

Concerns over proposed patent exemption for physicians and pharmacies in Switzerland

By Mark Schweizer, Reinhard Oertli and Simon Holzer

The Swiss lawmaker plans to introduce a new exemption from patent protection for physicians and pharmacies. The new exemptions aims to protect physicians and pharmacies from being involved in patent disputes concerning second medical use claims according to the EPC 2000 (purpose-limited product Claims).

From Swiss-type claims to purpose-limited product claims

As is well know, the Enlarged Board of Appeal of the European Patent Office held in a widely reported decision that under the European Patent Convention in the version adopted in 2000, which entered into force on 13 December 2007, claims to a second or further medical use of known pharmaceutical products could no longer take the form “use of a substance or composition X for the manufacture of a medicament for use in treatment of Y” (so called “Swiss type claim” or “Swiss type of use claim”). For applications filed after 29 April 2011, second and further medical uses have to be claimed as purpose-limited product claims, i.e., “substance or composition X for use in the treatment of Y” (see [G2/08](#)).

Concerns for freedom of medical practitioners in their therapeutic choices

The new claim form raised immediately the concern whether physicians would infringe such claims to a second or further medical use when they prescribe a known drug for treatment of Y falling under a patent. The Enlarged Board of Appeal saw such a risk, but considered it no reason to disallow purpose-limited product claims for second and further medical uses. It dryly stated that “[i]f deemed necessary, the freedom of medical practitioners may be protected by other means on the national level.” (G 2/08, Reason 6.5).

The Swiss Federal Supreme Court shared the Enlarged Board of Appeal’s concern and was even more explicit in its recommendation: if physicians’ activities were considered worth sheltering from liability for patent violation, the legislator should introduce an exemption to the effects of a patent ([DFT 137 III 170 sect. 2.2.12](#)).

Subsequently, the Swiss Federal Council tasked the Institute for Intellectual Property with the assessment whether a special exemption for medical personnel was to be considered, taking into account the views of the concerned physicians and pharmaceutical companies, and making a suggestion for an amendment of the law if need be.

The Institute for Intellectual Property [suggested an addition to art. 9 of](#)

[the Swiss Patent Act](#), which lists the exemptions to the effects of the patent:

“The effects of the patent do not extend to

g. acts in the course of medical practice relating to a single person or a single animal and concerning pharmaceuticals, namely the prescription, administration or use of pharmaceuticals, by licensed persons;

h. the immediate single preparation of pharmaceuticals in pharmacies following a medical prescription and acts that concern the pharmaceuticals thus prepared.”

Concerns for scope of protection of patents for second and further medical uses

The proposed amendment of the Swiss Patent Act may achieve more than it intends: rather than only shielding physicians and pharmacies from patent liability, it may essentially shield commercial generic companies from liability for any activity related to off-label or cross-label use of their generics. The reason lies in the Swiss conception of indirect patent infringement, which is primarily a contributory infringement. Persons taking part in, aiding, abetting, facilitating or instigating patent infringement are liable for contributory patent infringement ([art. 66\(d\) Swiss Patent Act](#)). However, if there is no principal (i.e. direct) infringement of a patent in Switzerland, it could be argued that there is no contributory infringement, because promoting, facilitating and assisting in a legal act cannot be illegal.

Since the proposed amendment of the Swiss Patent Act exempts the actions of physicians and pharmacists from the scope of protection of the patent, their acts are legal. Hence, a pharmaceutical company that supplies a known drug to a doctor, might not infringe the purpose limited product claim format even if it knows or has reason to know that the doctor will use the drug for a patented medical use (“treatment of Y”): the concerned pharmaceutical company does not use the substance to treat Y, and its actions therefore do not fall within the scope of the purpose limited product claim. The physician who actually uses the substance to treat Y does nothing illegal, as his actions are exempted by the proposed art. 9(g) Swiss Patent Act.

The question now is whether the pharmaceutical company can rely on this exemption *even when it advertises the substance for the patented use* and thereby undoubtedly facilitates and even instigates the use of its drug for a medical use that falls under the patent.

Extending the exemption to such acts would go much further than protecting the medical practitioners’ therapeutic freedom and would eliminate essentially any protection conferred by purpose limited product claims for known pharmaceutical products.

Alternative option: shielding physicians from liability

It has therefore been suggested that rather than exempting physicians and

pharmacists from the scope of protection of the patent, they should only be exempted from liability for patent infringement, similar to the [legal situation in the United States](#). In other words, physicians would still infringe the patent, and their acts would still be illegal, but they could not be held liable, therefore effectively shielding them from any patent infringement action. The principal advantage of this approach is that it would leave pharmaceutical companies that advertise a known pharmaceutical product for a patented use liable for contributory infringement.

Current state of the proposal

This alternative has not been accepted, however. The Institute of Intellectual Property's proposal has been accepted by the Swiss Parliament. Although the bill has not become final, it is highly unlikely that any changes will be introduced to the proposed amendment at this late stage of the legislative process.

Liability for advertisement of patented medical use

Advertising a known substance for a patented second use or any further use ("treatment for Y") by a manufacturer or distributor of a generic drug violates the Swiss part of a European patent covering the use of that substance for treatment of Y.

Under Swiss patent law, also offering for sale and marketing of a patented invention fall under the protection of a patent. And advertising a drug for a patent-protected use cannot be considered otherwise than as offering for sale and marketing "X for use in the treatment of Y", which is protected by the patent. Thus, a party that manufactures and/or markets its drug with label instructions which describe the patented use commits an independent (i.e. direct) violation of the concerned patent.