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Council for Trade-Related Aspects of Intellectual Property Rights

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IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

NORWAY

The following communication, dated 13 September 2004, along with Annexes I and II, has been received from the Permanent Mission of Norway with the request that it be circulated to Members.

On 14 May 2004, Norway amended its patent legislation in order to implement the General Council Decision of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The amendments entered into force on 1 June 2004 and provided Norway with a fully operational legislative framework for the production of patented medicines for export under compulsory licence.

I. BACKGROUND

The WTO Declaration on the TRIPS Agreement and public health adopted in Doha 14 November 2001[1] was primarily intended to help alleviate the AIDS situation in southern Africa and the difficulties faced by the developing countries in obtaining vital patent-protected medicines at reasonable prices. The Declaration firmly established that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

However, according to Article 31(f) of the TRIPS Agreement, a compulsory license, i.e. a license 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. This provision has been widely regarded as the main obstacle to the effective use of compulsory licensing by WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find a solution to the difficulties faced by these members.

The Decision by the General Council of 30 August 2003[2] on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the General Council Decision) makes exceptions to this limitation on exports for pharmaceutical products. The Decision makes it

[1] WT/MIN(01)/DEC/2
[2] WT/L/540

possible for states that lack manufacturing capacity to import pharmaceutical products produced under compulsory licence.

II. THE CONSULTATION PROCESS

The Norwegian Government carried out extensive consultations with potential stakeholders before adopting the necessary amendments to Norwegian patent legislation. Substantive comments were received from the following institutions: the Biotechnology Advisory Board, the Bar Association, the Consumer Council, Helse Bergen (the regional health administration of Bergen), the Ministry of Health, the Competition Authority, the Confederation of Trade Unions, the Association of Pharmaceutical Manufacturers, the Intellectual Property Law Association, Norsk Patentingeniørers Forening (the association of patent engineers), the Ministry of Trade and Industry, the Patent Office and the Ministry of Foreign Affairs.

The consultation process revealed that there was strong general support for the draft proposal. None of the commenting bodies opposed the proposal, but some commented on the method of implementation. Possibly the most important outcome of the consultation process was the decision to extend the system to cover eligible non-members of the WTO. Moreover, it was decided to introduce more detailed requirements for labelling of the products that would clearly show that they were produced under this system.

The new provisions specifically stipulate that the production and export of these products are to cease if they are used "to an appreciable degree" for purposes not in accordance with the conditions for granting the licence.

III. THE AMENDMENTS TO NORWAY'S PATENT LEGISLATION

The first step in the implementation of the General Council Decision in Norwegian law was to amend the Norwegian Patents Act[3] to provide for exemptions from the requirements for the granting of a compulsory licence. A further amendment provides that the Competition Authority is authorised to grant compulsory licenses as well as the courts.

On 14 May 2004 the Patent Regulations[4] were amended to take account of the substance of the General Council Decision. These amendments are somewhat less detailed than the decision itself. It is a tradition in Norwegian law that if national provisions are unclear, they should be interpreted in the light of the international public law provisions.

As provided for in the General Council Decision, the regulations make the necessary derogation from the export restrictions of Article 31 (f) of the TRIPS Agreement. They also stipulate that the right holder is to receive "adequate remuneration", taking into account the economic value to the importing member.

The other provisions of Article 31 of the TRIPS Agreement and the Norwegian Patents Act will continue to apply in relation to applications for compulsory licences. In the case of the general requirements set out in Article 31 (b), for instance, this means that except in the event of a national emergency or in the case of public non-commercial use, prior efforts must have been made to negotiate an authorisation from the right holder on reasonable commercial terms and conditions.

The regulations establish that producers have a right to obtain a compulsory licence provided that the conditions of the General Council Decision and the TRIPS Agreement have been fulfilled.

[3] Act of 15 December 1967 No. 9 relating to patents
[4] The Regulations of 20 December 1996 No. 1162

Furthermore the Norwegian authorities should normally accept the information provided in the notification unless there are specific indications that the public health needs of the importing state have been inaccurately described. Thus, if the importing state's request is based on public health considerations and falls within the scope of the General Council Decision and the TRIPS Agreement, and if the product is being produced solely for export in order to meet that state's current need, a compulsory license should normally be issued.

The Competition Authority as well as the courts have been given the authority to grant compulsory licenses. An administrative decision of the Competition Authority may always be challenged before the courts.

IV. IMPLICATIONS OF THE LEGISLATIVE CHANGES

Given that Norway does not have a large pharmaceutical industry, at least in the product areas which are most likely to benefit from the General Council Decision, we do not expect the Norwegian industry to be a significant contributor under this system in the near future.

However, Norway's early implementation of the General Council Decision expresses its strong support for the mandate in the Doha Declaration on the TRIPS Agreement and public health. The threat to public health and economic development posed by HIV/AIDS, tuberculosis, malaria and other epidemics is as serious today as it was three years ago, and although it is no panacea to the world's health problems, the implementation of the General Council Decision is a very important contribution amongst other efforts to provide access to affordable, life-saving medicines. Norway hopes that its implementation of the General Council Decision will induce other WTO members, both developed as well as developing country Members, to follow suit, thereby helping to provide an effective remedy for countries with insufficient or no manufacturing capabilities in the pharmaceutical sector.

