gency.[1030] A patent holder is entitled to contest the compulsory license application. Whether or not the opposition would suspend the implementation of the license remains up to the Minister to decide.[1031]

The Dutch system places more specific obligations on physical safeguards. Thus, the obligation to make the licensed products more distinctive rests on the licensee. Only if the licensee is able to justify why the measures relating to labelling, colouring and packaging are unfeasible or too costly will the Minister grant the license without anti-diversion safeguards. The liability for the diversion of the pharmaceutical products is resolved as follows under the Dutch System: the importing country must take measures to prevent the re-export or diversion and the Dutch licensee will be liable under criminal law where he is 'wholly or partly responsible for the trade diversion'.

The pecuniary safeguards are contained in Article 5 of the Policy Rules. In terms hereof the remuneration shall be adequate, taking into account the value of the order in the importing country. This reflects a lowering of the standard Dutch remuneration level so that 'the pharmaceutical products should be affordable to everyone in the importing country'. This therefore implies that the remuneration will not use the average income as a basis for calculating the remuneration but a level that would ensure that the remuneration does not impede the access to the pharmaceuticals by the poor.

Upon the adoption of an EC Regulation to implement an Article 31*bis* system (see Chapter 8(E) Seite 238 below) the Netherlands will, to the extent necessary, harmonise the EC rules.[1032]

In comparison to Norway and Canada, the system adopted by the Netherlands may prove to be the most effective. The reason for this is not only the relatively simplicity of the system but also the substantial domestic pharmaceutical market. The Dutch pharmaceutical sector exports more pharmaceuticals than both Norway and Canada combined.[1033]

D. India

The Indian Patents (Amendment) Act, adopted on the 4th of April 2005 (the 'Amendment Act') took a major step in bringing its patent system in line with the TRIPS Agreement.[1034] Included in the Amendment Act was a new provision, section

1030 Patent Act for the Kingdom of the Netherlands sec 57(1).

1031 Policy Rules Art 6. Generally the review of an administrative decision will suspend the operation of the license; however, the Policy Rules presupposes the urgency of applications made under the Art 31*bis* system, thus preventing an appeal from suspending the operation of a license. Cf. *AIPPI*, Questionnaire No. 4 (2005) p. 3.

1032 Policy Rules Explanatory Notes.

1033 WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 8.

1034 Indian Patents (Amendment) Act, Act 15 of 2005 ('Amendment Act').

92A, to permit a compulsory license 'for the export of pharmaceutical products in certain circumstances'. Section 92A is comprised of 3 subsections and one explanation. In comparison to all the above implementations of Article 31*bis*, the brevity is remarkable.

It would be fair to say that section 92A represents the absolute minimum in provisions necessary to transpose the Article 31*bis* system. Section 92A(1) sets the scope by allowing compulsory licenses for:

> 'The manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India'.[1035]

The nature of the tool used to adopt the Article 31*bis* system is, like the Norwegian and the Canadian systems, a formal statutory amendment. Similarly, all three systems rely on the traditional patent system and not the public non-commercial compulsory license for the license grant.[1036]

No reference is made in the Amendment Act to either Article 31*bis* or the Public Health Declaration.[1037] In respect of the object of the compulsory license, the pharmaceutical product, the explanation to section 92A defines it in a manner that is largely a reflection of the definition in paragraph 1(a) of Article 31*bis* Annex.[1038]

Section 92A(2) states that, in addition to the situations when compulsory licenses can be granted, the granting authority, the Controller, can specify and publish terms and conditions for the license as he sees fit. This *carte blanche* is, regardless of whether one is a patent holder or a license applicant, somewhat disconcerting. As India does not have experience with regards to compulsory licenses for pharmaceutical products,[1039] there is no reference as to which conditions could be applied. Despite the present lack of legislative guidance a further review of the Patent Act may bring some light into this dark corner.[1040]

The lack of additional rules or regulations may also be seen as an attempt to permit the granting authority the flexibility to adopt measures best suited to the request

1035 Indian Patents (Amendment) Act, Act 15 of 2005 ('Amendment Act') p. 14.

1036 The Norwegian system does however provide for the competition authority to grant a license in terms of Art 31*bis*.

1037 An Indian representative to the WTO did however note that it intents to exercise its amendment of the Patent Act 'in conformity with the Decision'. Cf. India in the WTO Report to the General Council 'Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health' (03.11.2005) IP/C/37 p. 1.

1038 The only difference lies in the omission of the reference to the health problems 'recognised in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)'.

1039 'Industry Says Indian Drug Law Violates WTO, But No WTO Case Seen' *Inside US Trade* (15.04.2005).

1040 Cf. *Abbott*, 99 AJIL 2 (2005) p. 333 fn. 115.

for assistance made by the needy country.[1041] Rather than providing for an 'effective' system, the lack of guidance will more likely add to the uncertainty and absence of clarity. The existence of a large generic pharmaceutical sector in India and their supply of low cost generics have proven to be of great assistance to countries, in particular LDCs. Perhaps this track record will spur countries without an adequate pharmaceutical sector to seek assistance in India.

C. EC

Patent law is a national prerogative within the EC. Notwithstanding this, the EC is required to ensure that national legal systems do not bring about the distortion of competition between the common market Members and reserves the right to make appropriate rules with the unanimous consent of the EC Council.[1042] Upon this basis and the representative role the EC plays for its Member countries in the WTO the EC Commission decided to draft a regulation that would regulate and harmonise the implementation of the Article 31*bis* system into the domestic legal systems of all EC Members.[1043]

On the 17th of May 2006 the EC Regulation No. 816/2006 on 'compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems' was adopted (the 'EC Regulation').[1044] Being a regulation applies directly and overrides EC Member law.

The EC Regulation represents an uneasy balance between the facilitation of the Article 31*bis* exceptions and the protection of patent rights. The unease with the exception to Article 31(f) is evident in the introduction and solidification of comprehensive safeguard measures. In doing so the EC Regulation keeps close affinity to the terminology used in Article 31*bis*. Despite the adoption of definitions and concepts, the EC Regulation does not make reference to the Chairman's Statement.[1045] Notwithstanding this, the EC centres the regulation around the good faith use of the system.

1041 Compare India in the TRIPS Council Minutes (15.09.2005) IP/C/M/48 p. 26.

1042 The EC justified its intervention on Arts 95 (providing for the approximation of laws) and 133 (creation of a common commercial policy). Cf. EC Commission Proposal for a Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems COM(2004)737 (29.10.2004) ('EC Proposal') 5-6, *Hilf*, 6 EJIL 2 (1995) p. 245.

1043 The use of the regulation as a tool to implement the system was chosen to expedite the implementation of the system. Had the EC Members have been required to transpose a directive, the system would have required far longer to become operational. Cf. *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

1044 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation').

1045 *Cornides*, 10 JWILP 1 (2007) p. 71.