

Switzerland

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1. Small molecules

1.1 Product and process claims

Classic drug development works with small, chemically manufactured active-substance molecules. These small molecules can be processed into easily ingestible pharmaceutical products (tablets or capsules). If those tablets dissolve in the gastrointestinal tract, the dissolved active substance is absorbed into the bloodstream via the intestinal wall. From there, the small molecules can reach almost any desired destination in the body because of their tiny size. Their small structure and chemical composition can also help them to penetrate cell membranes easily. In the developed pharmaceutical markets, several important patents concerning small molecules have recently expired or will expire within the next few years.

Under Swiss Law, each independent patent claim may define one invention only, namely:

- a process;
- a product, ie, a means for performing a process or an apparatus;
- an application of a process; or
- the use for a product.

If the invention concerns a manufacturing process, the effects of the patent also extend to the products directly obtained by that process. If these latter products concern biological material, the effects of the patent extend, furthermore, to products obtained by propagating the biological material and which demonstrate the same characteristics (Article 8a of the Federal Act on Patents for Inventions (Patent Act, PatA, SR 232.14, which took effect on January 1 2012).

1.2 Scope of protection of claims and *Markush* formulae

The claims made under the patent determine the scope of protection conferred by it. Since Switzerland is a contracting state to the European Patent Convention (EPC, SR 0.232.142.2), the scope of protection of patents that apply to Switzerland is subject to different provisions, as follows:

- the scope of Swiss parts of European patents must be interpreted in accordance with Article 69 of the EPC and the Protocol on the Interpretation of Article 69 EPC of October 5 1973, as amended by the Act revising the EPC of November 29 2000.

- the scope of Swiss national patents is defined by Article 66 of the PatA, taken together with Article 51 of that statute. Pursuant to Article 66 lit a of the PatA, the use or imitation of a patented invention is deemed an infringement.

Although the scope of protection of the Swiss parts of European patents and that of Swiss national patents are subject to different provisions, there are no practical differences. The scope of protection encompasses both literal and equivalent infringement.

Having considered previous jurisprudence of the Swiss Federal Supreme Court (SFSC) as well as foreign court rulings (in particular, the decision of the German Federal Court of Justice in *Schneidmesser II*¹), the SFPC has held² that an equivalent infringement exists if the following three criteria are satisfied:

- a product or process substitutes certain feature(s) of the allegedly infringed patent claim with the same technical effect as the replaced feature(s);
- based on the patent, the substitute and its technical effect are obvious to the skilled person in the art;
- the substitute is equivalent to the patented teaching in the light of the patent claims as literally stated.

A *Markush* claim or structure allows multiple ‘functionally equivalent’ chemical entities in one or more parts of the compound. *Markush* claims use symbols to indicate a collection of chemicals with similar structures in the claimed depiction of the patented molecule. If a compound being patented includes several *Markush* groups, the number of possible compounds covered by the latter could be vast. This can create problems for patent searchers who are looking out for specific chemicals in patents. *Markush* claims are permitted and enforceable in Switzerland. They are used in the Swiss parts of European patents as well as in Swiss national patent claims (mainly – but not exclusively – in chemical patent claims).

1.3 Metabolites

Metabolites are the intermediate products of metabolic reactions catalysed by various enzymes that naturally occur within cells. Metabolites and prodrugs constitute the chicken and egg of biosciences. Inextricably connected – the one transforming to the other within the body – they remain structurally distinct, which raises the question: how can they be protected?

There is no Swiss case law dealing with the question whether the scope of protection of the prodrug, ie, the inactive form that is designed to break down inside the body to form the active drug, also covers the active metabolite (and vice versa).

1 BGH, decision of June 12 2002, X ZR 135/01 – *Schneidmesser II*.

2 SFPC, decision of March 21 2013, S2013_001, consid 17.2 *et seqq*.

2. Secondary patents

2.1 Combinations

Patents for combination products normally do not pose particular problems in Switzerland, as long as they do not involve Supplementary Protection Certificates (SPC(s)). SPCs for combination products have been granted in Switzerland on the basis of the so-called infringement test. This means that an SPC can be granted so long as the product which is the subject of the SPC falls within the scope of a process or product claim of a patent that is valid in Switzerland.

