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Second medical use or indication claims (Q 238)

REPORT OF SWISS GROUP*

Questions

I. Current law and practice

1. Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

Yes.

2. If the answer to Question 1. is yes, please answer the following sub questions.

a) What is the basis for patent protection?

For Swiss national patents:

- Before 1 July 2008: Case law of the Swiss patent office which introduced protection for second medical uses by means of what became known as the Swiss-type claim format.
- As of 1 July 2008: Article 7d Patent Act which codified the earlier practice.

For European patents:

- Before 13 December 2007: Case law of the Enlarged Board of Appeal (G 5/83) which confirmed patentability of second medical uses in the form of the Swiss-type claim format.
- As of 13 December 2007: Article 54(5) EPC which permits protection by means of purpose limited product claims. European patents have the same effects in Switzerland as a Swiss national patent.

b) What types of second medical use are patentable? See, for example, paragraphs 14)–17) above/WGLs.

According to case law of the Swiss Federal Supreme Court (BGE 137 III 170) and of the Enlarged Board of Appeal (G 2/08):

- a new therapeutic application (in general);
- 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;
- a new therapeutic application based on a different technical effect.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14)–17) above/WGLs.

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To the knowledge of the Swiss group there is no case law denying patentability of specific second medical uses.

For the sake of completeness it should be reminded that the general exclusions from patentability (in particular of 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) also apply to second medical use inventions.

d) *What forms of second medical use claims are permissible? See, for example, paragraphs 26)–33) above/WGLs.*

For Swiss national patents: The Swiss patent act prescribes the Swiss-type claim format.

For European patents: The EPC allows for the purpose limited product claim format; in G 2/08, the Enlarged Board of Appeal held that the Swiss-type claim format is no longer available.

e) *What forms of second medical use claims are not permissible? See, for example, paragraphs 26)–33) above/WGLs.*

See above answers ad d) e contrario: For Swiss national patents, all claim formats other than the Swiss-type claim format are not permissible, while for European patents all claim formats other than the purpose limited product claim format are not permissible.

In particular, method of treatment claims are not available both for Swiss national patents and for European patents. Article 53(c) EPC states: “European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”. The respective provision in the Swiss patent act (Article 2(2)(a)) is practically identical.

f) *Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of ‘treatment’, ‘treating’ or ‘use to treat’ integers in second medical use claims? See, for example, paragraphs 34)–39) above WGLs.*

No.

3. If your country permits second medical use claims:

a) *Who may be liable for infringement of such claims?*

i) *For example: the party marketing the drug with label instructions which describe the patented use;*

ii) *the physician prescribing the drug for such use;*

iii) *the pharmacist dispensing a drug for such purpose;*

iv) *the patient using the drug for such purpose?*

	Swiss-type claim		Purpose-limited product claim	
	Direct infringement	Contributory infringement ¹	Direct infringement	Contributory infringement ²
Patient taking the drug for the patented use	No (private use exemption; see question)		No (private use exemption; see	

¹ Under Swiss law, liability for contributory infringement requires that the person in question contribute to an act that qualifies as illicit direct infringement.

² See fn. 1.

	3)b)		question 3)b)	
Physician prescribing the drug for the patented use	Possibly no (obiter dicta in EBA G 2/08 ³ and Swiss Federal Supreme Court judgment BGE 137 III 170)		Probably yes (untested in Switzerland)	
Pharmacist dispensing a drug for such purpose	Possibly no (obiter dicta in EBA G 2/08 and Swiss Federal Supreme Court judgment BGE 137 III 170)		Probably yes (untested in Switzerland)	
Party manufacturing and/or marketing the drug with label instructions which describe the patented use	Yes		Yes	
Party manufacturing and/or marketing the drug with label instructions which do not describe the patented use, if drug is then dispensed for patented use (cross-label use)		Possibly no because there is no direct infringement		Probably yes because there is direct infringement by physicians and pharmacists; provided, however, that further requirements for contributory infringement are fulfilled

b) *Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?*

The Swiss patent act provides for the following privileges that may be relevant in the context of the infringement of second medical use claims:

- Article 9(1)(a) provides for a private use exemption. A patient taking a non-patented substance for a patented second medical use is exempt from infringement under this provision.
- Article 9(1)(b) states a research and experimental use exemption. Accordingly, whoever uses a non-patented substance in the research related to a patented second medical use is exempt from infringement.
- Article 9(1)(c) contains a Bolar-type exemption. Whoever makes use of a second medical use claim in the context of obtaining the marketing authorization for a non-patented substance for a patented second medical use is exempt from infringement.

