B. Canada

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

Schedules 2 and 3 to the Act list the countries eligible to take advantage of the system, either as a LDC or as a developing Member State.[985] Excluded from the lists are those Member States that have chosen to opt-out of the system or only to use it in emergency situations.[986] Lastly, although the Canadian system serves to implement the Article 31*bis* system, its focus lies on the 'humanitarian' assistance.[987] Whereas this may be the effective result of the system, the Article 31*bis* system serves to enable the effective use of the patent system.[988]

The system adopted in Canada sets more onerous measures on the licensee than the Norwegian system and more onerous than is required by Article 31*bis*.[989] This implementation of the Article 31*bis* system signals the Canadian intention to keep a tight control on the use of the system. To this effect, the Canadian system requires:

- a solemn or statutory declaration verifying that the prior negotiations were unsuccessful, were not carried out over a period of less than a 30 days and had provided the patent holder with essentially the same information as is set out in the compulsory license application[990]
- a solemn or statutory declaration verifying that the importing country is a WTO Member State, the patent status of the pharmaceutical product in that Member State and that it is identified in the schedules to the Act (either as a LDC, a developing Member State or a Member State having partially opted out of the system)[991]

of vaccines in the Canadian list, as set out in schedule 1 to the Jean Chrétien Pledge to Africa Act. The list includes the dosage form, the strength and the route of administration of the 56 pharmaceuticals. Absent from the list are, at present, medical devices. Cf. Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1117

985 A number of countries have however been excluded from the list: for example East Timor, Turkmenistan and Vietnam. Like the list identifying the eligible pharmaceutical products, the list of countries may be amended either to include or exclude country. The amendment is done by the Governor in Council on recommendation from the Ministers of Foreign Affairs, International Trade and International Cooperation. In the case of a LDC, the status must have been determined by the UN. Cf. Canadian Patent Africa Act sec 21.03(1)(b). Like the list for the eligible products, the list for countries has also been criticised as an unnecessary restriction on the Art 31*bis* system. Cf. *t'Hoen*, (2005) p. 5.

986 Those countries that have agreed to a limited opt-out are identified in schedule 4.

987 Sec 21 of the Canadian Patent Act is now titled 'Use of Patents for International Humanitarian Purposes to Address Public Health Problems'.

988 Public Health Declaration para 6.

989 Elliot refers to the Canadian system as a 'TRIPS-plus' entitlement for Canadian patent holders. Cf. *Elliott*, 7 Bridges 8 (2003) p. 21.

990 Canadian Patent Act RSC 1985 c P-4 sec 21.04(3)(c).

991 This condition, *inter alia*, prevented MSF from obtaining a compulsory license under the Canadian system. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

- the production of a certified copy of the notice sent to the WTO setting out its intention to use the system[992]
- the submission of a solemn or statutory declaration to the granting authority and the patent holder setting out the number of pharmaceutical units are to be sold and their monetary value
- prior to the exportation of the product, the creation and maintenance of a website disclosing the particulars of the license[993]
- the payment of royalties, within a prescribed period, to the patent holder in accordance with the prescribed formula
- the identification of the quantity, product, importing country and all known persons handling the shipment of the product to the importing state.[994] This information is also required to be furnished to the patent holder, the importing country and the purchaser each time a shipment of products is exported.[995]
- the licensee must carry records that would enable the audit of the licensee's exercise of the compulsory license and
- the compulsory license is granted for a period of two years.[996]

The Canadian system is strewn with safeguards. Each solemn declaration and form deters the unlawful use of the system and increases the accountability of the licensees. Not only is the misuse of the system by the licensees deterred; the Canadian system sets certain requirements that – directly and indirectly – limit the 'full' use of the system by the importing Member State. Thus for example, the inability to acquire a compulsory license without the prior negotiations being conducted with the patent holder has meant that Canada is unwilling to acknowledge foreign circumstances of extreme urgency or public non-commercial use in their license applications.[997]

992 992 Where the importing country is not a WTO Member State, the Canadian system requires a certified copy of the notice sent to the Canadian Government requiring assistance.

993 Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

994 Further, the Canadian Intellectual Property Office will contain a link to the website. Cf. Canadian Patent Act RSC 1985 c P-4 secs 21.04(2) and 21.06(1).