This derives from the *Fosinopril* decision of the SFSC in 1998.³ In this decision, the court confirmed the jurisprudence according to which the certificate would be granted as long as the product, a process for manufacturing it or a use of it was protected by the patent (Article 140b, paragraph 1a of the PatA).

The Court of Justice of the European Union (CJEU) – in its more recent decisions *Eli Lilly*⁴ and *Medeva*⁵ – has rejected the infringement test applied by the Swiss Federal Institute of Intellectual Property (FIIP) and the SFSC. According to the CJEU, what has to be considered is whether all the active ingredients in a combination product are specified in the wording of the claims of the basic patent relied on in support of the application for the SPC.

Switzerland is not a member of the EU and Swiss courts and authorities are not bound by CJEU case law. The FIIP has noted, however, that the CJEU jurisprudence rejecting the infringement test has been and will be implemented by the national patent offices of the EU member states. In its view, this trend will lead to a narrower practice in the granting of patents which cannot be ignored in Switzerland because, in the long term, Swiss practice should – whenever possible – be compatible with European law. The FIIP therefore recommends adopting the interpretation test utilised in the CJEU jurisprudence and accordingly recommends determining whether the product is specified in the wording of the claims of the basic patent from the viewpoint of a person skilled in the art.

Another issue addressed by the CJEU in recent case law concerns the question whether Article 3 lit c of the Council Regulation concerning the creation of a supplementary protection certificate for medicinal products (469/2009 EC) precludes the grant of more than one SPC per patent, even where the patent covers more than one product. In its decisions in *Actavis*⁶ and *Georgetown II*,⁷ the court held that this provision should be interpreted as – in principle – not precluding the granting of more than one SPC per basic patent. In a case, however, where the invention relates to an innovative substance on the one hand and, on the other, to the combination of this substance with other products that are not ‘protected as such’ by the patent, an additional SPC cannot be granted. According to the CJEU, the additional substance must form part of the “core inventive advance” of the invention. In

3 SFSC, decision of July 10 1998, 124 III 375 – *Fosinopril*.

4 CJEU, judgment of December 12 2013, C-493/12 – *Eli Lilly and Company v Human Genome Sciences*.

5 CJEU, judgment of November 24 2011, C-322/10 – *Medeva v Comptroller*.

6 CJEU, judgment of December 12 2013, C-443/12 – *Actavis v Sanofi et al.*

7 CJEU, judgment of December 12 2013, C-484/12 – *Georgetown University v Octrooiencentrum Nederland*.

conclusion, there can only be one SPC per core incentive advance per patent. The FIIP believes that the CJEU case law in this regard is coherent and aims at limiting extended SPC protection resulting from the granting of multiple SPCs. The FIIP therefore recommends adopting this jurisprudence as well.

The FIIP asked all stakeholders to comment on its plans to implement the European case law by the end of April 2015 and will decide how to proceed after all comments have been considered.

2.2 Enantiomers

An enantiomer is one of two stereoisomers that are mirror images of each other and non-superposable (i.e. not identical but similar in the same sense that one's left and right hands are the same, save for their opposite orientation). Like all inventions, the chiral compounds contained in pharmaceuticals must meet the statutory requirements of novelty and non-obviousness in order to be patentable. Because of the economic importance and unique structural characteristics of chiral molecules, challenges to the patentability of enantiomers in Switzerland on the basis of novelty and non-obviousness remain the subject of major litigation.

The approach of Swiss case law is consistent with that of the European Patent Office (EPO), which is that a single enantiomer deduced from a patented racemate is to be regarded as a product on its own if the enantiomer develops a pharmacological impact. A patent claim which asserts a specific enantiomeric excess of one of two enantiomers can be novel and inventive (ie, not obvious).⁸

2.3 Selection inventions

Swiss law does not impose specific limitations with regard to the technical field of application of selection inventions. In terms of novelty and inventive step, the Swiss approach is in line with that of the EPO.

With regard to the assessment of novelty, the prior art is considered to disclose both express and implied content. Novelty may arise out of a combination of features if the selection is deduced from 'two or more lists of a certain length' (the so-called 'two-list principle').

A selected sub-range from a broader numerical range of the prior art is considered novel if it is cumulatively:

- small compared to the known one;
- sufficiently far away from (a) any specific examples disclosed in the prior art, and (b) from the end-points of the known range; and
- not an arbitrary specimen of the prior art but a purposive selection (and therefore a new invention).

