Chapter 8 The realisation opportunities afforded by the Public Health Declaration

The waivers of Articles 31(f and h) of the TRIPS Agreement (found in the Decision) and the Article 31*bis*[950] mark an exception from the minimum patent standard required by the TRIPS Agreement. This means that a Member State with a TRIPS-conform intellectual property system will have to amend its domestic law before it will be able to make use of the system.[951] Hence, a Member State seeking to export pharmaceutical products under a compulsory license in terms of Article 31*bis*(1) will be required to amend its compulsory license system before it can authorise the compulsory license for export purposes. This applies *mutatis mutandis* to the exceptions in Articles 31*bis*(2 and 3). The actual methods used by Member States to implement the Amendment are left to the Member States themselves to regulate, subject to the relevant safeguards being effectively implemented.

A number of Member States were quick to take up the task of legitimising Article 31*bis* in their domestic legal systems. The measures taken, or in the process of being taken, are selectively discussed below.

A. Norway

Norway was actively involved throughout the paragraph 6 negotiations. With the adoption of the Decision Norway went about swiftly implementing the Decision into domestic law.[952] Despite the large domestic support from the implementation of the Decision, including from the Norwegian Association of Pharmaceutical Manufacturers, it was not anticipated that the relatively small number of Norwegian pharmaceutical manufacturers would be able to make a significant contribution to assisting those countries with inadequate domestic pharmaceutical production capacities.[953]

950 For convenience sake, subsequent references made to the provisions contained in the Decision will be done in terms of Art 31*bis*. Where applicable, the footnotes will make a corresponding reference to the specific location of the original source of the provision in the Decision.

951 *Law*, 18 ELDB 3 (2006) p. 6.

952 The implementation of the provisions of the Decision into the Norwegian Patent Act enacted by Act of 19.12.2003 no 127 and Royal Decree of 14.05.2004 and entered into force on 01.06.2004. Cf. WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427.

953 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 2. Norway notes that all parties consulted, including the Association of Pharmaceutical Manufacturers expressed a 'strong general support' for the amendment.

The implementation of the Decision in Norway was achieved by an amendment of the Patent Act. The solution was founded on the Norwegian King's authority to permit a deviation to the rule that a compulsory license 'shall be issued mainly with a view to supplying the domestic market'.[954] In terms of the amendment, a Norwegian pharmaceutical producer is entitled to apply for a compulsory license in order to manufacture pharmaceutical products for their export. In order to obtain a license, the producer may only export the products to the eligible importing countries. The Norwegian amendment defers to the Decision for determining what a 'product', an 'eligible importing State' and inadequate production capacities are.[955] In addition, the amendment extends the scope of the eligible importing country to all LDCs designated as such by the UN.[956] Where the conditions for a license have been fulfilled, the producer has a 'legal right' to the license.[957]

The Norwegian approach to the implementation of Article 31*bis* is characterised by a respect for the sovereignty of the decisions made by the importing Member States. As such, the Norwegian system will not second-guess a Member State's assessment with respect to its inadequate domestic production capacity nor will it question the volume of pharmaceuticals requested.[958] Only where there 'are specific indications that the public health needs of the importing state have been inaccurately described' will an importing Member State's acts be questioned.[959] Where such evidence is absent to this effect, 'a compulsory license should normally be issued'. The Norwegian system accordingly places the onus on the party opposing the license grant to disprove the importing Member State's claims. Accordingly and unless there is evidence to the contrary, the compulsory license granting authority (either the Competition Authority or the courts) will presume the information provided to be true.

The details of the Norwegian system echo those of Article 31*bis*. The reason for this is that the amendment is less specific than the system set up in terms of Article 31*bis*. Norwegian legal practice will ensure that where the statute is inadequate or unclear interpreters will look to the founding public international rules for assistance.[960] The Norwegian system does however incorporate the essential requirements of Article 31*bis*, for example:

954 Norwegian Patent Act sec 49 (fifth paragraph).
955 Norwegian Patent Act secs 108(2) and 107(1) respectively.
956 Norwegian Patent Act sec 107(1).
957 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 7.
958 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.
959 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 3.
960 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 2.

- a notification by the importing country to the TRIPS Council[961]
- it must confirm that it intends to use the system (unless it is a LDC)
- it must include the name and intended amounts of the product it requires
- it must state that it has insufficient or no production facilities for the production of the product[962] and
- it must confirm that it has granted a compulsory license for the product in its own territory or intends to do so.

