



CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences & Pharma IP Litigation 2023

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Switzerland: Law & Practice Thierry Calame and Peter Ling Lenz & Staehelin

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Law and Practice

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Contents

1. Life Sciences and Pharma/Biopharma				
P	atent Litigation	p.4		
1.1	Claimants/Plaintiffs to an Action	p.4		
1.2	Defendants/Other Parties to an Action	p.4		
1.3	Preliminary Injunction Proceedings	p.5		
1.4	Structure of Main Proceedings on Infringement/Validity	p.8		
1.5	Timing for Main Proceedings on Infringement/ Validity	p.8		
1.6	Requirements to Bring Infringement Action	p.9		
1.7	Pre-action Discovery/Disclosure	p.10		
1.8	Search and Seizure Orders	p.11		
1.9	Declaratory Relief	p.11		
1.10	Doctrine of Equivalents	p.11		
1.11	Clearing the Way	p.11		
1.12	Experts	p.11		
1.13	Use of Experiments	p.12		
1.14	Discovery/Disclosure	p.12		
1.15	Defences and Exceptions to Patent Infringement	p.13		
1.16	Stays and Relevance of Parallel Proceedings	p.14		
1.17	Patent Amendment	p.14		
1.18	Court Arbiter	p.15		
2. G	eneric Market Entry	p.15		
2.1	Infringing Acts	p.15		
2.2	Regulatory Data and Market Exclusivity	p.16		
2.3	Acceptable Pre-launch Preparations	p.16		
2.4	Publicly Available Drug and Patent Information	p.16		
2.5	Reimbursement and Pricing/Linkage Markets	p.17		

3. E	Biosimilar Market Entry	p.17
3.1	Infringing Acts	p.17
3.2	Data and Regulatory Exclusivity	p.17
3.3	Acceptable Pre-launch Preparations	p.17
3.4	Publicly Available Drug and Patent Information	p.18
3.5	Reimbursement and Pricing/Linkage Markets	p.18
4. F	Patent Term Extensions for	
F	Pharmaceutical Products	p.18
4.1	Supplementary Protection Certificates	p.18
4.2	Paediatric Extensions	p.19
5. F	Relief Available for Patent Infringement	p.19
5.1	Preliminary Injunctive Relief	p.19
5.2	Final Injunctive Relief	p.20
5.3	Discretion to Award Injunctive Relief (Final or Preliminary)	p.20
5.4	Damages	p.21
5.5	Legal Costs	p.22
5.6	Relevance of Claimant/Plaintiff Conduct on Relief	p.23
6. Other IP Rights		
6.1	Trade Marks	p.23
6.2	Copyright	p.23
6.3	Trade Secrets	p.23
7. Appeal		
7.1	Timing to Appeal Decision	p.24
7.2	Appeal Court(s) Arbiter	p.25
7.3	Special Provisions	p.25

SWITZERLAND

8. Other Relevant Forums/Procedures		
8.1	Other Relevant Forums/Procedures	p.25
9. Alternative Dispute Resolution		p.25
9.1	ADR Options	p.25
10. Settlement/Antitrust		
10.1 Considerations and Scrutiny		p.25

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1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

The patent owner always has standing to sue for patent infringement.

Exclusive licensees have standing to sue for patent infringement, unless the licence agreement specifically excludes this right. However, the exclusive licensee's standing to sue exists only with regard to licence agreements entered into or renewed after 1 July 2008. The exclusive licensee's standing to sue does not depend on the licence being registered with the Patent Register.

Where an exclusive licensee brings the action for infringement, the patent holder does not need to be joined to the proceedings.

Non-exclusive licensees have no statutory standing to sue for patent infringement. However, they can join a damages claim to claim their own damages. Therefore, for non-exclusive licensees, it is essential that the relevant licence or distributorship agreement contain a clause requiring the patentee to take action for patent infringement.

Distributors are often granted a licence to distribute the patented products, whereas such licence can be implicit. Therefore, the same rights apply as for licensees – unless expressly excluded in the agreement. An exclusive distributor can take action against unlicensed distributors, whereas non-exclusive distributors are prevented from taking legal action.

Where a patent is owned by two or more persons, each of them can bring an action for infringement of the patent (Article 33, paragraph 2, Patent Act) and does not need to join the other co-owners.

As previously outlined, exclusive licensees are entitled to bring infringement claims in their own right. "Exclusive licence" within the understanding of Swiss law means a licence where the right granted is exclusive even vis-à-vis the patent owner.

Under Swiss civil procedure, it is generally not possible to add parties during litigation without the other parties' consent. However, a (co-) claimant can withdraw any particular claim made against any or all of the defendants.

Any person who can demonstrate an interest in the invalidation/nullity of the IP right concerned can file a nullity action. The threshold of the standing to sue for invalidity is, in practice, low – for example, a competitor whose business is disturbed by the registered IP right can sue for invalidity, regardless of whether they are already distributing a potentially infringing product.

1.2 Defendants/Other Parties to an Action

Any person who is allegedly infringing or threatening to infringe an IP right has standing to be sued and can thus be a defendant. In practice, suppliers, manufacturers and local distributors/ wholesalers are typically targeted when it comes to IP infringement litigation in the life sciences space.

Since 2019, "acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product" – such as the prescribing, dispensing or use of medicinal products by legally authorised persons – have been explicitly exempted from the scope of the patent (Article 9(1)(g) PA). The same is true of the

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"direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription or to acts concerning medicinal products prepared accordingly" (Article 9(1)(h) PA). Therefore, medical practitioners – in particular, doctors, nurses or pharmacists – cannot be sued for patent infringement in relation to acts involving medicinal products. Importantly, these provisions do not apply to acts of medical practitioners that do not involve medicinal products, such as the treatment of the human body or the use of medical devices.

Health regulatory authorities do not need to be notified of infringement lawsuits and do not need to be given an option to join such proceedings. In the event that they contribute to the infringement of IP rights, a government entity (the Swiss Confederation or the relevant canton or local government) can have standing to be sued for infringement. However, with regard to damages claims against the state, special regulations are applicable, including different rules on jurisdiction.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available if the following requirements are met:

- there is a prima facie case of infringement and validity;
- the applicant will suffer not easily reparable harm if the injunction is not granted;
- the requested relief is proportionate to the harm caused by the alleged infringement; and
- the requested relief is urgent.

With regard to the final requirement, the case law of the Federal Patent Court requires only "relative urgency". Relative urgency applies whenever the decision on the PI can be handed down earlier than a decision in ordinary proceedings on the merits if the patentee initiates such proceedings immediately upon becoming aware of the infringement. In practice, relative urgency generally applies if the applicant files a request for PI less than 14 months after learning of the infringement.

Ex Parte Injunctions

In cases of special urgency and where there is a strong prima facie case of infringement, ex parte injunctions are available. "Special urgency" means that immediate action is required and the claimant cannot be expected to wait until the conclusion of inter partes PIs or that hearing the other side would defeat the purpose of the injunction. The claimant is expected to act immediately – ie, generally not more than a few days after learning of the infringement. However, in practice, ex parte injunctions are rarely granted in patent matters.

