Denmark
Danemark
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Report Q202

in the name of the Danish 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?*

Yes, a research or experimental use exception is recognised under Danish Patent law. According to section 3(3)(3) of the Danish Patents Act, "The exclusive right shall not extend to: ... acts done for experimental purposes relating to the subject-matter of the patented invention.

The research and experimental exemption is not restricted to non-commercial purposes.

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, a Bolar-type exception is recognised under Danish Patent law, vide section 3(3)(4) of the Danish Patents Act stating that: "The exclusive right shall not extend to: ... actions which are restricted to the object of a patented invention which actions are necessary in order to get marketing authorisation for a medicament to humans or animals in EU, in an EU member state or in other countries". In Denmark, the Bolar exception is limited to drugs. It is to be noted that, in Denmark, the Bolar exception is not restricted to generic medicaments, but relates to any medicament.

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?*

According to section 3(3)(2) of the Danish Patents Act the exclusive right related to a granted patent in Denmark does not include actions with regard to products marketed by the patentee or with the patentee's explicit consent in Denmark or in any other country within the European Economic Area (EEA).

Section 3(3)(2) of the Danish Patents Act comprises only situations where the product is marketed in Denmark or in another EEA country. If the product is marketed outside the EEA, the patentee may thus continuously prevent import of products based on the patent to Denmark.

A principle of *regional* exhaustion of rights thus applies in Denmark, making parallel imports of patented products (including medicines and medical devices) within the EEA legal.

Based on the legal history of section 3(3)(2) of the Danish Patents Act as well as case law (ECJ case No C-19/84 Pharmon v Hoechst) it is, however, assumed that imports of patented products within the EEA are *not* allowed in situations where the products are made available on the market under a compulsory license only.

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

Yes, an individual prescriptions exception is recognised under Danish Patent law, vide section 3(3)(5) of the Danish Patents Act according to which "The exclusive right shall not extend to: ... preparation in a pharmacy of a medicinal product according to a prescription in individual cases or acts concerning the medicinal product so prepared.

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?*

In Denmark, methods of treatment are not patentable subject matter, vide section 1(3) of the Danish Patents Act and Art. 53(c) EPC 2000.

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.*

The provisions on compulsory licenses are included in chapter VI (sections 45-50) of the Danish Patents Act. These provisions are in conformity with TRIPS.

In Denmark, the competence to grant compulsory licenses lies exclusively with the courts. According to section 49 of the Danish Patents Act the basic requirements for granting compulsory licenses are:

1) The licensee must prove to be able to use the invention in a reasonable and justifiable manner and in accordance with the conditions of the license.

2) The licensee must prove to have tried in good faith to obtain a license by agreement with the patentee on reasonable terms.

The *specific* requirements for granting compulsory licenses follow from sections 45-48 of the Danish Patents Act. In relation to public health issues, the following provisions should be pointed out.

1) It follows from section 45(1) of the Danish Patents Act that if a patented invention 3 years after the grant of patent *and* 4 years after the filing of the patent application has not yet been worked "to a reasonable extent", a third party intending to commercialize the invention in Denmark may obtain a compulsory license to do so *unless* there are reasonable grounds for the patentee's omission to use the invention.

   However, according to Denmark's EU and international (WTO) obligations, working of the invention within EEA or in a WTO country is considered to correspond to working in Denmark.

   There is no recent case law on section 45(1) of the Danish Patents Act, but in a Supreme Court decision of 17 June 1966 it was confirmed that the Danish pharmaceutical company *Løvens Kemiske Fabrik* had rightfully been granted a compulsory license by the

Swiss pharmaceutical company *J.R. Geigy AG* regarding a process for manufacture of Phenylbutazone. (UfR 66/566 H). The Supreme Court referred in its reasoning to the fact that the patented process – without any reasonable grounds – could not be considered to have been worked to a reasonable extent taking into account the demand for the product manufactured by use of the patented process. The amount actually produced in Denmark was about 30% of the total sales. The royalty was fixed at 5% of the sales. It should be noted that prior to the grant of the compulsory license, the Supreme Court had found that Løven infringed on Geigy's patent.

2) According to section 47 of the Danish Patents Act a third party intending to commercially use a patented invention may be granted a compulsory license to do so in case *important public interests* make it necessary.