One chamber of Swiss parliament accepted proposed additional Articles 9(1)(g) and 9(1)(h) which would exempt from infringement (i) any act involving a medicament performed in the context of medical practice and (ii) the preparation of drugs in pharmacies on the basis of a medical prescription. These provisions are intended to ensure that physicians and pharmacists do not become liable for infringement of a second medical use claim in the purpose limited product claim format by prescribing, dispensing and preparing a medicament. If these exemptions are enacted, the second, third and last lines in table 2 change above.

³ Consideration 6.5: "In respect of second and further medical indications the EPC now allows use-related product claims directed to the substance itself whereas under EPC 1973 decision G 5/83 allowed claims directed to the use of a substance for the manufacture of the drug for a therapeutic indication ("Swiss-type claims"). It appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics."

Although the Swiss group had filed a third party observation suggesting introducing these additional privileges not in the form of exemptions from infringement but as defenses against enforcement, this suggestion had not been taken into account. The Swiss group's suggestion aims at preventing the privileges from also benefitting manufacturers and suppliers of skinny labeled generics.

c) *Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.*

	Swiss-type claim		Purpose-limited product claim	
	Direct infringement	Contributory infringement ⁴	Direct infringement	Contributory infringement ⁵
Physician prescribing the drug for the patented use	Possibly no (obiter dicta in EBA G 2/08 and Swiss Federal Supreme Court judgment BGE 137 III 170)		Probably yes (untested in Switzerland) <u>No</u>	
Pharmacist dispensing a drug for such purpose	Possibly no (obiter dicta in EBA G 2/08 and Swiss Federal Supreme Court judgment BGE 137 III 170)		Probably yes (untested in Switzerland) <u>No</u>	
Party manufacturing and/or marketing the drug with label instructions which do not describe the patented use, if drug is then dispensed for patented use (cross-label use)		Possibly no because there is no direct infringement		Probably yesno because there is no direct infringement by physicians and pharmacists; provided, however, that further requirements for contributory infringement are fulfilled

4. If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

This primarily depends on whether the summary of medicinal product characteristics (SMPC) and the patient information leaflet (PIL) contain any reference to the patented indications. A generic drug with SMPC/PIL referring to the patented indications is considered to fall within the scope of protection of a second medical use claim. Making, supplying or otherwise using such generic drug constitutes a direct infringement.

If the SMPC/PIL do not refer to the patented indication, making, supplying or using the drug may constitute contributory infringement, as set out in the above tables. Liability as contributory infringer would further require that the respective person knows, should know or promotes such use.

5. If the answer to Question 4. is yes, please answer the following sub questions in that context.

a) *Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts constitute infringement.*

Yes.

b) *Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?*

Yes.

c) *If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?*

It is required that the party knows, should know or promotes an infringing use.

d) *If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.*

See 5.c.

6. How do the courts determine infringement of a second medical use claim? What are the legal tests and evi-dentiary requirements?

There is no pertinent Swiss case law.

7. What relief is available for infringement of a second medical use claim:

a) *at a preliminary/interim/interlocutory level?*

There is no pertinent Swiss case law. Generally, Swiss law provides for the following preliminary relief: preliminary injunction and preliminary taking of evidence.

b) *by way of final relief?*

There is no pertinent Swiss case law. Generally, Swiss law provides for the following final relief: permanent injunction and monetary relief (damages, reasonable royalty or account of profits).

8. In respect of Question 7.a), can a preliminary/interim/interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

If the product packaging mentions the patented second medical use, preliminary relief should be available on that basis.

If the product packaging does not mention the patented second medical use, the question arises whether a prescription will suffice to establish that the drug has been dispensed by the pharmacists for the patented second medical use. In Switzerland, prescriptions typically name the prescribed drug by its brand name or the INN of the active ingredient, and they mention the dosing. Typically, they do not name the medical indication for the treatment of which the drug is prescribed. Depending on the specific circumstances, a prescription may, therefore, establish that a drug has been dispensed for a patented dosage regime, a patented form of administration or to a patented group of subjects, but it will most likely not suffice to establish that the drug has been dispensed for a patented indication. Most likely, additional evidence will be necessary. There is, however, no pertinent Swiss case law that addresses these issues.

