Section 57(1) of the Patent Act for the Kingdom of the Netherlands states:

> 'The Minister may, if he considers it in the public interest, grant a license under a patent, the content of which shall be described precisely by him, to a person designated by him'.

By structuring and expanding his authority under section 57(1) of the Patents Act to grant compulsory licenses the Minister of Economic Affairs was able to create a system whereby Article 31*bis* could be implemented into Dutch law in a relatively simple manner. In terms of the Dutch 'Policy Rules on issuing compulsory licenses pursuant to WTO Decision WT/L/540' (the 'Policy Rules')[1018] the Minister sets terms and conditions for the interpretation and application of the public interest compulsory licenses pursuant to Article 31*bis*.[1019]

In the Explanatory Notes to the Policy Rules the Minister expressly stated that section 57(1) 'may be interpreted as including the addressing of a public health problem in another WTO Member or in one of the least developed countries'.[1020] This amounts to a global appreciation and understanding that the concept of 'public interest' is not merely a national issue but that it can extend beyond borders.

Under Dutch law a policy rule 'lays down a general rule for weighing interests, determining facts or interpreting statutory regulations in the exercise of a power of an administrative authority'.[1021] It does not carry the weight of a statute but instead provides the structure for the implementation of a statute, in this case section 57(1) of the Patent Act. As such, the Policy Rules serve to guide the Minister's powers in terms of section 57(1). The Explanatory Notes to the Policy Rules further make it clear that, in exercising the 'policies' the aims thereof must be borne in mind. As such not only do the Policy Rules ensure that there is a balance between the rights of the individuals affected by the system but also that the Policy Rules reflect the aims of Article 31*bis*.

The simplicity of the Dutch system derives principally from its close resemblance to the Article 31*bis* system. Thus it is that the scope of the Dutch system derives directly from the Article 31*bis* system and that the term 'pharmaceutical product', 'importing state' and 'countries within a regional trade agreement' all directly derive their meaning from Article 31*bis*. As such the scope of the Dutch system mirrors that of the Article 31*bis* system. There is however no mention in the Dutch system to the Chairman's Statement. Further, the Dutch system does not make express mention of the concepts of 'good faith', 'industrial or commercial policy objectives' or 'best practices'. The lack of reference to the Chairman's Statement indicates that

1018 Policy Rules on issuing compulsory licenses pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995, Staatscourant (21.11.2004) nr. 246/p. 11 ('Policy Rules').

1019 General Administrative Law Act Art 4:81.2.

1020 Policy Rules Explanatory Notes.

1021 General Administrative Law Act Art 1:3.4.

only when the Policy Rules and Article 31*bis* are unable to establish the meaning of a certain provision will there be a potential need to consult the contents of the Chairman's Statement.

In addition to the scope of the system, the actual licensing system created by the Policy Rules adopts major portions of the procedural rules incorporated into Article 31*bis*.[1022] The Dutch system does however exceed Article 31*bis*'s scope by allowing the export of pharmaceuticals under a compulsory license to non-WTO Member States, provided the country has an inability to produce sufficient pharmaceuticals itself and has taken steps to prevent the diversion of the licensed products once they enter their borders.[1023] The Dutch system does however note that the decision to allow or deny a compulsory license will be based on the principle of proportionality. In other words the license must be 'commensurate' with the public health problem.[1024] Thus it follows that the Minister, the granting authority, will evaluate whether or not the importing Member State's license will be acknowledged and 'respected' in the Netherlands.[1025] Although this could theoretically lead to a review of the importing country's decisions there is an assumption that the importing country's actions are in accordance with the Article 31*bis* system.[1026] It thus follows that only where the Minister is in the possession of information that rebuts the presumption or when the prejudice suffered by the patent holder is unreasonable will the Minister be able to limit or even deny the compulsory license.[1027]

The Policy Rules adopt a pragmatic approach to safeguarding the interests of the patent holder. In terms of the General Administrative Law Act and the Policy Rules the system can only be exercised to the extent that it seeks to solve the public health problems'.[1028] Accordingly, where this is not the case a compulsory license would no longer be in proportion to the aims of the Policy Rules.[1029] Aside from the general safeguard provision, the Dutch system has a number of other safeguards. For instance, section 57(1) of the Patent Act requires the prior negotiation with the patent holder for a voluntary license, although this may however be waived in times of ur-

1022 Policy Rules Arts 2(2 and 3), 3(2, 4 and 5), 4, and 5.

1023 Whereas the Norwegian Regulation uses the UN designation for determining which countries are deemed to by LDCs, the Dutch policy rules makes no reference to a specific list for determining which states would be eligible as importing Member States.

1024 Policy Rules Explanatory Note to Art 2. Art 4:84 of the Dutch General Administrative Law Act requires the 'administrative authority shall act in accordance with the policy rule unless, due to special circumstances, the consequences for one or more interested parties would be out of proportion to the purposes of the policy rule'.

1025 The commentary to the Policy Rules state that once a notification has been made to the TRIPS Council by the importing country it will be presumed to have met the requirements. Cf. Policy Rules Commentary to Art 4.

1026 Policy Rules Explanatory Note to Art 6

1027 Dutch General Administrative Law Act Art 3:2.

1028 The Explanatory Note to Art 3 of the Policy Rules makes it clear that the license may only be exercised 'as part of the solution to the public health problems of the importing country'.

1029 Dutch General Administrative Law Act Art 4:84.

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').