   Section 47 of the Danish Patents Act has successfully been claimed in a Supreme Court decision from 1972. (UfR 72/325 H). This case did, however, not concern medicines or medical devises (but rather catapult seats for fighter planes). On the other hand, it is quite clear that the public's need for supply of necessary medical products falls within the core of section 47 of the Danish Patents Act.

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.

Article 31bis of TRIPS as stipulated by the WTO Council at its meeting on 6 December 2005 has been ratified by EU (and thus Denmark) by Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents in relation to the manufacture of pharmaceutical products for export to countries with public health problems.

According to the available information no compulsory licenses have been granted according to Article 31bis of TRIPS for exportation of pharmaceutical products from Denmark to eligible importing countries in need of such products in order to address public health problems.

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, Danish Patent law has no such provisions.

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

Previous Danish Patent Acts included specific provisions on the possibility to expropriate a patent on condition of full compensation to the patentee.

The present Danish Patents Act does not include such a provision on expropriation simply because it is superfluous due to the general provision on expropriation in the Danish Constitution ("Grundloven"). According to section 73 of the Danish Constitution the right of property shall be inviolable. Expropriation may, however, take place under the following *invariable* conditions:

1) It is required due to public interest,
2) it is done by or in accordance with statute and
3) full compensation is awarded.

No such expropriation has been granted and it is believed that the compulsory license provisions will provide sufficient remedy.

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.*

The Danish Patents Act does not have any such provisions. Information tools like the Orange book is not available in Denmark.

Indirectly, however, the access to medicines is facilitated by the fact that the Danish Medical Agency pay no attention to patents or possible infringement thereof when granting marketing authorizations, and that there is no obligation for the generic companies to submit any such information. Also Danish pharmacies have the duty to undertake "generic substitution", unless the prescribing doctor has explicitly prescribed the original product.

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?

The Danish group is of the opinion that Patent law should provide for research and experimental use exception, the Bolar exception, the individual prescriptions exception and compulsory licensing provisions subject to equitable compensation to the patentee. All of these provisions could be phrased as they are in the Danish Patents Act. In this connection, we want to stress that the Bolar exception must be restricted to actions which are necessary in order to get marketing authorization for the medicament in question.

Furthermore, it is important to note that, e.g., in several European countries, Bolar exception for generic medicaments has been specified in the law, whereas it is questionable whether the provision also covers non-generic medicaments.

We are of the opinion that the Bolar exception should cover both generic and non-generic medicaments. Non-generic medicaments could also be designated innovative medicaments. We see no reason to have provisions which are more favourable to the marketing of generic products than to the marketing of non-generic medicaments, rather the contrary. Mostly, generic products are identical (or almost identical) to an original product already marketed. Non-generic medicaments are medicaments which are mostly developed by innovative companies. In the case of a non-generic medicament for which the Bolar exception applies in relation to a specific patent, there may or may not already be another medicament on the market covered by the patent in question. In one typical case, an innovative company has developed a new medicament (with a surprising effect) and, just by chance, the medicament is covered by a patent which may not cover other medicaments marketed or foreseen to be marketed Alternatively, the therapeutic efficiency of a given compound has inspired other innovative companies to look for structurally similar compounds which might arguably be selection inventions under the original patent.

Danish Patent law does not specifically provide for a medical treatment defence, but the Danish group is willing to favourably consider a more specific proposal in this respect.

The Danish group rejects the general principle of international exhaustion of rights with regard to patented medicines. Parallel import of patented medicines on regional levels due to economic free markets (such as the EEA) should however be accepted, thus stipulating a principle of regional exhaustion of rights.

Patent law should not provide for expropriation of rights. The basic provisions on expropriation of property in each country should suffice.

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?*

We think that the limitation provisions mentioned above will contribute sufficiently to a balanced public health situation as far as patents are concerned.

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?*

Yes, they should all be harmonised as mentioned above.

National Groups are invited to comment on any additional issue concerning the impact of public health issues on the patentee's exclusive rights which they find relevant.

All member countries should be strongly encouraged to ratify the new Article 31bis of TRIPS so as to make the Doha decision from 2003 permanent.