The Norwegian compulsory license applicant must base the application on the notification[963] and:

- the compulsory license applicant must have attempted to obtain a voluntary license from the patent holder[964]
- the product is a pharmaceutical product, an active ingredient or a diagnostic kit
- it is produced solely for the export to the eligible importing country and
- the product must not be patented in the importing country or it must be subject to a compulsory license or is in the process of being compulsory licensed.

The attempt to acquire a voluntary license forms a significant part of the Norwegian system. The potential licensee must seek to obtain a voluntary license on reasonable commercial terms and conditions. This obligation is however tempered by the qualification that the reasonable license fees should also take into account the 'economic value to the importing State of use of the invention'.[965] Notwithstanding this obligation, the Norwegian authorities are clear that most of the requests for assistance will come from the governments of the importing countries. Recognising this, the Norwegians have allowed their compulsory license system to recognise the foreign grounds for the compulsory licenses in their own compulsory license system.[966]

The Norwegian system, characterised by relative simplicity, avoids overcomplicating the Article 31*bis* system. This 'minimalist' approach is evident not only in amendment being 'less detailed' than Article 31*bis* but also ensuring that the discre-

961 Where the importer is a WTO Member State.

962 The determination of an insufficient manufacturing capacity is made in terms of the Annexure to the Decision.

963 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9. The quantity is limited to the 'current need' of the importing country. Accordingly, a compulsory license could not be increased without bringing a new application for a license.

964 The Explanatory Note confirms that this will not be necessary where the license is based on extreme urgencies or non-commercial use grounds. Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 8.

965 Norwegian Patent Act sec 108.

966 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) 8, *Abbott*, 99 AJIL 2 (2005) p. 342.

tionary provisions remain discretionary under Norwegian domestic law. Article 31*bis*(2)(b)(ii)[967] states that the supplier 'should', where 'feasible', make a distinction in the production of the products. The language used by the Member States indicates that the obligation, although important, remains discretionary.[968] This flexibility is transposed into the Norwegian system by giving the granting authority the ability to compel these requirements.[969] The Norwegian system also abstains from limiting when the system can be used (i.e. the public health problem), it does not limit the scope of diseases[970] and from imposing any time restriction on the license duration. Further evidence of the minimalist approach is the absence of any time restriction on the license duration and Norwegian quality or admission requirements. The Norwegian system intelligently avoids imposing such requirements and leaves the obligation to determine safety and efficacy to the importing country.[971]

The Norwegian implementation of the Article 31*bis*(3)[972] obligation – to remunerate the patent holder according to the economic value of the license to the importing Member State – does not mention the possibility that the importing Member State may have provided for the remuneration of the patent holder itself. It is however assumed that the requirement to take into account the 'economic value' of the license will have due regard for the remuneration granted by the importing Member State and adjust the Norwegian remuneration accordingly.

The protection against the diversion of the licensed products is sensibly resolved by the Norwegian system: when the licensor learns that the products are not being

967 Decision para 2(b)(ii).

968 The Explanatory Note expressly states that these 'provisions are based on paragraph 2(b)(ii)' of the Decision. As the Regulation does not include the grounds for the conditionality of provisions in the Decision it is assumed that they will nevertheless be required to consider these factors in determining the discretionary nature of the provisions. The Explanatory Note also states that the Regulations purpose is to allow the granting of export licenses 'in accordance' with the Decision. Notwithstanding this, it is clear from the Explanatory Note that the principal concern of the granting authority is to prevent the unauthorised use of the compulsory license. Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9-10.

969 Norwegian Patent Act sec 108. These include: (i) the packaging, including its container, should be distinguishable form the original packaging in Norway or other states in which the patent holder markets its product; (ii) the packaging must identify that they have been produced under a Norwegian compulsory license and that they are destined for a specific market. The discretionary nature of sec 108 is contradicted by the Explanatory Note which states, in reference to the relevant provisions in sec 108, that the 'grant of a compulsory license *must* include conditions to guard against its unauthorised use' (emphasis added). Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.

970 Compare *Abbott*, 99 AJIL 2 (2005) fn. 130 p. 333.

971 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9. Manufacturing requirements will however remain applicable.

972 Decision para 6(i).

used, to an 'appreciable degree', in accordance with the grant of the license, the manufacture and export of the products shall cease.[973] This obligation to cease is however a discretionary requirement that the granting authority may impose. Similarly well resolved is the question of actions available to the patent holder in terms of the paragraph 4 to the Annex.[974] Instead of making special arrangements or remedies the Norwegian system makes reference to existing remedies under patent law.[975] The transparency in the Article 31*bis* system will ensure that the patent holder has sufficient information to overview the compliance with the system and the license requirements.

