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The impact of public health issues on exclusive patent rights (Q 202)

REPORT OF SWISS GROUP*

I. Analysis of current law and case law

Preamble:

The answers are given based on the revised Swiss Patent Law (PL) which is foreseen to enter into force on July 1, 2008.

1. Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

Yes, while Art. 9, par. 1 lit. a PL deals with exemption for uses in the private sphere, lit. b deals with research and experimental use:

1 The effect of the patent does not extend to

a. …

b. acts for the purpose of research and experimentation, which serve to gain insight about the object of an invention including its uses; in particular any scientific research on the object of the invention is allowed;

… (non-official translation)

Accordingly scientific or experimental research for gaining further insights into the patented invention is allowed even if the focus of the experiments is commercial. This is in line with German case law of the BGH "Klinische Versuche I (1995)" and "Klinische Versuche II (1997)".

The materials for the law revision expressly indicate that scientific research is exempted also if experiments are done with a commercial aim, as long as they serve to obtain insight into the patented invention. The exception not only covers basic research, but also applied research; however, stockpiling seems to be excluded. Further to that, Art. 40b PL grants a licence of right under patents protecting biotechnology research tools (see below). Research and experiments in the field of medicines is dealt with in a separate paragraph of the law to minimize uncertainties, see question 2), "Bolar-type exception".

However, the precise scope of the exception and the limit between forbidden and allowed commercial use is still subject to legal interpretation by the courts.

2. Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?

Yes. Further the general research and experimental exception of Art. 9, par.1, lit. b PL (Question 1), lit. c expressly deals with uses connected with requests for marketing authorisation:

1 The effect of the patent does not extend to

…

c. acts required for the obtainment of a market authorisation of a medicament in Switzerland or in a country with a comparable drug control system;

… (non-official translation)

As can be seen from the materials, this exception covers all experiments done in view of a request for a marketing authorization, such as pre-clinical and clinical testing, production, import and storage of samples and validation batches for the purpose of registration, except stockpiling as defined in the WTO dispute settlement panel EU v. Canada of 2000 (WT/DS114/R). During discussion in parliament the article was amended to include not only acts done in view of requests of marketing authorization in Switzerland, but also as required by the drug agencies of other countries with a comparable system for marketing authorization. No definition is available what "comparable" means in this respect. There is no doubt that experiments in view of registration in a EU country (and in the US) are included, since harmonization with the legal framework in the European Union (article 8 of Directive 2004/27/EC of March 31, 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use) was intended.

The law uses the expressions "Arzneimittel" (German), "médicament" (French), "medicamento" (Italian). As far as biological products are concerned it is the position of the Swiss group that they do fall under the exception as long as their commercialisation requires authorization by the respective authorities, but it remains open whether medical devices are covered. It may be noted in this respect that the Swiss law on medicaments and medicinal products makes a distinction between medicaments (drug products of chemical or biological origin) and medicinal products (medical devices, instruments, in vitro diagnostics, software and other objects for medicinal use).

Since the exploitation of patented Research Tools such as screening assays as a rule do not require any market authorization their application seems not to be exempted under Art. 9 par. 1 lit. c PL.

Again the precise scope of the exception and the limit between forbidden and allowed commercial use is still subject to legal interpretation by the courts.

3. Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

Switzerland does not allow parallel import of patented goods. The principle of national exhaustion of patented goods is applied following the jurisdiction of the Federal Supreme Court in its judgement of 7.12.1999 (Kodak SA vs. Jumbo Markt AG).

The revised Swiss Patent Law does not contain an explicit ruling of parallel imports. In fact the proposed Article 9a par. 1 PL has been removed in the current revision of the patent law.

Art. 9a PL which rules misuse and which in principle allows international exhaustion for patented goods where patent protection plays a minor role remained. This article seems to support the principle of national exhaustion in Switzerland.

In light of Swiss antitrust legislation market foreclosure is forbidden. Swiss Federal Cartel Statute article 3 exempts from its applicability on the one hand all effects deriving from the laws on intellectual property rights but states expressly that import limitations are subject to the Cartel Statute.

It is the position of the Swiss Group that the same principle, i.e. national exhaustion, applies, if the products originate from markets where they were made available under a compulsory license.

4. Is an individual prescription exception recognised under your patent law? If so, under which conditions?

No, the Swiss Patent Law does not know a ruling similar to e.g. in Germany with §11(3) German Patent Law.

5. Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?

Methods of medical treatment are not patentable subject matter in Switzerland.

6. Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.

Existing Art. 40 of the Swiss Patent Law foresees that licenses are available on public interest in case a patentee declines to grant a license without plausible reasons.

The revised Swiss Patent Law added Art. 40 b which rules that a license of right can be obtained for research tools and Art. 40 c PL which states that a compulsory license is available for diagnostic products or diagnostic processes.

However, no actual cases of compulsory licenses are known in Switzerland, thus an interpretation of the law by the courts is lacking.

7. Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003?

Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

Yes, Article 31bis TRIPS has been translated into Art. 40 d of the revised Swiss Patent Law which foresees the availability of a compulsory license for the manufacture of patented pharmaceutical products for export to a country which has no or insufficient capacities to manufacture.

Switzerland declared that it will not use the system as importing member for the purposes of Article 31bis TRIPS and its Annex.

However, no actual cases of compulsory licenses are known in Switzerland, thus an interpretation of the law by the courts is lacking.

8. Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

No!

9. Is the government allowed to expropriate a patent and, if so, under which conditions?

Yes. Art. 32 Swiss Patent law allows the Federal Government to expropriate a patent, if the public interest requires so. The patentee has a right for full compensation. No actual cases of patent expropriation are known.

10.If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.

No!

II. Proposals for adoption of uniform rules

1. Should patent law provide for

– *Research and experimental use exception*

The Swiss group is of the opinion that patent law should provide for a limited research and experimental use exception. The exception should not be dependent on whether results of such research may be or will be used commercially, but whether such use leads to a gain of scientific knowledge

and/or practical insight into the patented invention. The exception should not cover the use of a patented invention as a tool in research on other objects.

– *Bolar exception*

The Swiss group is of the opinion that patent law should provide for a Bolar-type exception. The exception should exempt all acts done in preparation for a request of marketing authorization. Such Bolar-type exception falls under the general research and experimental use exception as defined in the preceding paragraph, but further allows the use of patented inventions in bioequivalence studies, batch validation and the like going further than a general research exception. The Bolar-type exception should not allow stock-piling and preparation for large scale manufacturing going beyond batch validation.

– *Parallel import of patented medicines:*

The Swiss group is of the opinion that patent law should not allow parallel import of patented medicines. In almost all countries the drug market is highly regulated, imposing price limits and other restrictions. Parallel imports would only mean that such state interventions into the drug market are exported to other countries. In the end the parallel importers would benefit from price differentials at the cost of the patent owner, and usually without or only with very limited benefit for the end user and the health system as a whole. Moreover, parallel import bears the danger of supply shortages in low-price countries and should therefore be seen as an obstacle rather than a means of facilitating access to medicines.

– *Individual prescriptions exception*

The Swiss group is of the opinion that there is no need for the patent law to provide a ruling for individual prescription exceptions.

– *Medical treatment defence*

Since in Switzerland methods of medical treatment are not patentable subject matter no answer can be provided for this question.

– *Compulsory licensing*

The Swiss group is of the opinion that the patent law shall allow compulsory licensing. The measures for compulsory licenses shall comply with the TRIPS rules provided by the WTO.

– *Expropriation*

The Swiss group is of the opinion that patent law should not allow expropriation of a patent. The measure of compulsory licenses as defined in the TRIPS agreement gives enough flexibility for states in a health emergency to deal with patent owners unwilling to cooperate in solving such an emergency.

– *Any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like? If so, under what circumstances? If not, why not?*

See 2) below.

2. Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?

The Swiss group is of the opinion that patents are not an obstacle to the access to medicines but to the contrary stimulate research and ensure that new medicines are found and brought to the market. Patents form the essential framework of the research-based industry and, in view of the substantial investments in time and capital and the high risk of failure, are vital to sustain continued R & D into

new treatments. Because of patents as an incentive to find and market new medicines, the general public profits by having access to better medical treatment. Moreover, patent applications are published, providing thus transparency of the research done. Sharing this information with the scientific community forms the basis of the generation of more knowledge and further development of new and innovative products. Without patent protection of the published research, any dissemination of innovation, and thus, faster progress in the development of new medicines, is highly unlikely. It is therefore apparent that the notion that patents hinder the access to new medicines is a misconception.

The present provisions in the law, namely the research exception, the Bolar exception as well as compulsory licenses in emergency situations, are sufficient to facilitate further the access to medicines without destroying the incentive to spend enormous amounts of time and money to develop new medicines and to share information on such innovations. In fact they strike a fine balance between rewarding innovation without unduly monopolizing same.

It should be borne in mind that the major impact on the accessibility of medicines is not due to patent protection. Consequently, no further limitations to the exclusivity conferred by patents are required. Most of the drugs classed by the WHO as essential drugs are either available off-patent or are not patent protected, yet over a third of the world's population still has no access to these essential drugs. Access to medicines is rather facilitated by a combination of appropriate development policies, health policies, best practices applied in the health system, a rational use of medicines, and adequately funded health services. The patent law does not affect any of these.

3. Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?

The Swiss Group is of the opinion that a harmonization of the major exceptions, namely the Bolar exception and the experimental use exception, would be desirable in view of ensuring fair conditions of competition between different countries. Harmonization would also lead to more legal certainty which can only be beneficial for everyone involved and would avoid or at least minimize national legal disputes.

However, any harmonized ruling should not go beyond reliable boundaries as e.g. outlined above for the experimental use exception in the answer to question 1 and for the Bolar exception in the answer to question 2.