By the same token, the member countries should be encouraged to take reasonable measures as defined in sections 3 and 4 of the annex to Art 31bis TRIPS to prevent reexportation of products that have been imported subject to the provisions of Art31bis TRIPS (Paragraph 6 of the Doha Declaration).

Any erosion of the patent rights results in a lower motivation to develop improved medicaments by the companies. The challenge is to find the right balance between, on the one hand, the companies' possibilities of obtaining a sufficient patent protection on medicaments and, on the other hand, to secure that the patients get the best possible treatment. We think this challenge has been met by the above rules and measures.

Summary

The Danish group is of the opinion that the decision of August 30, 2003 under paragraph 6 of the Doha declaration as now expressed in Article 31bis TRIPS and its annexes strikes a reasonable balance between the legitimate interests of the innovative pharmaceutical companies and those of the countries facing public health problems, the solution of which might partly be hampered by existing patent rights. Therefore, an early ratification of Article 31bis TRIPS is strongly encouraged by all countries not having ratified yet.

Already Article 30 TRIPS provided for introduction of limited exceptions to the exclusive rights conferred by a patent by the member states, and a harmonization of such exceptions as suggested by the Danish group is recommended. In particular, the Bolar exception should cover both generic and innovative medicaments, but only such measures as are necessary in order to get marketing auhorization should be encompassed by the exception.

International exhaustion of rights is rejected, but regional exhaustion might be acceptable in accordance with the relevant regional jurisprudence and/or as provided by national law.

Résumé

Le groupe danois est d'avis que la Décision du 30 Août 2003 en vertu de section 6 de la Déclaration de DOHA comme exprimée maintenant dans Article 31bis TRIPS et ses annexes a bien équilibré les intérêts légitimes des entreprises pharmaceutiques innovatrices et ceux des pays se trouvant en face des problèmes de santé publique dont la solution pourrait être freinée par droits de brevet existants. Donc, la ratification anticipée de l'Article 31bis TRIPS est fortement encouragée par tous les pays n'ayant pas encore ratifié.

Déjà Article 30 TRIPS instituait l'introduction des exceptions limitées aux droits conférés par un brevet par les états membres, et une harmonisation de telles exceptions comme suggérée par le groupe danois est recommandée. Particulièrement, l'exception Bolar doit couvrir les médicaments génériques aussi bien que les produits innovateurs, mais exclusivement les moyens jugés nécessaires pour obtenir l'autorisation de mise sur le marché doivent se trouver englobés par l'exception.

Epuisement international des droits est rejeté, mais épuisement régional peut être acceptable selon la jurisprudence régionale pertinente et/ou comme prévu par le droit nationa

Zusammenfassung

Die dänische Gruppe ist der Auffassung, dass die Entscheidung vom 30. August 2003 unter Abschnitt 6 der Doha-Erklärung, wie sie nun in Artikel 31bis TRIPS und seinen Annexen ausgedrückt ist, die rechtmässigen Interessen innovativer pharmazeutischer Firmen und diejenigen von Ländern mit Problemen in der öffentlichen Gesundheitspflege, deren Lösung teilweise durch bestehende Patentrechte behindert werden könnte, einigermassen ausgewogen berücksichtigt. Deshalb wird eine zeitige Ratifizierung des Artikels 31bis TRIPS durch Länder, die dies noch nicht getan haben, stark unterstützt.

Artikel 30 TRIPS hat bereits die Einführung begrenzter Ausnahmen durch Mitgliedstaaten von durch Patente erteilten Exklusivrechten vorgesehen, und eine Harmonisierung solcher Ausnahmen, wie von der Dänischen Gruppe vorgeschlagen, wird empfohlen. Insbesondere sollte die Bolar-Ausnahme sowohl generische als auch innovative Medikamente umfassen, allerdings sollten nur Massnahmen, die notwendig für die Erteilung einer Vermarktungsgenehmigung sind, von der Ausnahme umfasst werden.

Die Doktrin internationaler Erschöpfung von Rechten wird abgelehnt, allerdings mag in Übereinstimmung mit relevanter regionaler Rechtsprechung und/oder durch nationale Gesetze vorgesehene regionale Erschöpfung akzeptierbar sein.