LTP) prohibits counterfeiting medicinal products and the distribution of medicinal products that are not authorised and provides for severe sanctions. Switzerland signed the Medicime Convention of the Council of Europe in 2011. Parliament approved the Convention and corresponding changes to the LTP and the Code on Criminal Procedure on 29 September 2017 and the changes came into force together with the implementing ordinances on 1 January 2019. The legislative amendments equip Switzerland with the tools necessary to step up the fight against counterfeit medicines, and help enhance the safety of medicines in Switzerland. Among other things, the amendments improve medicine control and traceability in the distribution chain. This particularly affect intermediaries, who will assume greater responsibility in the medicines market.

Swissmedic and the cantons monitor compliance with manufacturing and marketing authorisations. They verify by periodic inspections that the conditions for the authorisations are met. Swissmedic and the competent authorities of the cantons can generally take any administrative measure necessary to enforce the LTP.

They can order therapeutic products under a fictitious name if there is a suspicion of unlawful manufacture, import, export or placing on the market of therapeutic products, and previous clarifications have been unsuccessful or further clarifications would otherwise be pointless or disproportionately difficult (*Article 66 para 3, LTP*).

The customs authorities are entitled to hold back shipments of pharmaceutical products at the Swiss border or in a customs warehouse if they suspect an infringement of the LTP (*Article 66 para 4, LTP*).

In criminal administrative proceedings, Swissmedic and the Federal Customs Administration are allowed to order observation and even secret surveillance measures including concluding fictitious transactions (*Article 90a, LTP*).

According to Articles 59 para. 3bis of the LTP and 62a of the Ordinance on Pharmaceuticals, anyone who manufactures or places on the market medicinal products must report to Swissmedic any suspicion of illegal drug trafficking by third parties in connection with his/her activities, with one of his/her products or with its components immediately, but no later than five days after the discovery.

IP AND COMPETITION LAW ISSUES

14. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The relevant legislation in the field of competition law is the:

- Federal Act of 6 October 1995 on Cartels and other Restraints of Competition (Cartel Act, CartA).
- Ordinance of 17 June 1996 on the Control of Concentrations of Undertakings (Merger Control Ordinance, MCO).
- Ordinance of 12 March 2004 on Sanctions imposed for Unlawful Restraints of Competition (Cartel Act Sanctions Ordinance, CASO).

The competent administrative authority for the enforcement of Swiss competition law is the Swiss Competition Commission (ComCo). ComCo acts on its own accord or upon complaint by anyone.

In case of unlawful agreements among competitors on prices, territories or quantities, unlawful vertical agreements on absolute territorial protection or resale price fixing or abuse of a dominant position, ComCo can impose fines going up to 10% of the turnover of the last three business years of the undertaking concerned.

Private parties can also sue other parties in civil courts. Any person hindered by an unlawful restraint of competition from entering or competing in a market is entitled to request the elimination of or desistance from the hindrance, damages and satisfaction and/or surrender of unlawfully earned profits, in accordance with the provisions on agency without authority.

Although due to the price regulation of reimbursed medicinal products the pharmaceutical sector is to a wide extent excluded from the scope of application of the Cartel Act, there have been a number of investigations. In 2000 ComCo had decided that the market regulations established by the Sanphar association infringed Cartel law. The market regulations provided among others for rebate band widths for manufacturers and wholesalers and margins for pharmacies and self-dispensing doctors. Soon after this decision, the Sanphar association was dissolved.

Also in 2000, ComCo had decided that the price fixing cartel regarding vitamins was illegal.

In 2009, ComCo held that price recommendations for retail prices of the drugs Viagra, Cialis and Levitra amounted to unlawful resale price maintenance. The prices of these drugs are not subject to governmental price control. The reasons for the decision were among others that the recommendations were followed by more than 80% of pharmacies and that the retail prices were entered into a very widely used IT system. The three companies in question were fined with a total of over CHF5 million. A first decision of the Federal Administrative Court, which annulled ComCo's decision based on the reasoning that the Cartel Act was not applicable, was revoked by the Federal Supreme Court in 2015. In 2017, the Federal Administrative Court issued a new decision on the case, which again annulled ComCo's decision. This time, the Federal Administrative Court reasoned that ComCo had failed to prove a vertical constraint and that maximum price recommendations do not have an anti-competitive effect, but rather prevented price excesses. The decisions have again been appealed and the cases are once more pending before the Federal Supreme Court.

In 2016, ComCo imposed a sanction of CHF4.5 million on the health software and information vendor HCI Solutions for alleged abuse of a dominant market position regarding the publication of medicinal product information.

Besides these cases, many mergers of pharmaceutical companies have undergone Swiss merger control.

ComCo has been conducting a preliminary investigation regarding the distribution of pharmaceutical products in Switzerland since September 2010. Apart from a final report of 11 May 2015 on a partial aspect of the preliminary investigation (regarding allegations of abuse of market dominance against Alloga, the biggest pre-wholesaler in Switzerland) no findings have become known yet.

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

According to the Cartel Act, agreements fixing prices or quantities and agreements allocating geographical markets or customer groups between effective or potential competitors are defined as "hard core" cartels and are subject to a direct sanction regime.