Actions started through an ex parte application require confirmation in inter partes proceedings. In addition, all PI proceedings require confirmation in main proceedings. After issuing a preliminary judgment, the court will set a deadline for the commencement of the main proceedings. If no main proceedings are initiated, the injunction lapses and the applicant is liable for any damages caused to the defendant.

PI proceedings in patent matters are normally conducted within six months – although they may last four to ten months and can take up to one year in highly complex cases.

The defendant can (and often will) dispute the validity of the patent in PI proceedings. It is sufficient to make a credible showing of the invalidity of the patent under a "more likely than not" standard. Unlike in some other jurisdictions, the Federal Patent Court will examine the valid-

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ity and infringement of the patent-in-suit rather thoroughly in PI proceedings.

In the area of patent law, the Federal Patent Court decides as the court of first instance and only one appeal (limited to matters of law) to the Federal Supreme Court is available. The appeal to the Federal Supreme Court is very limited in Pl cases and is inadmissible on most occasions.

The Federal Patent Court will almost always appoint a hearing in PI cases. The main hearing generally takes place within a few months of the filing of the request.

Decisions upon ex parte requests are generally handed down very quickly. If there is a high sense of urgency, the Federal Patent Court can decide on the day of the filing of the request.

Filing of a Preliminary Injunction Request

Preliminary relief is available if the above-mentioned requirements are met (ie, prima facie case of infringement and validity, not easily reparable harm, proportionality, urgency).

The applicant must credibly show that they are the owner (or exclusive licensee, as per Article 75, Patent Act) of a patent formally in force in Switzerland and that the defendant is infringing or threatening to infringe the scope of protection of this patent through acts attributable to them. (Federal Patent Court of 28 February 2019, S2018_006, consid. 16).

There are no translation or validation requirements with regard to European patents in Switzerland.

The patent must have been granted at the latest when the decision is handed down. The Federal Patent Court allows the request for a PI to be filed before grant, although it will assess the probable timeline of the grant.

If it appears that the patent grant will be delayed (eg, because a parallel entitlement lawsuit is pending), the court will suspend the proceedings until the grant (Federal Patent Court of January 4, 2022, S2021_007). If the grant is imminent, the final wording of the patent-to-be-granted is known and there are no reasons to think the grant will be delayed, the Federal Patent Court will conduct the proceedings as though the patent were already granted; however, it will not issue a decision before the actual grant of the patent (Federal Patent Court of 2 June 2022, S2022_002).

The claimant must show that either:

- infringing acts have already occurred and there is a risk of reiteration; or
- the infringement is imminent.

Specific Considerations in Life Sciences Cases

Imminent infringement requires a certain minimum intensity. Filing for regulatory authorisation of a medicinal product is, in itself, generally not sufficient for a finding of imminent infringement.

However, further acts are considered sufficient for a finding of imminent infringement, including:

- the request for reimbursement from the health regulatory authorities;
- enquiries with pharmacists for future placement of orders; or
- the inclusion of the product into third-party product databases aimed at potential clients (notwithstanding the fact that no actual orders are possible).

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Notification of a Preliminary Injunction Request

Court decisions – ie, the decision on the grant or dismissal of the PI (inter partes and ex parte) – and submissions of the opposing party are subject to a qualified service effected by the court via the Swiss Post, municipal authorities or the local police (if in Switzerland) or via diplomatic notification channels (if outside Switzerland). Receipt must be acknowledged.

Within Switzerland, service is generally effected within a day. If acknowledgment of receipt is not possible, the delivery is deemed to have occurred seven days after the unsuccessful delivery attempt. In the case of personal delivery, if the addressee refuses the receipt and this is recorded by the person delivering the item, service is deemed effected on the day of the refusal.

Notifications abroad are subject to the delays inherent in diplomatic notifications and can take anywhere between a few days and several months, depending on the country. In some cases, ex parte decisions have been issued precisely because it seemed impossible to effect notification of the relevant court documents within a reasonable deadline.

The court can notify by publication in the local official journal or in the Swiss Official Gazette of Commerce if:

- the defendant does not have any known address (inside or outside Switzerland) and reasonable attempts to locate one have failed; or
- a notification would be impossible or overly complicated and the defendant has not designated an address for service in Switzerland.

The Federal Patent Court generally sets fixed deadlines (dates) if the party is domiciled in Switzerland or has appointed an address for service in Switzerland.

Submission of the Opposing Party

If the PI request is not obviously inadmissible or unfounded, the opposing party is given the opportunity to submit a written statement in all cases.

Ex parte injunctions must always be confirmed inter partes. The defendant will be invited to a hearing or given a time limit in which to submit a written response. After hearing the parties, the court immediately decides whether the ex parte injunction is:

- to remain in force as a PI;
- · to be amended; or
- to be revoked.

In complex cases, the court may order a second exchange of written submissions (reply and rejoinder).

Admissible means of evidence are limited in PI proceedings. All evidence must, in principle, be provided through documents. Other means of evidence are only admissible if they do not significantly delay the proceedings or if the purpose of the proceedings so requires.

Filing of Protective Letters

A party who fears that it may be subject to an ex parte request can file a protective letter. The court will not notify the protective letter to the potential claimant and keep it on record until an ex parte application is filed.

If an application is filed, the court will consider the arguments set out in the protective letter to

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determine whether to grant an ex parte injunction. If no ex parte application is filed within six months, the protective letter will be returned to the potential defendant.

In the Federal Patent Court, the protective letter may be renewed for subsequent periods of six months.

Factors to Consider in the Grant of a Preliminary Injunction

If the risk of a PI request is known, it is often advisable to file a protective brief with the Federal Patent Court.

Companies in the pharma and medical device industry should be aware that the Federal Patent Court does not examine the public interest when issuing a PI. In other words, if there is a strong case of infringement and validity but the alleged infringer wants to argue that there is a compelling public interest to leave its product on the market, it is advisable to file a request for a compulsory licence under the applicable provisions of the Patent Act.

1.4 Structure of Main Proceedings on Infringement/Validity

The defendant in infringement proceedings can challenge the validity of the patent by way of a defence or a counterclaim. Infringement and invalidity are dealt with in the same proceedings before the same court (ie, there is no bifurcation). Therefore, if the defendant in infringement proceedings seeks to invalidate the patent, the invalidity action can be brought in the same proceedings.

Nullity proceedings related to the Swiss part of a European patent can be brought regardless of whether opposition (or appeal) proceedings are pending in the European Patent Office (EPO). The Federal Patent Court can – but will not necessarily – suspend the proceedings pending the outcome of the EPO proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

In principle, a revocation (nullity) action can be brought at any time after patent grant, even several years after the patent has been granted by anyone who has standing to sue for revocation.