Summary

The revised Swiss Patent Law, which should enter into force on July 1, 2008, foresees a research exception. Scientific or experimental research for gaining further insights into the patented invention are allowed even if the focus of the experiments is commercial. Also experiments done in view of a request for a marketing authorization for pharmaceuticals in Switzerland and in countries with a comparable system are exempted. However, this exception seems to be restricted to drugs of chemical or biological origin and does not encompass medicinal devices. Parallel imports of patented pharmaceuticals are not allowed. Under the revised Swiss Patent Law it is possible to get a compulsory license not only for reasons of public interest, but also for research tools and diagnostic products and processes, and for export of pharmaceuticals to countries with no or insufficient manufacturing capacity in line with TRIPS Art. 31bis.

The Swiss group is of the opinion that research and experimental use exception and Bolar-type exception should be internationally harmonized. Any rules on compulsory licensing should comply with the conditions set out in TRIPS. In our opinion patents are not an obstacle to the access to medicines but to the contrary stimulate research and ensure that new medicines are found and brought to the market. Because of patents the general public profits by having access to better medical treatment. A research exception, Bolar exception as well as compulsory licenses in emergency situations strike a fine balance between rewarding innovation without unduly monopolizing same.

Zusammenfassung

Das revidierte Schweizer Patentgesetz, das am 1. Juli 2008 in Kraft treten soll, sieht eine Ausnahme für Forschung vor. Wissenschaftliche Forschung und Versuche mit dem Ziel, weitere Einsichten in eine patentierte Erfindung zu gewinnen, sind zugelassen, auch wenn die Zielsetzung kommerziell ist. Versuche im Hinblick auf einen Zulassungsantrag für Vermarktung von Pharmazeutika in der Schweiz und in Ländern mit einem vergleichbaren System sind auch zugelassen. Diese Ausnahme scheint jedoch auf Medikamente chemischen oder biologischen Ursprungs beschränkt zu sein und nicht für medizinische Geräte zu gelten. Parallelimporte von patentierten Pharmazeutika sind nicht zugelassen. Unter dem revidierten Schweizer Patentgesetz ist es möglich, eine Zwangslizenz nicht nur aus Gründen öffentlichen Interesses, sondern auch für Forschungshilfsmittel, diagnostische Produkte und Verfahren und für den Export von Pharmazeutika in Länder ohne oder mit ungenügender Herstellungskapazität gemäss Art. 31bis TRIPS zu erlangen.

Die Schweizer Gruppe ist der Ansicht, dass die Ausnahme für Forschung und für die Vorbereitung der Marktzulassung von Pharmazeutika international harmonisiert werden sollte. Regeln zu Zwangslizenzen sollten in Einklang mit den Bedingungen in TRIPS sein. Unserer Meinung nach sind Patente kein Hindernis für den Zugang zu Medikamenten, sondern fördern im Gegenteil die Forschung und sichern damit, dass neue Medikamente gefunden und auf den Markt gebracht werden. Wegen Patenten profitiert die Öffentlichkeit vom Zugang zu besserer medizinischer Behandlung. Ausnahmen für Forschung und für die Vorbereitung der Marktzulassung sowie Zwangslizenzen in Notlagen ergeben ein Gleichgewicht der Belohnung für Innovationen ohne ungehörige Monopolisierung.

Résumé

La loi suisse des brevets d'invention modifiée, qui doit entrer en vigueur le 1 juillet 2008, comptera une exemption expérimentale. La recherche expérimentale ou scientifique servant à obtenir des connaissances sur l'objet de l'invention est permise même si l'intérêt des expérimentations est commercial. Les actes expérimentaux, en vue de l'obtention d'une autorisation de mise sur le marché pour un médicament en Suisse ou dans un pays possédant un système comparable, sont également exemptés. Toutefois, cette exemption parait être limitée aux médicaments d'origine chimique ou biologique et n'inclut pas les dispositifs médicaux. Les importations parallèles de médicaments brevetés ne sont pas autorisées. D'après la loi de Brevet Suisse modifiée, il est possible d'obtenir une licence obligatoire non seulement pour des raisons d'intérêt public, mais également pour des instruments de recherche, des produits ou procédés de diagnostic, et pour l'exportation de produits pharmaceutiques vers un pays n'ayant aucune ou une capacité insuffisante de fabrication en accord avec l'art. 31bis des accords TRIPS.

Le groupe Suisse est d'avis que l'exemption des actes de recherche et d'utilisation expérimentale, ainsi que l'exemption dite de Bolar devraient être harmonisées au niveau international. Toutes les lois de licences obligatoires devraient se conformer aux conditions visées dans les accords TRIPS. Nous sommes d'avis que les brevets ne sont pas un obstacle à l'accès aux médecines, mais au contraire, encouragent la recherche et assurent la découverte et l'introduction sur le marché de nouveaux médicaments. C'est par le biais des brevets que le public bénéficie d'un accès à de meilleurs traitements médicaux. L'exemption des actes à titres expérimentaux, l'exemption de Bolar ainsi que les licences obligatoires dans des situations d'urgence, permettent un juste équilibre entre une récompense de l'innovation et un monopole trop injuste de celle-ci.

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