Austria
Autriche
Österreich

Report Q202

in the name of the Austrian Group
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The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

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?*

Austrian Law does not feature a general research or trial exception in its patent law.

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?*

Section 22 of the Austria Patent Act 1970 (Federal Law Gazette 1970/259 – *'Patentgesetz 1970' or 'PatG'*) outlines the effects of a patent, giving the patentee the exclusive authority to produce, to circulate, to keep for sale, to use and to import for any of the aforementioned actions or to own goods according to the patent granted. Even though the patent confers exclusive authority, a patentee is in the execution of the patent pursuant to Sec. 30 PatG still bound by substantive Austrian law, for example, covering drugs and medicines. "Use" as understood by Austrian Patent law, is every use within a business enterprise; solely use for personal purposes, home use and use for teaching purposes[1] is not covered by the provision.

Austrian Patent law does recognise a Bolar-type exception as put forth in Sec. 22 para. 3 PatG, clearly exempting clinical studies and related tests as well as practical requirements evolving out of them from the scope of a patent, as far as they are necessary to obtain an authorisation for a product under pharmaceutical laws.

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?*

Parallel imports into Austria are permitted when, and only when, the respective products have already been introduced into the market of the EEA by the patentee[2].

There is no case law whether this also applies in the case of compulsory licenses.

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1 Friebel/Pulitzer, Patentrecht², 213.

2 Urlesberger, Gibt es einen gemeinsamen Markt für Arzneien?, ÖBl. 2006, 4.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Austrian patent law does not recognise an explicit exception for individual prescriptions. In any case, the question remains whether a one time infringement by an individual person may fulfil the criterion of commercial use which can be defined as being based on repeatable economic activity which follows a certain plan.[3]

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?*

Austrian Patent Law does not allow for patents on methods of medical treatment (§ 2 (1) Z 2 PatG in accordance with Art 27 para.3 TRIPS).

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.*

Sections 36 and 37 of the PatG provide for compulsory licenses, but set forth a series of requirements for compulsory licenses to be granted and also distinguish between various grounds, on which a compulsory license might be granted. Especially Sec. 36 paras. 1, 4 and 5 are of interest for the response to the question above.

Sec. 36 para 1 PatG establishes the case for compulsory licenses on the ground of dependency. In the case, that a younger patent can only be used by infringing an older patent, its proprietor is, under the prerequisite that the younger patent represents an important technical progress of considerable economic value, entitled to a non-exclusive license for the older patent. Austrian law provides also for the proprietor of the older patent to be able to claim a licence for the younger patent in return.

A completely different scenario is dealt with in Sec. 36 para. 4 PatG, where compulsory licenses of non-exclusive nature are foreseen should a patent not be used or not be used to an appropriate extent within the borders of Austria. Under the condition that the patentee has not undertaken all necessary steps for the exercise of the patent in an appropriate manner, anybody can claim a license for his company, unless the patentee can prove that insurmountable obstacles impede the full, or as a second option broader exercise of his rights to the patent.

The third, and for the purpose of this examination, most important norm on compulsory licenses can be found in Sec. 36 para. 5 PatG. It provides for non-exclusive licenses for anybody's company in case public interest demands licensing of a patented invention. The federal government does not need prove its need of the license for a company.

Should, in the first two case scenarios, the holder of the older patent refuse to grant a license to an applicant, who exerted himself to receive the necessary approval within an appropriate period of time, the applicant may turn to the Austrian Patent Office and move to be granted such a compulsory license within the procedural rules for the challenge of patents. This rule, set forth in Sec. 37 para. 1 Pat G does, however, not apply to cases of compulsory licenses based on Sec. 36 para. 5 PatG, as theses licenses can, in times of national states of emergency or other situations of utmost urgency, be granted via a preliminary authorization.

To this date, we are not aware of any compulsory licenses published within the territory of Austria.

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[3] Austrian Supreme Court 22.5.1973, ÖBl 1973, 126.

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.*

Austria, who joined the GATT (General Agreement on Tariffs and Trade) on January 1, 1951, is also a member state of the WTO[4], thus a probable addressee of TRIPS-rules.

The August 30, 2003 decision by the WTO General Council on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health removed certain limitations put on compulsory licenses especially in connection with less- or lesser developed countries, which cannot themselves produce drugs, but would need to import them. In 2005, a protocol of amendment to the TRIPS was adopted to permanently transfer this waiver into WTO law.[5]

As a member of the European Union, Austria is bound[6] by the declaration of the presidency of the Council of the European Union where the Presidency titled "Instrument of Acceptance"[7], which declared all member states of the European Union to be bound by protocol implementing the decision of August 30, 2003. As soon as the amendment will enter into force, Austria will thus be bound by its content.

Up to this moment, we are not aware of any compulsory license granted for the importation or exportation of pharmaceutical products with regards to Austria.

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?*

Under no circumstance is the government allowed to make use of a patented invention without previous license with the only exception being the possibility of a preliminary authorization in the case of a compulsory license pursuant to Sec. 36 para. 5 PatG and the prevalent state of public emergency according to Sec. 37 para. 3 PatG.

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

As a patent is nothing but an asset, its protection from any violation from the side of the government has to be analyzed from the view of Art 5 of the Constitutional Act of 1867 ("Staatsgrundgesetz"). This article protects any private property from any violation and clearly states that expropriation is only permitted if it is provided for by Austrian laws. Which further leads us back to the Patent Act, where a permission to expropriate cannot be found.

However, one has even at that point to bear in mind, that compulsory licensing within the framework of Sec. 36 para. 5 and Sec. 37 para. 3 PatG indeed provides for something very close to expropriation, licensing in a preliminary ruling in cases of emergency. It is exactly the wording "states of emergency and other situations of utmost urgency" that will justify a violation, as it is a rule set forth by Austrian law – the requirement for Art 5 leg. cit.

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.*

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4 Country Information on Member States – Austria, http://www.wto.org/english/thewto_e/countries_e/austria_e.htm, last visited on July 9, 2008.

5 Amendment to the TRIPS Agreement of 8 December 2005, WT/L/641, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

6 See also Article 300 para. 7 of the EC-Treaty.

7 Available online under http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

The only reference to public emergency, also covering public health crises, is put forth in Sec. 37. para 3. PatG where it is stated that in case of public emergency compulsory licenses may be granted in a preliminary decision. Apart from this, public emergency does not pose as an exception of Austrian patent law.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *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?

No, because investments in innovation needs to be compensated and expropriation, compulsory licensing and a lot of exceptions is contrary to it.

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?

No.

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?

No, because we are against too many limitations. The first two examples are already more or less harmonized. Harmonization is also not necessary since research will be made in countries where it is allowed and if a country wants to attract more research, it will react on its own and, if not, why should it be forced to do it? We also think that harmonization is practically impossible – most countries have research exceptions either I the written law or by case law under the concept "patents should not hinder further innovation" but what exactly is allowed and what not, differs widely and could only be harmonized by a common Supreme Court like the ECJ.