Infringement actions can also be brought at any time after the patentee learns of the infringing acts. Although an infringement action can be filed before the patent grant, the decision of the court will not be issued before the grant (see 1.3 Preliminary Injunction Proceedings).

However, IP-related claims are subject to forfeiture. Forfeiture is not to be assumed lightly, according to settled Supreme Court practice. IP claims are forfeited if the following (cumulative) requirements are met.

- The infringement has been going on for a long time. There is no fixed deadline, as the acceptable time before taking action depends on the specific circumstances and the intensity of the infringement. Generally, forfeiture is not assumed before two years and it is generally accepted that claims are forfeited after the right-holder has waited for more than eight to ten years after learning of the infringement.
- The right-holder has been aware of the infringing act (actual knowledge) or, at least, should have been aware of it the right-holder observed the market diligently (constructive knowledge).
- The infringer has acquired a position on the market that is worthy of protection.

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• There is evidence of good faith on the part of the alleged infringer.

Claims for financial compensation (damages, hypothetical licence fee, disgorgement of profits) are subject to the statute of limitations. The limitation period is three years from the knowledge of the existence of the claim (relative period) and, in any event, ten years after the occurrence of the damaging event at the latest (absolute period).

The procedure for notifying the alleged infringer of an infringement action or notifying the patentee of a nullity action is the same as per service in the case of preliminary injunction requests (see 1.3 Preliminary Injunction Proceedings).

The timeframe of patent infringement proceedings (main proceedings on the merits) depends on the complexity of the technology in question, the number of patents and/or patent claims allegedly infringed, and the defences raised. In principle, the Federal Patent Court aims to conclude patent infringement proceedings within 18 to 24 months, except in cases involving complex technology. In order to reach this goal, the Federal Patent Court generally sets binding deadlines of:

- six weeks for filing the statement of defence and answer to the counterclaim; and
- four weeks for filing the reply, rejoinder, and reply to the counterclaim, as well as the rejoinder to the counterclaim and the comments on new allegations and new evidence in the defendant's rejoinder.

Parties can generally obtain a single two-week extension of these deadlines. Further extensions can generally only be obtained with the other party's consent. However, in complex cases or under extraordinary circumstances, the court can grant longer extensions.

The Federal Patent Court and some cantonal courts will summon the parties to an instruction hearing after the first exchange of briefs, which is a few months after the filing of the statement of claim. The goal of this hearing is to clarify any procedural issues, provide a first informal opinion of the case and attempt a settlement. Between 20% and 50% of main proceedings are settled, usually at the instruction hearing.

If no settlement is reached, the court will order a second exchange of briefs. At the Federal Patent Court, the technical judge of the panel will then issue a written opinion on the question of validity and infringement. Eventually, the proceedings are concluded in a main hearing. If non-documentary evidence is to be taken (party declarations, witness testimony, court-mandated experts), further hearings can be appointed.

Fast-track procedures are available in cases where the facts are undisputed or can be immediately proven and the legal situation is clear. These cases are handled in summary proceedings and a judgment can generally be expected within six months.

1.6 Requirements to Bring Infringement Action

The timeline for filing a main infringement action is the same as that for PI proceedings (see **1.3 Preliminary Injunction Proceedings**) and, similarly, there are no requirements regarding the grant, translation or validation of European patents in Switzerland.

In patent infringement proceedings, the plaintiff must allege and prove all relevant facts – in particular, the infringing acts, the existence and

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amount of the damage and, if the infringing defendant raises corresponding objections, the validity and scope of protection of the patent.

It is usually difficult to prove infringing acts in the case of process patents. The owner of a process patent also enjoys protection for the direct products of the process.

The Federal Patent Act contains a reversal of the burden of proof in favour of the patent owner in one case – namely, if the invention concerns a process for the production of a new product, any product of the same quality is deemed to have been produced according to the patented process until proven otherwise. If this reversal of the burden of proof is not applicable because the product was not new, the law still alleviates the burden of proof of the patentee by stating that it is sufficient to establish a prima facie (more likely than not) case of infringement.

1.7 Pre-action Discovery/Disclosure

US-style pretrial discovery is not available in Switzerland. Generally, parties do not have an obligation to disclose relevant documents and materials to their opponent. However, some limited – yet effective – options are available for obtaining documents and materials before initiating infringement proceedings.

Under the Patent Act, the court can order – as a preliminary measure – a description or seizure of the allegedly infringing product, process and means of production based on a prima facie showing of actual or imminent infringement. This option is available before initiating proceedings and the findings resulting from the description or seizure can be used in later infringement proceedings in Switzerland or abroad. The party seeking this measure does not need to show irreparable harm (ie, that the evidence is likely to be destroyed or abandoned). Showing another legitimate interest (aside from the interest necessary to establish whether an infringement has been committed) is not required either. A member of the Federal Patent Court carries out the order and, if necessary, is assisted by a courtappointed expert or local authorities (eg, the police).

In addition, a party can request at any time (that is, even before initiating proceedings) the court order the provisional seizure of evidence if it is prima facie established that the relevant evidence is likely to be destroyed or abandoned.

Fishing expeditions are not allowed. The applicant must give details on:

- the documents or items that are the object of the description or seizure;
- why it believes that these documents or items can be found at the relevant site; and
- their relevance to its case for infringement.

During the proceedings, a party can ask the court to order that the other party surrender documents (except for documents subject to legal privilege) that are relevant for the proceedings and that are controlled by the other party. However, there are no direct sanctions if the other party refuses to comply, except for taking the refusal into account when weighing the evidence and drawing negative inference from it.

There are no general restrictions on the use of material obtained through a seizure or description order in a Swiss court. However, upon request of the targeted party, the court can order specific confidentiality measures, which can include a prohibition from using the relevant information outside of the Swiss proceedings.

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1.8 Search and Seizure Orders

The means of collecting evidence in a pretrial situation, as described in **1.7 Pre-action Discovery/Disclosure**, are also available during the proceedings.

In addition, a party can ask the court to order the other party to surrender documents (apart from those subject to legal privilege) that are relevant to the proceedings and that are controlled by the other party. However, there are no direct sanctions if the other party refuses to comply – although the refusal will be taken into account when weighing the evidence and negative inference may be drawn from it.

1.9 Declaratory Relief

Under Swiss law, an alleged infringer can bring a lawsuit to obtain a declaratory judgment that an act does not – or that a proposed act would not – constitute an infringement of a patent, provided it has a legitimate interest in obtaining such judgment. This is usually the case if either:

- the alleged infringer has received a ceaseand-desist letter; or
- the patent owner has otherwise asserted that, in its opinion, the claimant is infringing the patentee's patent.

An alleged infringer is generally barred from bringing a lawsuit to obtain a declaratory judgment on non-infringement if the patent owner has not yet given any indication that it considers the alleged infringer's activities to be infringing. However, in disputes involving foreign IP rightsholders, it is recognised that an alleged infringer in Switzerland can also bring proceedings to obtain a declaratory judgment of non-infringement to secure a forum in its home jurisdiction in order to avoid practical disadvantages (eg, a foreign jurisdiction or the use of a foreign language).