995 Failure to comply with these requirements results in the prohibition of exportation of the products. Cf. Canadian Patent Act RSC 1985 c P-4 sec 21.16(2). An earlier Canadian proposal sought to give the patent owner a 'right of first refusal' allowing it to assume the role of the generic producer in a supply contract. This proposal was however dropped. Cf. ICTSD 'Canadian Drug Patents Law for Poor Countries Released for Comment' *Bridges Weekly Trade News Digest* (13.10.2004) 5, *Abbott*, 99 AJIL 2 (2005) p. 341-342.

996 Canadian Patent Act RSC 1985 c P-4 sec 21.09. The duration may be extended if the license holder pays an additional license fee and states under oath that the products exported were less than was authorised in the license. All other requirements set out for the initial application must be repeated for the renewal. Only one renewal may be granted. Cf. Canadian Patent Act RSC 1985 c P-4 sec 21.12.

997 Cf. *Abbott*, 99 AJIL 2 (2005) p. 342.

The pecuniary safeguard of the patent holder's interests is expressly regulated in the Canadian system.[998] The Act speaks of a mandatory obligation on the licensee to compensate the patent holder. In determining the amount of remuneration the granting authority, the Governor in Council, must take into consideration the humanitarian and non-commercial reasons behind the license. These grounds are seen to be effectively incorporated into a formula used in the Canadian system to calculate the remuneration. The formula multiplies the monetary value of the pharmaceutical supply agreement by an amount which fluctuates according to the basis of the importing countries standing on the UN Human Development Index (the 'UNHDI'). In terms of the formula the royalty rate will not be lower than 0,02% and not more than 3,6% of the monetary value of the supply agreement.[999]

If it transpires that the agreement between the producing party and the importer is 'commercial in nature' a court is permitted to terminate the compulsory license. In terms of the Act, an agreement is commercial where the cost of the product is more than a quarter of the price of the patent holder's product.[1000] In other words, if the licensed product is less than 75% cheaper than patent holder's prices the patent holder can apply to have the license cancelled or the royalty rate increased.[1001] The Canadian legislators justify this provision on the 'good faith' clause in the Chairman's Statement.[1002] By limiting the opportunities licensees have to profit from the Article 31*bis* system the Canadian approach prevents the system from potentially becoming an 'instrument to pursue industrial or commercial objectives'.[1003]

998 Canadian Patent Act RSC 1985 c P-4 sec 21.08(1).

999 Hence, the calculation for Nigeria, which was ranked number 151 of 177 countries in the UNHDI in 2004, would be as follows: [(1+177-151)/177] x 0.04 = 0.0061 or 0.61% of the value of the pharmaceutical supply contract. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1149.

1000 Determining that the price of the pharmaceutical product is 25% or more of the equivalent patented brand name pharmaceutical in Canada is a prerequisite for determining if the use of the license is commercial in nature. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1150.

1001 A court tasked with considering such an application must take into account the need for the producer to make a reasonable return on the production, that ordinary profit is permissible and the international prices for humanitarian medication. The courts must however deny a termination on these grounds where the producer can prove that the price being charged is not more than the direct supply cost plus a mark-up of 15%. Cf. Canadian Patent Act RSC 1985 c P-4 secs 21.08(7) and 21.17(2, 5 and 6). In terms of sec 21.14(f) the license may also be terminated where, with the knowledge of the licensee, the products are being re-exported contrary to the Art 31*bis* system.

1002 Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 at 1150, 1155. The statement expressly notes that it does not consider the Chairman's Statement's 'good faith clause' to set a requirement for the implementation of the Art 31*bis* system.

1003 It is also theoretically possible for the pharmaceutical producer to frustrate a license (or bring about its termination) by lowering its prices resulting in the price difference being less than the required 75%.

In addition to safeguards protecting the patent system and the rights of the patent holder, the Act also inserts safeguards securing the quality of the product. In this regard the Act prohibits the exportation of the pharmaceutical product if it does not meet the Canadian efficacy, safety and quality standards.[1004] The Act does not detail exactly what tests will be required and how long they would take to complete.[1005] It would however be expected that this process be restricted to a chemical and quality analysis as the Canadian system already sets out what pharmaceuticals and in what dosage will be permitted.[1006] The list must be assumed to constitute a list of pharmaceuticals that are – in their specified state – effective and safe. As the admission of a pharmaceutical is generally the task of the country in which the product is consumed this requirement effectively requires two quality assurance tests.

