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 is a State or a customs territory 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 a compulsory licence or legal proceedings to obtain such a licence have been initiated 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.