The threshold for an alleged infringer to sue for invalidity is generally lower. An alleged infringer will have standing to sue for invalidity if the parties are in a competitive relationship and the scope of protection of the patent extends to the alleged infringer's field of activity.

1.10 Doctrine of Equivalents

The doctrine of equivalents (DoE) is an integral part of Swiss patent law. To extend the scope of protection beyond the strict literal meaning of the words of the claim, any element that is equivalent to an element specified in said claim is taken into account. Therefore, the scope of protection conferred by a patent claim is not limited to the identical use of the features of the construed claim by the defendant's product or process. It also extends to equivalent elements if the following three conditions are met:

- · the equivalent element has the same effect;
- this same effect is obvious to the skilled person; and
- a skilled person would have considered the equivalent element as having the same value.

1.11 Clearing the Way

In general, there is no obligation to "clear the way" ahead of a new product launch. However, failing to clear the way can be taken into account when assessing the amount of court costs or a damages claim, for example, as failing to clear the way can be a sign of negligence or intentional breach.

1.12 Experts

In general, only testimony by court-appointed experts is formally considered a means of evi-

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dence in Swiss civil procedure. Private expert reports are considered mere party allegations.

To date, the Federal Patent Court does not appear to have appointed experts or heard court-appointed expert witnesses because the Federal Patent Court has a vast group of technical judges who are relied upon for technical issues within the panel of judges. In patent infringement and validity cases, the opinion of the technical judge is formally notified to the parties before the main hearing and the parties can comment on it either in writing or orally at a hearing.

Private Experts

Opinions of private experts are sometimes used in support of specific allegations (for example, in relation to infringement and validity issues or calculation of damages). The evidential value of private expert opinions is relatively low, as the Federal Supreme Court and the Federal Patent Court consider them mere party allegations rather than proper evidence. Nonetheless, Swiss courts – and, in particular, the Federal Patent Court – will review and take into account private expert reports if they are scientifically and technically sound and well-founded. Private expert opinions can also be important, as they provide guidance to the (technical) judges and any courtappointed expert.

Court-Appointed Experts

Before the establishment of the Federal Patent Court, court-appointed experts played a significant role in patent proceedings in Switzerland. However, this has changed, as there is always at least one judge with a technical background, which allows the court to decide without retaining further experts. In highly complex cases or cases relating to a remote field of technology, external court experts may still be needed and appointed – although this does not appear to have occurred yet.

1.13 Use of Experiments

The Code of Civil Procedure lists the admissible means of evidence exhaustively: testimony, documents, inspection, expert opinion, written information, and party questioning. An experiment can be conducted (and was conducted in at least one past case) as an "inspection" before the court during an evidentiary hearing.

1.14 Discovery/Disclosure

In Swiss civil procedure, the parties must present to the court the facts and all means of evidence on which they base their legal claims. In principle, no evidence is taken ex officio and the other party is not obliged to help in collecting evidence. Therefore, Swiss civil proceedings are heavily front-loaded: both parties need to present all facts and means of evidence in their briefs.

As set out in 1.7 Pre-action Discovery/Disclosure and 1.8 Search and Seizure Orders, description and seizure orders are available in certain cases both before and after filing a lawsuit.

Additionally, the front-loaded character of civil proceedings is alleviated by the following two mechanisms.

• During the proceedings, the court can order a party to produce specific documents that are in the party's custody if the party seeking the production can prove their relevance to the outcome of the case. No fishing expeditions are permitted. Failure to comply with a court order can be taken into account by the court when weighing the evidence. The court can also compel third parties to produce specific

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documents relevant to the outcome of the case.

• The court can order the production of a defendant's accounting documents and information on the extent of infringing activities, in order to allow the claimant to quantify its monetary claims (damages and disgorgement of profits).

1.15 Defences and Exceptions to Patent Infringement

An alleged infringer can use the following defences.

- The product/process does not fall within the patent claims if properly construed.
- The patent is invalid.
- Exemption from patent infringement. Under Swiss law, patent rights do not extend to:
 - (a) acts done privately for non-commercial purposes;
 - (b) acts done for experimental purposes;
 - (c) acts done for the purpose of obtaining a marketing registration (Bolar-type exemption);
 - (d) use on vehicles, ships, and aircraft temporarily or accidentally entering Switzerland;
 - (e) acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product

 in particular, the prescribing, dispensing or, use of medicinal products by legally authorised persons; and
 - (f) the direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription, or acts concerning medicinal products prepared in this way.
- Exhaustion of rights this applies if the patented product or the product resulting from a patented process has been sold in Switzer-

land or in the European Economic Area (EEA) by the patentee or with the patentee's consent. Generally, Switzerland adheres to the principle of regional exhaustion – except for patented products with regulated prices (such as pharmaceuticals), to which the principle of national exhaustion applies. Biological materials can also be multiplied for their intended use.

- Antitrust violation in the case of parallel importation of patented products from a country outside Switzerland and the EEA – albeit only in exceptional circumstances
- Prior user right this only applies if the alleged infringer had already used or made all necessary preparations to use the invention claimed by the patent at the patent's priority date.
- The patentee is estopped from enforcing an otherwise valid and infringed patent because they have delayed the lawsuit for a substantial period of time. However, this defence is limited to rare cases where the patentee – through its conduct – has given the alleged infringer reasonable grounds to believe that it would not bring any claim for patent infringement. Mere inactivity of the patentee, even for a long period of time, is generally not sufficient.

Compulsory Licensing

If none of the above-mentioned defences proves successful, the alleged infringer can argue that it is entitled to a compulsory licence – in particular, when:

- the alleged infringer has an invention that is dependent on the prior invention;
- the patented invention is not exploited in Switzerland; and
- there is a public interest in granting a compulsory licence.

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The grant of a compulsory licence must be requested in separate proceedings and it can be filed as a counterclaim to an infringement lawsuit.

There are currently no published decisions related to standard essential patent (SEP) disputes in Switzerland.

1.16 Stays and Relevance of Parallel Proceedings

Switzerland is not a member state of the EU. Therefore, the Brussels Regulation (recast) is not applicable to Switzerland. However, Switzerland is a signatory state of the Lugano Convention and Swiss courts generally follow the CJEU case law issued under the (substantively identical) provisions of the Brussels Regulation.

As a general rule, where proceedings are already pending between the same parties on the same subject matter before a foreign court, a Swiss court will stay proceedings until the foreign court issues a decision on its jurisdiction. Some scholars have argued that if the foreign court in which the lawsuit was filed has clearly no jurisdiction to hear the case ("torpedo" action), the action before the foreign court constitutes an abuse of law and should not justify a stay of the Swiss proceedings.

Under the most recent case law, if the plaintiff files a preliminary injunction request and a statement of claim in main proceedings on the same subject matter, the Federal Patent Court will stay the main infringement proceedings until the decision on the co-pending Pl.