Presently, a physician does not need to write a prescription if he directly dispenses the drug to the patient.

9. In respect of Question 7.b), what level of proof is required to obtain a final injunction?

There is no pertinent Swiss case law.

II. Policy considerations and proposals for improvements to your current law

10. If your country permits second medical use claims, please answer the following sub questions.

a) *What are the policy reasons behind permitting such claims?*

The Swiss patent office did not give policy reasons when it admitted the Swiss-type claim format for the protection of second medical use inventions in 1984. The Enlarged Board of Appeal held the following when it adopted that claim format in G 5/83:

“No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention; nor can it be deduced from the legislative history of the articles in question.”

It is the understanding of the Swiss group that the policy reasons for permitting protection of second medical use inventions are that such inventions may provide benefits that are as important and desirable as any other inventions in the field of health care. The industry should be incentivized to allocate research funds also to the improvement of existing drugs, e.g. by reducing side effects or enhancing patient compliance, and to the search for further applications of existing drugs.

b) *Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?*

There is no broad consensus on this in Switzerland. On the one hand, the Federal Supreme Court and representatives of the Swiss patent office are concerned that the purpose limited product claim format envisaged by the EPC will restrict the freedom of medical practitioners to prescribe or administer generics. The above-mentioned proposal for the adoption of additional exemptions from infringement (proposed Articles 9[1][g] and 9[1][h]) is the Swiss government's response to this concern.

The pharmaceutical industry, on the other hand, takes a different view. The claim format is only one element that determines the scope of protection actually conferred by a patent. Further elements that need to be taken into account are statutory exemptions, the statutory requirements for liability as contributory infringer, and, above all, the regulatory framework. As shown in the above tables, the adoption of the additional exemptions proposed by the Swiss government would have the effect that a second medical use claim – regardless of whether such claim is in the Swiss-type claim or in the purpose limited product claim format – may not be enforced against a generic company providing a skinny labeled generic that is then used cross-label for the patented second medical use. This is considered problematic in particular because the regulatory framework in Switzerland encourages patent-infringing cross-label use in such circumstances: doctors do not need to indicate the use on the prescription; pharmacists are encouraged to dispense generics rather than branded drugs; because the prescription does not indicate the intended use, the pharmacist is not in a position to verify compliance of the intended use with the label of the dispensed generic; health insurance companies reimburse cross-label use of a generic. So while the regulatory framework encourages patent infringing uses, it is feared that patent law alone will not provide the adequate means to effectively counter such infringing uses.

c) *Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?*

See answer to b).

d) *If there is any empirical or anecdotal data available, please address the following.*

i) *What is the prevalence of second medical use claims in your country?*

Very many pharmaceutical patents in force in Switzerland contain second medical use claims.

ii) *What is the profile of patentees for second medical use claims in your country?*

Patentees include universities, start-ups and established research-oriented pharmaceutical companies.

11.If your country does not permit second medical use claims, please answer the following sub questions.

- a) *What are the policy reasons behind not permitting such claims?*
- b) *Would such claims serve the interests of relevant stakeholders?*
- c) *Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?*

12.To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

There is no empirical data available.

It is believed that the fact that patent protection for second medical uses is available strengthens Switzerland in patent-related negotiations with third countries.

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.

13.Is it desirable to permit second medical use claims?

Yes. Permitting second medical use claims alone does, however, not ensure that the pharmaceutical industry is actually incentivized to further develop and improve known drugs and that the availability of second medical use patents there-fore attains its goal. This also depends on the scope of applicable privileges (exemptions), on the requirements for con-tributory infringement, on the available remedies and on the regulatory framework.

14.Is harmonisation of laws relating to second medical use claims desirable?

Yes. For the above reasons, harmonization should, however, not be limited to the specific claim format but include all aspects that determine the actual protection conferred by such a claim. What should be harmonized is not only the format of the available claim but the protection it confers.

15.Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

- a) *Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14)–17) above/WGLs.*

The Swiss group sees no reasons for limiting the types of second medical uses that may be permissible subject matter. Rather, the limits should be drawn by the standard requirements for patentability, in particular the requirements of novelty and inventive step.

- b) *Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14)–17) above/WGLs.*

See answer to a).