The amendments to the Norwegian Patent Act and Regulations will be notified to the Council for TRIPS pursuant to Article 63.2 of the TRIPS Agreement. They are also attached to this communication as Annexes I and II.

ANNEX I

The present document reproduces amendments to the Act of 15 December 1967 No. 9 relating to patents and the Patent Regulations of 20 December 1996 No. 1162, in order to implement the General Council Decision of 30 August 2003[5] on paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health.

Sections 49 and 50 to the Act of 15 December 1967 No. 9 relating to patents as amended by Act of 19 December 2003 no. 127:

Section 49:

A compulsory licence may only be granted to a person who has made efforts to obtain a licence on reasonable commercial terms by agreement without succeeding in this within a reasonable time, and who may be presumed able to exploit the invention in a manner which is acceptable and in compliance with the terms of the licence.

A compulsory licence shall not prevent the patent holder from exploiting the invention himself or from granting licences.

A compulsory licence shall only be assignable in conjunction with the enterprise where it is exploited or in which exploitation was intended. Furthermore, a compulsory licence obtained pursuant to section 46, first paragraph, may only be assigned in conjunction with the dependent patent.

In the case of semi-conductor technology, a compulsory licence may only be granted for public non-commercial use or pursuant to section 47 (2).

A compulsory licence shall primarily be granted with a view to supply of the domestic market. The King may by regulations lay down rules that deviate from this.

Section 50:

A compulsory licence shall be granted by the court pursuant to this section or by the Norwegian Competition Authority pursuant to section 50 a.

In a decision concerning a compulsory licence, it shall be decided to what extent the invention may be exploited as well as the amount of remuneration and the other terms of the licence. The remuneration shall be adequate in relation to the circumstances of each case. Assessment shall take into account the economic value of the licence.

[5] WTO Doc. WT/L/540

ANNEX II

Pursuant to sections 49 and 69 of the Act of 15 December 1967 No. 9 relating to patents, the Ministry of Justice and the Police laid down the following regulations by Royal Decree of 14 May 2004:

I

The Regulations of 20 December 1996 No. 1162, which have been issued pursuant to the Patents Act, shall be amended as follows:

New section 107 shall read as follows:

Section 107. When the requirements set out in section 108 have been complied with, a producer of pharmaceutical products in Norway shall be granted on application a compulsory licence pursuant to section 47 of the Patents Act to manufacture pharmaceutical products for export to an eligible importing State that has requested the producer to supply the products. For the purpose of these regulations, an eligible importing State or customs territory is one that:

1. at the time in question has been designated by the UN as a least developed country or customs territory, or that has insufficient manufacturing capacity in accordance with the Annex to the decision of the WTO General Council of 30 August 2003 (the General Council Decision); and

2. has made a notification to the Council for TRIPS in accordance with the General Council Decision, paragraphs 1(b) and 2(a).

States that are not party to the WTO Agreement shall make the notification referred to in the first paragraph (2) above to the Norwegian Ministry of Foreign Affairs.

New section 108 shall read as follows:

Section 108. A compulsory licence may only be granted pursuant to section 107 if

1. the producer has tried to obtain a licence by agreement in Norway insofar as this is required pursuant to section 49, first paragraph, of the Patents Act;

2. the product is covered by paragraph 1(a) of the General Council Decision;

3. the product is only to be produced for export to the eligible importing State in order to cover the said State's current need for the product for health purposes, as described in the notification mentioned in section 107; and

4. the invention is not protected by a patent in the eligible importing State or the eligible importing State has granted or has undertaken proceedings to obtain a compulsory licence pursuant to Article 31 of the Agreement of 15 April 1994 on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) and the General Council Decision.

When assessing what are reasonable commercial terms and conditions pursuant to section 49, first paragraph, of the Patents Act, and when determining the remuneration pursuant to section 50, second

paragraph, of the Patents Act, account shall be taken of the economic value to the importing State of the use of the invention.

More detailed requirements for granting a compulsory licence may be imposed in the decision to grant such a licence, cf. section 50, first paragraph, of the Patents Act. These shall include the following requirements:

1. the packaging and container shall be distinct from those of products being offered for sale in Norway or in another state by the patent-holder himself or with his consent;

2. the products shall be labelled so as to clearly indicate that the pharmaceutical product has been manufactured under compulsory licence in Norway for export to a specified importing state in accordance with the General Council Decision; and

3. the manufacture and export shall cease if the licence-holder learns the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence, cf. first paragraph (3).

New section 109 shall read as follows:

Section 109. The competent court or the Competition Authority shall make a notification to the Council for TRIPS concerning the compulsory licence in accordance with the General Council Decision, paragraph 2(c). States that are not party to the WTO Agreement shall make a notification to the Norwegian Ministry of Foreign Affairs.

The holder of a compulsory licence shall post information on its website in accordance with the General Council Decision, paragraph 2(b)(iii).

II

These regulations enter into force on 1 June 2004.