If opposition or appeal proceedings are pending before the EPO, defendants can request the stay of Swiss proceedings. However, the Federal Patent Court does not normally stay the proceedings in these circumstances, unless a final decision of the EPO is expected shortly or the stay is requested by both parties.

If a defendant is sued in Switzerland for the infringement of a foreign IP right and the defendant challenges the validity of the foreign right, Swiss courts no longer have jurisdiction over the dispute - given that the question of validity of the foreign patent falls under the exclusive jurisdiction of the courts of the country in which the patent was issued. According to case law, this does not only apply in the case of a counterclaim, but also if the defendant challenges the validity of the IP right by way of a defence.

In practice, if the defendant challenges the validity of a foreign patent, the court will stay the infringement proceedings and order the defendant to initiate invalidity proceedings in the country in which the patent was issued. If the defendant fails to initiate invalidity proceedings, the court will deal with the question of invalidity as a preliminary question to infringement.

Although foreign decisions do not bind any Swiss court, the Federal Patent Court gives some deference to decisions issued in parallel proceedings by other European courts. The Federal Patent Court will, in general, look in great detail into the reasoning of the foreign court and decide on a case-by-case basis whether it will follow the same argument or decide differently.

1.17 Patent Amendment

It is possible for the patentee to amend the patent claims during proceedings (both in infringement and invalidity proceedings), but only until the closure of the exchange of briefs, which occurs after the second exchange of briefs in main proceedings and with the first exchange of briefs in PI proceedings.

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The patent claims can only be limited and never extended. The patent can be restricted by eliminating patent claims altogether or by combining independent patent claims and dependent claims. In addition, patent claims can be restricted by adding further features based on the description. In such cases, the restricted claims must relate to the same invention and define an embodiment that is still supported by the description of the original application (as well as the published patent in the case of Swiss patents).

If invalidity is only raised by way of a defence (and not by way of a counterclaim), the patent can be limited with inter partes effect only – that is, the patent will remain in the register as it had been granted, irrespective of the outcome of the proceedings.

1.18 Court Arbiter

All patent cases are decided by judges; there are no juries in Switzerland.

Forum shopping is limited to non-patent IP cases, as all patent infringement and validity cases (both in main proceedings and in PI proceedings) are dealt with in first instance by the Federal Patent Court. Non-patent IP cases are dealt with by cantonal high courts and forum shopping/forum running is available in these cases, provided that several cantonal courts potentially have jurisdiction (eg, where the infringing acts have occurred in all of Switzerland).

2. Generic Market Entry

2.1 Infringing Acts

If infringement is imminent, but has not yet started, the Federal Patent Court requires evidence of imminent acts of a certain minimum intensity. In generic entry cases, an application for marketing authorisation in itself is generally not sufficient for a finding of imminent infringement. However, further acts are considered sufficient for a finding of imminent infringement (see **1.3 Preliminary Injunction Proceedings**).

The rules governing the infringement of second medical-use patents have been subject to some controversy since the amendment of the Patent Act in 2019. Under the relevant amendment, "acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product" (eg, the prescribing, dispensing or use of medicinal products by legally authorised persons) have been explicitly exempted from the scope of the patent (Article 9(1)(g) PA). The same is true of the "direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription or to acts concerning medicinal products prepared accordingly" (Article 9(1)(h) PA).

Under the current case law of the Federal Supreme Court, contributory infringement of patent rights only qualifies as an infringement if the main infringing acts take place in Switzerland and are unlawful. In the case of second medicaluse patents, the main infringing act – ie, the prescribing, dispensing or use of medicinal products by medical professionals – is not "unlawful" under the new law. Hence, it is unclear under what legal theory the manufacturer or the distributor of a product protected by a second medical-use claim qualifies as a contributory infringer. It is expected that the Federal Patent Court will clarify these issues in the coming years.

The Federal Supreme Court has held that a patentee who has a dominant position in the relevant market can be liable for an antitrust violation if it enforces its patent in order to pre-

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vent the parallel import of a patented product already sold in another country. However, this only applies if the following conditions are met:

- the patentee has a dominant position in the relevant market;
- the legal and economic conditions of the country where the first sale occurred are comparable to those of Switzerland; and
- the enforcement of the patent only seeks to maintain substantially higher prices in Switzerland, thereby sealing off Switzerland in an abusive way.

Some scholars have argued that market-dominant patentees are generally obliged to grant compulsory licences if both:

- the use of the patented technology is indispensable for a third party that wishes to offer new products; and
- the patentee does not have legitimate grounds to refuse the grant of a licence.

Finally, the Federal Patent Act specifically provides for compulsory licences on diagnostics in the case of antitrust violations. There is no published case law on compulsory licenses so far in Switzerland.

2.2 Regulatory Data and Market Exclusivity

The Swiss Agency for Therapeutic Products (Swissmedic) grants the following data exclusivity periods for medicinal products:

- ten years for a medicinal product containing at least one new active substance;
- three years for a new dosage or route of administration;
- three years for a new indication, but a tenyear period can be granted for a new indica-

tion if a significant clinical benefit over existing treatments can be expected as a result;

- ten years for medicinal products specifically and exclusively destined for a paediatric indication, if the indication is supported by relevant clinical data;
- 15 years for an important medicinal product for orphan diseases; and
- ten years for a fixed combination of medicinal products if the combination contains at least one new active substance.

There is no data exclusivity granted for a new device for administration of the same product, unless it results in a new route of administration.

Challenges to data exclusivity are possible. Decisions of Swissmedic can be appealed to the Federal Administrative Court and, in the final instance, to the Federal Supreme Court. Appeals to the Federal Administrative Court typically last 12 to 30 months, depending on the complexity of the case. Appeals to the Federal Supreme Court are generally decided within seven to nine months.

2.3 Acceptable Pre-launch Preparations

The scope of a patent does not extend to acts undertaken for research or experimental purposes in order to obtain knowledge about the subject matter of the invention (ie, the experimental use exemption). Similarly, the scope of a patent does not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control (Bolar-type exemption).

2.4 Publicly Available Drug and Patent Information

There is no equivalent of the Orange Book in Switzerland. Swissmedic does not verify nor

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takes into account the existence of patent rights when issuing marketing authorisations (MAs).

Granted MAs are published in the Official Journal of Swissmedic once a month. In order to obtain access to the content of the MA request, a Freedom of Information request must be filed with Swissmedic, whereby Swissmedic will not disclose any personal data, confidential information or data protected under the data exclusivity regulations.

Swissmedic does not proactively inform MA holders of generic MAs.

2.5 Reimbursement and Pricing/Linkage Markets

Neither the grant of an MA nor the pricing or reimbursement are linked with patent status. The regulatory authorities (Swissmedic and the Federal Office of Public Health) do not take into account the patent status and will decide to issue MAs or approve pricing irrespective of existing patents.