- c) *Form of permissible claims. See, for example, paragraphs 26)–33) above/WGLs.*

It is the view of the Swiss group that the claim format is less important than the actual scope of protection conferred by a second medical use claim. Nevertheless, the Swiss group favors the purpose limited product claim formats.

d) *Form of impermissible claims. See, for example, paragraphs 26)–33) above/WGLs.*

As long as one of the formats named under c) is permissible, the Swiss group sees no reasons for not allowing also other formats.

e) *Who may be liable for infringement?*

It is the view of the Swiss group that anybody should be liable who (i) prepares or supplies a drug with instructions referring to the patented second medical use or (ii) prepares or supplies a drug with instructions that do not refer to the patented second medical use but otherwise promotes such use or at least knows or, in light of the circumstances, should know of such use but does not take adequate measures to prevent such use.

f) *Any parties/institutions that should be exempted from infringement or liability for infringement.*

It is the view of the Swiss group that it is not necessary to exempt certain parties or institutions from liability. It would suffice to provide that second medical use claims may not be enforced against certain parties or institutions, e.g. against patients, doctors and pharmacists.

g) *Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.*

- Preparing or supplying a drug with instructions referring to the patented second medical use.
- Promoting for a patented second medical use a drug with instructions that do not refer to the patented second medical use.
- Preparing or supplying a drug with instructions that do not refer to the patented second medical use if the respective person knows or should know in light of the circumstances that the drug is in fact used for the patented second medical use but does not take adequate measures to prevent such use.

h) *Relief available upon a finding of infringement:*

i) *at a preliminary/interim/interlocutory level; and*

ii) *by way of permanent relief.*

Standard remedies as in any other case of patent infringement.

i) *In each case for h)i) and h)ii), the level of proof for the granting of such relief.*

Standard level of proof as in any other case of patent infringement.

Summary

Second medical uses, e.g. the treatment of a new indication, the treatment of a new group of subjects, a different mode of administration, a new dosage regimen or a new therapeutic application based on a different technical effect, may be protected in Switzerland by way of a Swiss national patent or a European patent. The claim format prescribed by the Swiss patent act for a Swiss national patent is the Swiss-type claim format, while under the EPC only the purpose limited product claim format remains available. Possibly, the rights conferred by the two formats differ, the purpose limited product claim

format potentially providing broader protection. So far, this has, however, not been analyzed in detail in Swiss case law or literature.

Zusammenfassung

Eine zweite medizinische Anwendung, z.B. die Behandlung einer neuen Indikation, die Behandlung einer neuen Patientengruppe, eine neue Verabreichungsform, ein neues Dosierungsregime oder eine neue Anwendung beruhend auf einem anderen technischen Effekt, kann in der Schweiz mittels eines nationalen schweizerischen oder eines europäischen Patents geschützt werden. Das schweizerische Patentgesetz schreibt dabei für nationale Patente die sogenannte schweizerische Anspruchsform vor, während unter dem EPÜ nur noch das Format des zweckgebundenen Stoffanspruchs zur Verfügung steht. Möglicherweise hat ein für eine zweite medizinische Anwendung erteilter Swiss-type claim in einem Schweizer Patent einen kleineren Ausschlussbereich als ein unter dem EPÜ für dieselbe Erfindung erteilter zweckgebundener Stoffanspruch eines europäischen Patents. Rechtsprechung und Literatur haben dies bisher allerdings nicht im Detail analysiert.

Résumé

Les deuxièmes utilisations thérapeutiques, p.ex. le traitement d'une nouvelle indication, le traitement d'un nouveau groupe de patients, un mode d'administration différent, une nouvelle posologie ou une nouvelle application thérapeutique basée sur un effet technique différent, peuvent être protégées en Suisse par le biais d'un brevet national ou d'un brevet Européen. Le format des revendications, tel que prescrit par la loi suisse sur le brevet d'invention (LBI), dans le cas d'un brevet national suisse est le format de type suisse, alors que seul le format de revendications de produit limitées à une certaine fin reste admis par la CBE. Il est possible que les droits conférés par ces deux formats diffèrent; la revendication de produit limitée à une certaine fin fournissant potentiellement une protection plus large. Jusqu'à présent, cela n'a cependant pas été analysé en détail dans la jurisprudence suisse ou dans la littérature.