The Norwegian system refrains from any direct reference to the Chairman's Statement. This absence once again confirms the Norwegian approach to only implementing the essentials of Article 31*bis* system. Where the system is found to be lacking, interpretation will be sought in Article 31*bis* and potentially the Chairman's Statement. As the latter does not impose any direct obligations it will only play a role when the domestic rules and Article 31*bis* are unable to provide sufficient clarity.[976]

The Norwegian system is, from a policy standpoint, an ideal system to resolve the paragraph 6 dilemma. It is less complex than the Article 31*bis* system, it is stripped of unnecessary limitations spawned by policy thoughts in the Article 31*bis* system[977] and it only legislates those rules necessary for the effective operation of the system.[978] The approach taken by Norway represents an adoption of the spirit of the Public Health Declaration and the TRIPS Agreement at large. It is free of prejudgemental policy issues and ensures that only the essential operational issues are implemented. The remaining issues and fears as to the abuse of the system and the diminution of patent protection are not shifted to the operation of the system between the actual users and producers but left to the government to address – either between itself and other Member States on a government level or between the organs of government.

973 Norwegian Patent Act sec 108.

974 Decision para 5.

975 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.

976 The clear formulation of the Norwegian system indicates that the use of the Chairman's Statement will only likely be with regards to influencing the labelling restrictions. As the 'Best Practices' Guidelines are merely illustrative, the domestic licensee would be able to other labelling practices if it is able to show that the measures it adopts are more effective or more feasible.

977 Notions of 'good faith', 'pursue industrial and commercial policy', the definition of 'public health problem' and the scope of diseases are not regulated by the Norwegian Patent Act.

978 An example of the effectiveness of the system is the ability of a licensee to produce, under one license, pharmaceutical products for exports to more than one importing state. This permits cost reduction and avoids unnecessary bureaucratic obstacles.

The Canadian implementation of the Article 31*bis* system differs substantially from the Norwegian approach. Critics would claim that the Canadian system puts more emphasis on formalities, forms and solemn declarations than on a simple and efficient system to aid Member States without adequate domestic pharmaceutical production capacities.[979] Proponents would counter that the formalities are safeguards that will deter the abuse and circumvention of the patent system. Either way, the system implemented by the Jean Chrétien Pledge to Africa Act (the 'Act')[980] on the 14th of May 2004 is substantially more exhaustive than the Norwegian system.[981] Instead of examining the entire system, the examination of the Act concentrates on the material scope, system and safeguard differences that distinguish it from the Norwegian approach and discusses to what extent the Canadian system has adopted the underlying policy considerations of Article 31*bis*, the Public Health Declaration and the TRIPS Agreement.

The Canadian approach differs from the scope of Norwegian approach in a four noticeable ways. Firstly, the comprehensive nature of the system has made it necessary for both the Patent Act and the Food and Drug Act to be amended and the creation of a new system for the similar regulation of medical devices.[982] Secondly, the Canadian legislators have limited the scope of the system to a finite number of pharmaceutical products.[983] In terms of Schedule 1 of the Act, only 56 pharmaceutical products are considered potential exportable pharmaceutical products.[984] Thirdly,

979 The legislators themselves acknowledge that their system is 'quite detailed'. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1151.

980 The Jean Chrétien Pledge to Africa Act, Bill C-9, assented to on 14.05.2004, amending the Patent Act and the Food and Drugs Act. The Act brought about amendments to the Patent Act and the Food and Drugs Act that were to 'facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis malaria and other epidemics'. Although the Act was assented to prior to the Norwegian Regulation it only came into force on the 14th of May 2005.

981 An agreement was reached with the US to ensure that the NAFTA provisions will not impede the implementation of the Amendment. Cf. *USTR*, Special 301 Report (2006) p. 11.

982 Regulations Amending the Medical Devices Regulations (Developing Countries) SOR/2005/142, Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1117.

983 Canadian Patent Act RSC 1985 c P-4 sec 21.02. The *numerus clausus* list for the pharmaceuticals was rejected by the Member States during the para 6 negotiations. The Canadian list excludes certain AIDS combination medication recommended by the WHO. Cf. *t'Hoen*, (2005) p. 5.

984 Sec 21.03 of the Canadian Patent Africa Act states that additional patented products can be added to the list provided it is recommended by the Minister and the Minister of Health and is used to address health problems afflicting many developing and LDC Member States. On 21.09.2006 oseltamiv phosphate (Tamiflu) was added to the list. Noteworthy is the inclusion