Nonetheless, the Federal Office of Public Health will take the patent status into account when determining the applicable amount of the reimbursement. In particular, the Federal Office of Public Health will examine, upon patent expiry, whether the conditions of reimbursement - in particular, the condition of economic efficiency – is still fulfilled.

3. Biosimilar Market Entry

3.1 Infringing Acts

The details outlined in **2.1 Infringing Acts** regarding generics are also broadly applicable to biologics and biosimilars. In particular, requesting marketing authorisation alone is not sufficient for a finding of imminent infringement, but an imminent infringement will be found if additional steps have been taken in view of future distribution in Switzerland.

3.2 Data and Regulatory Exclusivity

Biosimilars can be authorised only with referencing to a medicinal product with complete documentation. In other words, biosimilars themselves cannot be authorised as reference products.

In principle, all indications and corresponding dosage recommendations of the reference product can be submitted for authorisation for the biosimilar.

An application for the authorisation of biosimilars can be submitted as early as two years before the ten-year data exclusivity (see **2.2 Regulatory Data and Market Exclusivity**) of the reference product expires. The decision will then be issued potentially before the document protection expires but with a date in the future (ie, the first day after the document protection expires at the earliest).

Biosimilars approved for the first time are not considered a new active substance and therefore no data exclusivity is granted, bar special cases as outlined in 2.2 Regulatory Data and Market Exclusivity.

3.3 Acceptable Pre-launch Preparations The details outlined in **2.3 Acceptable Prelaunch Preparations** regarding generics are also broadly applicable to biologics and biosimilars. In particular, the exemptions from the scope of the patent are identical.

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3.4 Publicly Available Drug and Patent Information

The details outlined in 2.4 Publicly Available Drug and Patent Information regarding generics are also broadly applicable to biologics and biosimilars.

3.5 Reimbursement and Pricing/Linkage Markets

The details outlined in 2.5 Reimbursement and **Pricing/Linkage Markets** regarding generics are also broadly applicable to biologics and biosimilars.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

The Patent Act provides for Supplementary Protection Certificates (Article 140a et seq, Patent Act). The rules in the Patent Act are directly inspired by the EU SPC Regulation (No 469/2009) and the Federal Supreme Court adheres to most of the case law of the CJEU on SPC matters, except where there is a compelling reason to depart from CJEU jurisprudence, in particular when it appears that the Swiss legislature sought to issue a different set of rules (see Federal Supreme Court, BGE 144 III 285).

The SPC is granted to the owner of the patent. The SPC is granted if, at the time of the application, the product (ie, the active ingredient or combination of active ingredients) is protected "as such" by a patent or if a process for manufacturing it or its use is protected by a patent. In addition, it is required that a medicinal product containing the relevant active ingredient (or combination) be authorised in Switzerland. In principle, one SPC will be granted per product and per applicant.

However, several SPCs may be granted for a product if the applications are based on different patents from different patent owners (Article 140c (3), Patent Act). A patent owner who submits several SPC applications based on different patents for the same product must choose only one of these applications in the course of the examination procedure. An applicant who has already been granted an SPC may not be granted further SPCs for the same product on the basis of another basic patent (Etanercept decision, BVGE 2010/48).

Combination products:

When assessing whether an SPC has already been granted, the following applies: If an SPC has been granted for an active substance A, an SPC may be granted for a combination of active substances A + B because it is a different product. This also applies in the reverse order, and even if it is the same basic patent.

In 2018, the Federal Supreme Court initiated a change in case law to follow the practice of the CJEU (BGE 144 III 285): If the basic patent designates only one of two active substances, a product cannot be claimed as an SPC if it is composed of two active substances. Rather, Article 140b of the Patent Act is to be interpreted in accordance with the EU Regulation (Article 3 of Regulation [EC] No 469/2009) in such a way that the active substances of the product must be claimed in the basic patent by naming them in the patent claims or by the patent claims interpreted in the light of the description (Article 51(3), Patent Act; Article 69, European Patent Convention 2000) - at least implicitly but necessarily referring to these active substances, and in a specific manner.

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Because the product of the SPC must be protected by the basic patent, a patent with a combination of active substances as the subject matter of the invention may not be used as the basis for a "single substance" SPC. This is not affected by the fact that the individual active ingredients can be administered separately.

Contrary to the European Union, Switzerland has not implemented an SPC manufacturing waiver. Although a parliamentary motion on this topic is pending, it is unclear whether it will be pursued and the introduction of a manufacturing waiver is not imminent.

4.2 Paediatric Extensions

Both independent paediatric supplementary protection certificates and paediatric extensions of supplementary protection certificates are available in Switzerland.

The duration of a paediatric SPC is six months from the expiry of the longest term of the patent. The conditions of the grant of a paediatric SPC are that (i) the medicinal product reflects the results of all studies performed in accordance with the paediatric test concept and (ii) the application was made no later than six months after the application for initial MA in the EEA for the medicinal product containing the relevant active ingredient. The paediatric SPC and the "ordinary" SPC are mutually exclusive, that is, no "ordinary" SPC will be granted if a paediatric SPC has been granted and vice versa.

The paediatric extension of an SPC can be granted for six months if the MA contains confirmation that the information on the medicinal product reflects the results of all studies performed in accordance with the paediatric test concept and that the application was made no later than six months after the application for the initial MA in the EEA for the medicinal product containing the relevant active ingredient. The term of the SPC can only be extended once and paediatric SPCs cannot be extended.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In the event of an unjustified preliminary injunction, the claimant must pay compensation for damages suffered by the defendant. However, if the claimant filed the request for a preliminary injunction in good faith, a court can either dismiss or reduce the amount of the compensation.

If the preliminary injunction was unjustified, the defendant must be placed in the position it would have been in if no preliminary injunction had been issued. To this end, the defendant must substantially prove the loss it suffered as a result of the unjustified preliminary injunction, notably lost profits.

The Federal Patent Court can order the claimant to post a bond to ensure payment of compensation in the event of an unjustified preliminary injunction. The amount of the bond is determined by the Court. The bond is released once it is clear that no damages are claimed. The Federal Patent Court can impose a time limit on the defendant for filing a damages action.

Actions started through an ex parte application require confirmation in inter partes proceedings. In addition, all preliminary injunction proceedings require confirmation in main proceedings. After issuing a preliminary judgment, the Federal Patent Court will set a deadline for the commencement of main proceedings. If no main proceedings are initiated, the injunction lapses and

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the applicant is liable for any damages caused to the defendant.

In preliminary injunction proceedings, an appeal is only available if the defeated applicant can show that it would suffer an irreparable harm of a legal nature. The Federal Supreme Court has a strict interpretation of the requirement of legal irreparable harm, which means that the possibility to appeal a preliminary injunction decision is excluded in most cases.

5.2 Final Injunctive Relief

The patentee has the right to request a permanent injunction against the infringer.

An injunction is strictly confined to the infringing product or process. It only binds the defendant(s) to the proceedings and therefore has no direct effect on third parties (such as suppliers or customers) and cannot be enforced directly against them.