In the case of overlapping ranges, the same principles apply and novelty is destroyed either by an explicitly mentioned end-point of the known range, an explicitly mentioned intermediate value or a specific example of the prior art in the overlap. Furthermore, the question must be posed whether the skilled person 'would

8 Cf. SFPC, decisions of May 12 2014, S2013_003 and S2013_004.

seriously contemplate' applying the technical teaching of the prior art document in the range of the overlap. If the answer is 'yes', the invention is not novel.

In cases where no hints are available that lead a skilled person to the selection, the invention is inventive (ie, not obvious). The technical effect of the claimed range must be unexpectedly different or the same but of an unexpected degree with respect to the technical effect that occurs in the broader known range in order for it to be recognised as an inventive step.

2.4 Methods of use and secondary indications

Secondary medical uses of known compounds may be protected in Switzerland by way of a Swiss patent or a European patent. With regard to the claim format, there is a distinction between Swiss national patents and European patents. Secondary medical uses for a Swiss national patent must – in accordance with Article 7d of the PatA – be formulated in the so-called Swiss-type claim format. With regard to European patents, the Enlarged Board of Appeal of the EPO has held that, under the version of the EPC adopted in 2000 and which entered into force on 13 December 2007, second or further medical use claims can no longer be made pursuant to the Swiss-type claim format.⁹ European applications filed after April 29 2011 regarding second and further medical uses must therefore be claimed as use-related product claims (ie, 'substance or composition X for use in the treatment of Z').

According to case law, the following types of second medical uses are patentable in Switzerland (if all the other requirements, eg, novelty and non-obviousness, are also met):

- a new therapeutic application (in general);
- the treatment of a new indication;
- a new therapeutic application based on the group of subjects to be treated;
- a new therapeutic application based on a different mode of administration;
- a new therapeutic application based on a dosage regimen; and
- a new therapeutic application based on a different technical effect.

There is no Swiss case law concerning specific questions of the enforcement of second medical use claims. In its *Alendronic acid* decision of March 4 2011,¹⁰ however, the SFSC stated that the scope of the use-related product claims under the EPC also includes the prescription of pharmaceutical products by Swiss physicians. In the aftermath of this decision, the Swiss legislature has suggested amendments to the PatA to exempt prescribing doctors from patent-infringing activities. These amendments are likely to take effect by mid-2017 (see also section 11 below).

2.5 Methods of treatment

Methods of treatment claims are not available for either Swiss national patents or European patents. Article 53 lit c of the EPC states that European patents shall not be granted in respect of methods for treatment of the human or animal body by

⁹ See EPO EBA, decision of February 19 2010, G2/08 – *Dosage regime/Abbott Respiratory*.
¹⁰ SFSC, decision of March 4 2011, 4A_435/2010 – *Merck & Co v Mepha*.

surgery or therapy and diagnostic methods practised on the human or animal body. The corresponding provision in Article 2, paragraph 2 lit of the PatA is almost identical. Under Swiss practice, a single medical procedural step already suffices in order to exclude patentability. Thus, when considering diagnostic method claims for Switzerland, it is important not to include the step of treating the subject with the drug. Alternatively, claims can be reformatted as second medical use claims.

2.6 Formulations and physical forms

Formulations and physical forms of pharmaceutical products are basically patentable in Switzerland, provided that they satisfy the criteria of novelty and inventive step when compared to an already existing formulation or physical form. In addition, there is an inherent risk of the new formulation or physical form being deemed to be an equivalent infringement of an existing patent.

2.7 Reach-through claims

Reach-through claims (both product claims and process claims) may be protected in Switzerland, provided that the final product is marketed through its (bio-) chemical characteristics together with its biological effect and its physical characteristics. Besides industrial applicability, the description of the invention must also address how the products can be identified according to their structural characteristics and how they may be built. The claims themselves must be formulated in such a way that the products might be unambiguously identified (eg, on the basis of the sequences).

This is an extract from the chapter 'Switzerland' by Esther Baumgartner, Christoph Berchtold, Simon Holzer and Kilian Schärli in Intellectual Property in the Life Sciences: A Global Guide to Rights and Their Applications, Second Edition, published by Globe Law and Business.