Vertical agreements stipulating minimum or fixed resale prices or the prohibition of passive sales to other territories than the allocated territory are subject to the direct sanction regime. These types of restraints can be contained in licence agreements. To be lawful, these types of restraints and other types of restraints notably affecting competition must be justified by grounds of economic efficiency. There is little guidance in case law and literature defining the situations in which such restraints can be justified.

Further, the abuse of a dominant market position can also be directly sanctioned. Refusals to grant a license, unfairly high royalties and discrimination among licensees or customers may constitute abusive practices, if such conduct cannot be justified by legitimate business reasons.

16. Are there competition issues associated with the entry of generic pharmaceuticals in your jurisdiction?

There are no particular competition issues associated with the generic entry of pharmaceuticals and there is no corresponding case law. "Pay-for-delay" agreements are likely to be considered under the same criteria as in the EU.

Due to the price regulations for reimbursed products, generic entry as a rule leads to a considerable price reduction for the originator product.

17. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

In a preliminary investigation, ComCo assessed in 2006 whether the price for the pharmaceutical Thalidomid Pharmion was abusively high. In a prima facie analysis ComCo came to the conclusion that there were no indications of abusive pricing. ComCo specifically mentioned that the question would become moot once its price has been reviewed by the Federal Office of Public Health (FOPH) and accepted for reimbursement.

In 2015 ComCo issued a final report on a preliminary investigation regarding Alloga, the biggest pre-wholesaler in Switzerland, in connection with the allegation that the pre-wholesaler had abused its dominant position by threatening Amedis-UE (a wholesaler belonging to a competing group) to stop delivery if they did not agree to provide substantial securities. ComCo found indications for a market dominant position of the pre-wholesaler and for abusive behaviour, but did not open an in-depth investigation because the pre-wholesaler agreed in a settlement to change its practice.

In 2016, ComCo imposed a sanction of CHF4.5 million on the health software and information vendor HCI Solutions for alleged abuse of a dominant market position regarding the publication of medicinal product information. ComCo argued that the vendor had made access to the market more difficult for competitors and forced their trading partners to buy coupled services.

18. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

The Law on Therapeutic Products (LTP) requires that a parallel importer obtains a marketing authorisation for pharmaceuticals imported from other countries. Such marketing authorisation can only be granted if the products originate from a country with an equivalent marketing authorisation system.

Under patent law, generally the principle of regional exhaustion in the European Economic Area (EEA) applies (*Article 9a, Federal Patent Act*). The patent cannot be opposed either if the proprietor of the patent has placed patent-protected goods on the market outside the EEA or consented to their placing on the market outside the EEA and if at the same time the patent protection for the functional characteristics of the goods is only of subordinate importance. Subordinate importance is presumed unless the proprietor of the patent provides prima facie evidence to the contrary.

However, the Swiss patent owner's consent to parallel imports of patent protected products is always required if the price of the product in question is determined by public authorities in Switzerland or the country of origin.

For pharmaceutical products this is often the case. With regard to trade marks, the principle of international exhaustion applies according to the rules developed by the Swiss Federal Supreme Court. Although the *Kodak* decision of the Swiss Federal Supreme Court mentions that the use of a patent might amount to an abuse of a dominant position, there are no cases in which such an abuse was found.

19. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

There is generally no such requirement.

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Professional qualifications. Licence en droit, University of Neuchâtel, Switzerland, 1991; LL.M. in European Legal Studies, University of Exeter, UK, 1993; Dr.iur., University of Zurich, Switzerland, 1996; admitted to the Bar in Switzerland, 1999

Areas of practice. Pharmaceutical and health law; contract law; unfair competition and cartel law; advertising law; product liability law.

Recent transactions

- Advising and representing pharmaceutical companies on a regular basis regarding marketing authorisation and reimbursement, contracts, advertising, sponsoring and gifts, clinical trials and data protection.
- Representing pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.
- Advising and representing pharmaceutical companies in disputes concerning contracts, product liability and unfair competition.
- Advising pharmaceutical companies concerning outsourcing.

Languages. German, English, French

Professional qualifications. Lic.iur., University of Basel, Switzerland, 2001; LL.M. at University of Hastings, College of the Law, San Francisco, 2004, admitted to the Bar in Switzerland, 2006; CAS Brand Management (HSLU) 2007; Social Media Management (Somexcloud), 2011, Data Protection CIPP/E & CIPM certification, iapp, 2018

Areas of practice. Intellectual property law; advertising law; media law; life sciences; data protection law; product safety and liability law; unfair competition.

Recent transactions

- Advising companies on a regular basis regarding intellectual property law, in particular trademark and copyright law including licensing contracts, advertising.
- Advising companies on advertising regulation and data protection, in particular in relation to Swiss Data Protection and its interplay with the European Data Protection Regulation (GDPR).
- Advising and representing companies in legal proceedings concerning product safety and product safety compliance.

Languages. German, English

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Areas of practice. Pharmaceutical and health law; life sciences; product liability law; corporate and commercial law; information technology and data protection law; intellectual property law; unfair competition law; litigation.

Recent transactions

- Advising pharmaceutical companies and manufacturers of medical devices regarding contracts, co-operation with other stakeholders in the health sector, clinical trials and data protection on a regular basis.
- Advising and representing pharmaceutical and other companies in legal proceedings concerning product liability.
- Advising and representing pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.

Languages. German, English, French, Italian