The Federal Patent Court can grant cross-border or extra-territorial permanent injunctions if it has jurisdiction over the dispute (that is, if the defendant is domiciled in Switzerland and does not challenge the validity of the foreign patent).

Court decisions, including the final permanent injunction, are served on the parties or their representatives as judicial documents by Swiss Post. Injunctions in patent matters are enforced exclusively by the Federal Patent Court, while monetary awards are enforced through the general rules applicable to debt enforcement and bankruptcy.

The injunction can be enforced through a variety of means, such as (i) seizure and destruction of the infringing goods, (ii) a penalty for non-compliance for each day of continuing infringement and (iii) criminal proceedings for contempt of court against the directors of the infringing entity (a monetary penalty of up to CHF10,000). It is essential that the claimant specifically request these or further means of enforcement by filing appropriate motions at the outset of the main proceedings.

Permanent injunctions issued by the Federal Patent Court are immediately enforceable. An appeal to the Federal Supreme Court does not have suspensive effect, but the appellant can request that the Federal Supreme Court grant suspensive effect if the appellant can show that the enforcement of the injunction may cause irreparable harm. The Federal Supreme Court has broad discretion in granting suspensive effect for the duration of the appeal proceedings.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

It is currently the majority view in Switzerland that the court does not have discretion to refuse injunctive relief if it finds the patent valid and infringed. In particular, proportionality is not considered a pre-requisite of the grant of permanent injunctions. In addition, public policy considerations are currently not taken into account when determining whether a permanent injunction can be granted. In other words, if the patent is valid and infringed and the claimant requests a permanent injunction, the court has no discretion to deny the grant of the injunction. There are no exemptions for particular subject matter or for particular claimants, such as non-practising entities.

If the defendant claims that there is a compelling public interest to refuse a permanent injunction, the defendant needs to apply for a compulsory licence. Contributed by: Thierry Calame and Peter Ling, Lenz & Staehelin

The court cannot award damages in lieu of an injunction either.

5.4 Damages

Calculation of Damages

Similar to common tort actions, monetary remedies in patent actions are assessed on the basis that the claimant must be placed in the position it would have been in, if no infringement had occurred. The claimant can request:

- compensation for the pecuniary loss that it has suffered due to the infringement (damages);
- surrender of the profits the infringer made as a result of the sale of the infringing products (disgorgement of profits); or
- surrender of any unjust enrichment of the infringer deriving from the infringing act (notably a reasonable royalty).

The claimant must choose between damages, disgorgement of profits, or the surrender of unjust enrichment. Usually, the claimant will pursue multiple remedies in parallel as alternative claims, and, after the infringer has opened its books and provided information on the profit it made out of the infringement, choose the remedy that yields the best result.

In addition and cumulatively to damages, account of profits, or surrender of unjust enrichment, the claimant can seek damages for ancillary losses arising from the infringement. Ancillary losses can include:

- legal expenses incurred before initiating the action (for example, the cost of obtaining an opinion on infringement from patent counsel);
- expenses directed at mitigating the impact of the infringement (for example, advertising

expenses directed at minimising confusion in the market place); and

 lost sales of ancillary products (for example, lost sales of unpatented equipment, spare parts, and so on, which the patentee ordinarily sells alongside its patented articles).

Generally, the Federal Patent Court will first issue a decision on the permanent injunction and order the defendant to disclose internal accounting information about the turnover made with the infringing products. The quantum of monetary remedies is then assessed at a separate stage of the proceedings. Because almost all infringement cases are settled after the decision on the permanent injunction, there are only very few published decisions on the quantum of financial compensation. Therefore, there is no settled practice as to many essential issues, in particular the royalty rates for a hypothetical licence in the pharmaceutical/biopharma/medical device industries.

Typical Damages Awards

Financial compensation is only awarded in the final decision; provisional enforcement of financial compensation is not available.

If the court orders the payment of damages, the infringer must also pay interest on the amount of the compensation at the statutory rate (currently 5% per annum), calculated from the date of the relevant infringing acts. Treble damages or punitive damages are not available in Switzerland and foreign decisions awarding treble or punitive damages are not enforced in Switzerland.

The Supreme Court has made it clear that the basis for the calculation of damages in cases of complex devices where only a part of the device constitutes infringement is the "indivisible trade unit" in which the infringing element is included.

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The "indivisible trade unit" refers to the set of elements that are generally sold on the market as one product.

Financial compensation is payable immediately upon the notification of the decision of the Federal Patent Court, except if the losing party appeals the decision and successfully requests that the enforcement of the decision be suspended.

Damages for Wrongful Injunctions

In the event of an unjustified preliminary injunction, the claimant must pay compensation for damages suffered by the defendant. However, if the claimant filed the request for a preliminary injunction in good faith, a court can dismiss a compensation claim in full or reduce the amount of the compensation.

Furthermore, after issuing a preliminary judgment, the Federal Patent Court will set a deadline for the commencement of the main proceedings. If no main proceedings are initiated, the injunction lapses and the applicant is similarly liable for any damages caused to the defendant.

There are very few published decisions on damages for a wrongful injunction. Given that the threshold of proving actual loss is very high in Swiss law, many cases fail to yield a substantial amount of compensation.

Third-Party Damages

Non-exclusive licensees have no statutory right to sue for patent infringement. However, they can join a damages claim filed by the patentee or an exclusive licensee and claim damages covering their own loss. In practice, it is important for non-exclusive licensees and distributors that the relevant licence or distributorship agreement contains a clause requiring the patentee to take action for patent infringement.

5.5 Legal Costs

There are three types of costs involved in patent litigation:

- court costs;
- attorneys' fees; and
- · disbursements, including patent agent costs.

On average, a party should expect to incur between EUR90,000 and EUR230,000 to take a case through to a first instance decision. In complex cases, costs may be higher.

Court costs must be paid in advance by the plaintiff.

Court costs and the award for attorneys' fees both depend on a tariff based on the value of the litigation and the complexity of the case.

Under the "loser pays" rule, the losing party is eventually ordered to pay the court costs and reimburse the winning party's attorneys' fees. Disbursements of the winning party (including patent agent costs) must be paid by the losing party based on the amounts actually spent.

After assessment by the court, the successful party will generally recover about 20% to 50% of legal costs and all disbursements actually incurred in the proceedings. Patent agent costs are considered as disbursements and, therefore, fully recoverable in principle. However, the Federal Patent Court generally reduces compensation for patent agent costs to the amount of attorneys' fees awarded under the applicable tariff, unless an exceptionally complex technology justifies a higher amount.

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5.6 Relevance of Claimant/Plaintiff Conduct on Relief

The court can, exceptionally, refuse to make a costs award in favour of the winning party or can penalise this party if it has abused the process of the court, or has contributed to an undue delay of the proceedings in any other way.

If the plaintiff has filed a lawsuit without engaging in pre-action correspondence and the defendant does not resist the lawsuit, the court can also refrain from any cost award to the plaintiff or even order the (successful) plaintiff to bear all costs.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sectors are common in Switzerland. The rules on pharmaceutical trade marks are the general rules laid out in the Federal Act on Trade Marks and Indications of Origin and the specific rules laid out in the administrative regulations of Swissmedic.