To safeguard against the licensed product being diverted and used in the Canadian market the Canadian system requires both the label and the product itself must bear the marking 'XCL', be a 'significantly different' colour to the Canadian original pharmaceutical product and the label of the product contains an export tracking number and the wording 'FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA'.[1007] With these requirements the Canadian regulations seek to deter the diversion of the products by making the licensed products clearly distinguishable from the same product sold in Canada. Only if the product is distinguishable will it be permitted to be sold.[1008]

With the multitude of provisions, conditions and formalities found in the Canadian Act, there is the potential that either dogmatic administrative acts or judicially active patent holders will be able to frustrate or delay the granting or exercise of a compulsory license.[1009] The Canadian HIV/AIDS Legal Network noted that the Act

1004 Canadian Patent Africa Act sec 21.04(3), Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1118.

1005 Sec C.08.002 of the Canadian Food and Drugs Regulations C.R.C. 870 requires, *inter alia*, tests and clinical evidence that establishes the efficacy, potency, purity, stability and safety of a new drug. This would apply to a new drug under the Art 31*bis* system. Cf. Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.004(b). Medicines that are not new must comply with sec C.07.003(c). A Canadian representative at the WTO noted that the licensed products will be subject to the same health and safety review as products for domestic consumption, however, the licensed products would be afforded preference by way of a special expedited queue. Cf. Canada in the TRIPS Council Minutes (15.09.2005) IP/C/M/48 p. 25.

1006 Jean Chrétien Pledge to Africa Act schedule 1.

1007 Canadian Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.008. The export tracking number is assigned by the Minister of Health.

1008 Canadian Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.007.

1009 The Act and is supplementary regulations makes provision for 7 different solemn or statutory declarations and a number of certifications and notifications with regards to the exportation system. Cf. Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 at 1131-1137, *Canadian HIV/AIDS Legal Network,* press re-

contains 'unnecessary and unjustified hurdles to using it, and could undermine it'.[1010] Whereas the Canadian system sought to implement a local solution to the paragraph 6 dilemma, its conditions do not represent a 'liberal' or expedient implementation of the Public Health Declaration's policies. Hence, the Canadian approach lays more emphasis on comprehensive control mechanisms than on enabling the full use of the flexibilities permitted in the Public Health Declaration.[1011] The Canadian approach cannot however be accused of not reflecting the Public Health Declaration policies; it has taken measures to adopt a solution and has ensured that intellectual property rights are effectively and adequately protected in a manner it deems most appropriate.[1012]

Notwithstanding the formalist approach taken by Canada, it is more likely that it – and not Norway – will play a meaningful role in providing assistance to needy countries.[1013] This is not a result of the system created in Canada but rather a result of the more extensive generic pharmaceutical sector found in Canada.[1014] Not only do the generic producers have the capacity to help, they are also able to look back on a 'rich' compulsory license and generic production history in Canada.[1015] This experience, the ability and the resulting competitive advantage may make Canadian generic producers the first stop for needy countries – notwithstanding the rigid and bureaucratic system.[1016] A first step in this direction has already been taken.[1017]

lease from 13.05.2005. MSF has spent more than 2 years seeking to get a compulsory license under the Canadian system. It has called the system 'very "long" and "resource intensive"'. Cf. ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.10.2005) p. 3.

1010 Canadian HIV/AIDS Legal Network, (2005).

1011 It has been referred to as being 'just for one country, for one product and for a limited period'. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

1012 Compare TRIPS Agreement preamble, Art 1.1.

1013 Canada has become the first country to respond to a formal request to supply HIV/AIDS drugs under the Article 31*bis* system. *ICTSD*, Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda in First Test of WTO Procedure (2007) 11 *Bridges Weekly Trade News Digest* 32 p. 4-5.

1014 The Canadian output of pharmaceuticals is approximately 10 times that of Norway. Cf. WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 4.

1015 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 19.

1016 The history and make-up of the Canadian generic market and the compulsory license tools available have led to the first notification made to the WTO for the production and supply of a HIV/AIDS drug. *ICTSD*, Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda in First Test of WTO Procedure (2007) 11 *Bridges Weekly Trade News Digest* 32 p. 4-5.

1017 WTO Notification from Canada 'Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (05.10.2007) IP/N/10/CAN/1.

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.