Consultation – Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Rules | Date: 02/03/2004 | Ministry of Foreign Affairs
(http://www.regjeringen.no/en/dep/ud/id833/)

Consultation – Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (excerpts)

Enclosed please find a consultation paper on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in the Patent Regulations of 20 December 1996 No. 1162.

The TRIPS Agreement, which is part of the WTO Agreement, lays down that a compulsory licence, i.e. a licence issued by the public authorities to use a patented invention without the consent of the patent-holder, is to be issued mainly with a view to supplying the domestic market. The Decision by the WTO General Council of 30 August 2003 (the General Council Decision) makes exceptions to this limitation on exports for pharmaceutical products. The decision makes it possible for States that lack manufacturing capacity to import pharmaceutical products on the basis of a compulsory licence. The main purpose of the decision is to give developing countries access to key medicines.

The consultation paper proposes that the Patent Regulations should be amended in such a way as to allow companies in Norway to be granted compulsory licences to produce patent-protected medicines for export in accordance with the General Council Decision. The time limit for comments is 16 April 2004. Comments are to be sent to Justisdepartementet, Lovavdelingen, Boks 8005 Dep, 0030 Oslo. Comments could also be sent electronically to jd-arkiv-lovavd@jd.dep.no (mailto:jd-arkiv-lovavd@jd.dep.no) .

The recipients of this letter are requested to submit the consultation paper to bodies or individuals who are not on the list of addressees but who should be given an opportunity to express their views. The consultation paper and letter may be found in Norwegian at:
http://odin.dep.no/jd/norsk/publ/hoeringsnotater/index-b-n-a.html
(http://odin.dep.no/jd/norsk/publ/hoeringsnotater/index-b-n-a.html) .

Consultation – Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in Norwegian law

(Compulsory licence for the export of pharmaceutical products to developing countries)

1. Summary

This consultation paper describes the proposed amendments to the Patent Regulations of 20 December 1996 No. 1162, which will allow companies in Norway to be granted on request a compulsory licence to produce patent-protected pharmaceutical products with a view to exporting them in accordance with the WTO General Council Decision. The decision is enclosed with the consultation paper, and is also available on the Internet at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

2. Background

[Not translated]

3. The General Council Decision

[Not translated]

4. Relationship to Norwegian law

The provisions concerning compulsory licences in sections 45 ff. of the Norwegian Act of 15 December 1967 No. 9 relating to patents implement the provisions of Article 31 of the TRIPS Agreement. The General Council Decision allows exceptions to be made from the provisions of Article 31(f), which impose limitations on exports, and defines more closely the provision concerning remuneration set out in Article 31(h). Implementing the General Council Decision will make it necessary to incorporate these special provisions into the Norwegian legislation on compulsory licences.

It will also be necessary to lay down provisions specifying the scope of application of the General Council Decision, i.e. under what circumstances compulsory licences may be granted under this arrangement.

Section 49 of the Patents Act was amended by the Act of 19 December 2003 No. 127. Section 49, new fifth paragraph, which has not yet entered into force [ed. note: entered into force on 1 February 2004], reads as follows:

"A compulsory licence shall be issued mainly with a view to supplying the domestic market. The King may by regulations prescribe rules that deviate from this."

According to the legislative history, the main purpose of section 49, fifth paragraph, second sentence, is to make it possible to issue regulations that will allow Norwegian companies to manufacture pharmaceutical products under a compulsory licence with a view to exporting them to developing countries. Proposition No. 86 (2002-2003) to the Odelsting, p. 80, second column, states that:

The authority stipulated in the fifth paragraph, second sentence, to prescribe rules that deviate from this condition has primarily been laid down in connection with the current negotiations in the Council for TRIPS on the use of compulsory licences to ensure the supply of medicines to developing countries. The condition that compulsory licences are to be granted mainly with a view to supplying the domestic market means that countries that lack domestic manufacturing capacity may have problems in utilising the right to grant compulsory licences. This applies especially to developing countries. Depending on the outcome of the negotiations in connection with the TRIPS Agreement, it may in the future be possible for Norwegian companies to manufacture pharmaceutical products under a compulsory licence for export to developing countries. The authority to make exceptions from the requirements in section 49, fifth paragraph, first sentence, allows for such a situation.

It is therefore proposed that the provisions for implementing the General Council Decision are prescribed by regulations pursuant to section 49, fifth paragraph, of the Patents Act, cf. the general authority to lay down provisions in section 69, first paragraph, of the Act. It is proposed that the new provisions should be introduced in a separate chapter before what is currently Chapter 15, Miscellaneous provisions, of the regulations. The numbering of the chapters and sections of the draft regulations has been amended in relation to the new provisions that will be included in accordance with the entry into force of the provisions relating to the EC directive on the legal protection of biotechnological inventions.

Economic and administrative consequences

The implementation of the General Council Decision in Norwegian law will make it possible for companies in Norway to manufacture pharmaceutical products under a compulsory licence for export to States that are unable to produce these products themselves. This will help to give developing countries better access to key medicines.

The pharmaceutical industry in Norway is relatively small, and there are probably not many companies with the capacity to take on the task of manufacturing pharmaceutical products under compulsory licence for another State. It is therefore not certain what the consequences will be of the implementation of the General Council Decision.

The amendment to the regulations will not have appreciable economic or administrative consequences for the courts or the Competition Authority, which are the bodies authorised to grant compulsory licences in Norway.

Comments on the individual provisions of the regulations

Section 107

The first paragraph lays down that a pharmaceutical company in Norway may under certain specified conditions be granted a compulsory licence to use an invention protected by a patent with a view to manufacturing pharmaceutical products for export to another State. Thus producers that apply for a compulsory licence have a legal right to such a licence if the conditions have been fulfilled. This ensures a greater predictability than if compulsory licences are granted on a discretionary basis, and reduces the risks inherent in starting negotiations on supplying products before a compulsory licence has been granted in Norway. If the importing State's request to import the pharmaceutical product falls within the scope of the General Council Decision and the provisions of the TRIPS Agreement, the Norwegian authorities should not evaluate independently whether there are important public interests involved, cf. section 47 of the Patents Act. The question of whether there are important public interests indicating that a compulsory licence should be granted pursuant to section 47 of the Patents Act must be evaluated on the basis of the needs of the importing State.