Among the relevant rules of pharmaceutical trade mark law, it is notable that the use of a trade mark for a specific indication does not, in principle, count as use for all indications of pharmaceutical products in Class 5 of the Nice Classification. As a result, the owner of a trade mark in Class 5 cannot always prevent the use of a similar mark for pharmaceutical products for a different indication.

Brands for pharmaceutical products must be approved by Swissmedic. When assessing a new brand for pharmaceutical products, Swissmedic does not take into account the trade mark situation. Swissmedic is only responsible for ensuring that the name of a product does not lead to confusion with another product, that the name is not incorrect or misleading with regard to the indication, quality, risks or safety of the product, and that the name does not promote abuse of the product.

6.2 Copyright

Copyright law is based on the Federal Act on Copyright. Copyright has a generally limited relevance in the life sciences and pharma sector. Copyright can, however, be very important in the medical device space, in particular in relation to software as a medical device. The Swiss rules on copyright ownership and works made for hire can vary from other European jurisdictions and need to be assessed in each individual case.

6.3 Trade Secrets

Switzerland is not a member of the EU. Consequently, it is not obliged to implement and has not implemented the EU Trade Secrets Directive (the "EU TS Directive") in its national law.

Switzerland is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPS), which explicitly addresses trade secret protection in Article 39.

There is no separate statute in Switzerland that exclusively governs trade secrets. Rather, there are several sets of isolated provisions in various statutes. The following are the most relevant statutes under Swiss law:

- the Swiss Federal Act against Unfair Competition (UCA);
- the Swiss Criminal code (CC);
- the Swiss Code of Obligations (CO), in particular its sections on employment law, agency law and corporate law;

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- the Swiss federal act on data protection (FADP); and
- the Codes of Procedure (civil, administrative, criminal) related to the protection of trade secrets in proceedings before courts and administrative bodies.

As a consequence of the scattered nature of the legal sources, Swiss law does not have one single unified theory to protect all trade secrets. Instead, depending on the circumstances, trade secrets will be protected under the doctrine of tort law, contracts or criminal law.

In short, Swiss law does not treat trade secrets as a formal intellectual property right, but as a factual position that still enjoys strong protection under the various applicable legal sources.

In a case of trade secret misappropriation, the plaintiff can request injunctive relief and/or financial compensation. As set out in **5.4 Damages**, financial compensation can take the form of:

- compensation for the loss suffered by the plaintiff as a result of the misappropriation (damages, Article 41, Code of Obligations);
- payment of the unjust enrichment accrued with the infringer as a result of the misappropriation (Article 62, Code of Obligations); or
- the surrender of the profits made by the infringer through the use/distribution/sale of the infringing products (disgorgement of profits, Article 423, Code of Obligations).

Defences in trade secrecy litigation may include the following arguments by the alleged infringer:

 the relevant information is no longer confidential or has never been confidential (lack of secrecy);

- the trade secret owner has not taken appropriate measures to ensure secrecy and thus does not have an interest in maintaining secrecy (lack of subjective interest in secrecy);
- the trade secret was obtained lawfully from a third party;
- the alleged infringer understood in good faith that the disclosure of the trade secret was made with the authorisation of the trade secret owner;
- the alleged infringer has discovered or developed the trade secret independently;
- the relevant information does not constitute a trade secret but rather general industry expertise or knowledge; and
- the disclosure of the trade secret was authorised or required by law.

7. Appeal

7.1 Timing to Appeal Decision

There are special rules of jurisdiction regarding intellectual property litigation. Intellectual property cases are tried at first instance by the Federal Patent Court (patent cases) or the high court of the relevant canton (non-patent cases). In both patent and non-patent cases, only one level of appeal exists to the Federal Supreme Court.

Appeal proceedings in the Federal Supreme Court generally last seven to nine months.

An appeal in civil matters against a decision (on preliminary injunctions or in main proceedings) must be lodged with the Federal Supreme Court within 30 days of its notification.

The appeal is limited to a review of legal issues (as opposed to facts). More specifically, the

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appellant must show that the first instance court misapplied or misinterpreted federal law (that is, patent law or procedural law) or international law. Findings of fact and the assessment of evidence can only be reviewed if they are blatantly wrong or arbitrary.

In preliminary injunction proceedings, an appeal is only admissible if the appellant can show that it suffers irreparable harm of a legal nature as a result of the decision. The Federal Supreme Court has a strict interpretation of the requirement of irreparable harm of a legal nature, which means that appeals against preliminary injunction decisions are inadmissible in most cases.

7.2 Appeal Court(s) Arbiter

Appeals against decisions of the Federal Patent Court or of the cantonal High Court are decided by a panel of three or five judges of one of the civil law senates of the Federal Supreme Court. There are no specialist or technical judges at the Federal Supreme Court.

7.3 Special Provisions

There are no special provisions for intellectual property proceedings in the Federal Supreme Court.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

The owner of an intellectual property right can request that the customs authorities seize any infringing goods. Upon notification, the patentee needs to file a request for an (ex parte) preliminary injunction within ten days, otherwise the customs authorities will release the goods. The patentee can collect samples and verify whether the goods infringe upon the intellectual property right.

If the seizure or destruction of the goods proves to be unjustified, the right-holder is liable for the resulting loss.

9. Alternative Dispute Resolution

9.1 ADR Options

Arbitration is available to resolve patent disputes if the parties to the dispute have agreed on the competence of an arbitral tribunal. In Switzerland, both patent infringement and invalidity disputes can be submitted to arbitration. However, arbitration proceedings are rarely used to resolve pure patent infringement and invalidity disputes. It is more common for parties to conclude an arbitration agreement in patent licensing agreements, which also empowers the arbitral tribunal to decide on underlying patent infringement and validity issues.

An arbitral award declaring a patent invalid will be recognised and enforced by the Swiss Institute for Intellectual Property in the same manner as a court order to the same effect.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Federal Supreme Court has held that a patentee that has a dominant position in the relevant market can be liable for an antitrust violation if it enforces its patent to prevent the parallel importation of a patented product already sold in another country. However, this only applies if the following conditions are met:

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- the patentee has a dominant position in the relevant market;
- the legal and economic conditions of the country where the first sale occurred are comparable to those of Switzerland; and
- the enforcement of the patent seeks only to maintain substantially higher prices in Switzerland, thereby sealing off Switzerland in an abusive way.

Some scholars have argued that patentees with a dominant position in the relevant market are generally obliged to grant compulsory licences if both:

- the use of the patented technology is indispensable for a third party that wishes to offer new products; and
- the patentee does not have legitimate grounds to refuse the grant of a licence.

Finally, the Federal Patent Act specifically provides for compulsory licences on diagnostics in the case of antitrust violations. There is no published case law on compulsory licences so far in Switzerland.

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