CANADA'S ACCESS TO MEDICINES REGIME -- CONSULTATION PAPER

Canada

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1.0 Introduction

As a first step in the Government's accelerated statutory review of Canada's Access to Medicines Regime (CAMR), the purpose of this paper is to solicit comments as to how the regime can better deliver on Canada's commitment to improve access to less expensive medicines that are urgently needed to treat HIV/AIDS, malaria, tuberculosis, and other epidemics in developing and least-developed countries, while remaining compliant with World Trade Organization (WTO) rules.

2.0 Background

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out the minimal norms and standards WTO Members must adhere to in protecting intellectual property rights.[1] As regards patents, these include the requirement that 20-year patent protection be available for all inventions, whether products or processes, in almost all fields of technology. Article 31 of TRIPS allows for the compulsory licensing or governmental use of patents, without the authorization of the patent owner, under certain conditions. One such condition, Article 31(f), is that the compulsory licence or government use of the patented invention be predominantly for the supply of the domestic market.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health recognized that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector face difficulties making effective use of compulsory licensing under the TRIPS Agreement. This is because Article 31(f) prevents WTO Members with manufacturing capacity in the pharmaceutical sector from issuing compulsory licences authorizing the manufacture of lower-cost, generic versions of patented medicines for export to countries with little or no such capacity. Council for TRIPS was thus instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

After two years of negotiations, on August 30, 2003, WTO Members agreed to waive Article 31(f) and (h)[2], subject to certain terms and conditions (see Annex A), so as to give Members with pharmaceutical manufacturing capacity the right to issue compulsory licences authorizing the manufacture and export of pharmaceutical products to countries with insufficient or no pharmaceutical manufacturing capacity. The stated purpose of this waiver is to facilitate developing and least-developed countries' access to less expensive medicines needed to treat HIV/AIDS, tuberculosis, malaria and other epidemics. It is important to note that the remaining obligations under Article 31 were not waived.

On December 6, 2005, WTO Members approved changes to the TRIPS Agreement to transform the August 2003 agreement into a permanent amendment. The amendment will formally become part of the TRIPS Agreement once two-thirds of WTO Members ratify the change. Members have until December 1, 2007 to do so.

In September 2003, Canada was the first country to announce its intention to implement the WTO waiver. This followed from Canada's broader commitment to address public health problems in the developing world, as well as its participation in the negotiations leading up to the decision. In doing so, Canada faced the unique challenge of developing an unprecedented compulsory licensing for export regime that advanced the waiver's humanitarian objectives, while balancing a number of competing policy objectives, namely:

- complying with other relevant international obligations under TRIPS and the North American Free Trade Agreement (NAFTA);
- respecting the rights and interests of divergent stakeholders groups; and
- maintaining the integrity of the domestic patent regime.

On May 14, 2004, the legislative framework for CAMR received Royal Assent.[3] This framework consists of amendments to the *Patent Act*, authorizing the Commissioner of Patents (the "Commissioner") to grant compulsory licences allowing the manufacture and export of lower-cost versions of patented pharmaceutical products, and to the *Food and Drugs Act*, authorizing the Minister of Health to review these products for safety, efficacy and quality. One year later, on May 14, 2005, following passage of the regulations necessary to round out this legislative framework, CAMR came into force.

3.0 Statutory Review of CAMR

Although CAMR received all party support and was developed in collaboration with interested stakeholder groups, there were conflicting views on how the various terms and conditions of the WTO waiver should be reflected in the amending legislation, and how it ought to balance the various competing policy objectives mentioned above.

In light of this, and of the unprecedented nature of the initiative, the amending legislation included a clause calling upon the Minister of Industry to review the relevant provisions of the *Patent Act* (sections 21.01 to 21.19) within two years of its coming into force, and to table a report of that review in Parliament within 15 days of the report's completion.[4]

Despite being in force since May of 2005, CAMR has not yet resulted in the export of any eligible pharmaceutical products to eligible importing countries. Similarly, there have been no exports under comparable regimes in other countries that have implemented the WTO waiver.[5] Critics have cited a number of reasons for this but a definitive diagnosis will prove difficult until such time as a compulsory licence is granted. Nevertheless, given the pressing humanitarian concerns which gave rise to the waiver and which underlie CAMR, a decision has been made to initiate the statutorily mandated review in advance of what is required in order to meet the May 2007 deadline for its completion.

The present document marks the first step in that accelerated review process and is intended as a discussion piece which will serve to focus dialogue between stakeholders and government on how CAMR might better meet its humanitarian objectives, without derogating from international trade obligations or undermining the intellectual property rights necessary for continued innovation in Canada.

What follows is a brief description of the key features of CAMR. Each section begins with an identification of the particular part of the WTO waiver or TRIPS the feature is intended to implement, followed by a description of the particular means chosen to implement it and the rationale for doing so, and concluding, where circumstances permit, with a comparison between this aspect of CAMR and similarly intentioned measures in other developed countries that have also sought to incorporate the waiver into domestic law (see Annex B for a comparative table).

A non-exhaustive list of questions is also included under each section, in order to assist parties interested in submitting representations to the government in respect of CAMR. These are intended to serve as a discussion aid only and do not reflect a particular orientation on the part of the government as to what changes to CAMR, if any, may be considered upon completion of the review. Additional comments are welcome.

4.0 Eligible Importers

The WTO waiver defines an "eligible importing Member" as "…any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[6]

Under CAMR, the various classes of eligible importing countries are categorized in Schedules 2 through 4 of the *Patent Act*. These schedules are organized according to level of development and WTO membership status and may be amended as required by the Governor-in-Council.[7] Although the waiver suspends certain obligations between WTO member countries only, for humanitarian reasons Canada implemented it in a manner that enables both WTO and non-WTO Members to import pharmaceutical products under licence. Non-governmental organizations (NGO) may also participate in CAMR by purchasing pharmaceutical products, with the permission of an eligible importing country.[8]

Schedule 2 is composed of least developed WTO and non-WTO Members, Schedule 3 is composed of developing country WTO Members and Schedule 4 is composed of WTO Members that have signalled their intention to rely on the waiver only in cases of national emergency or extreme urgency. Non-WTO Members that have been identified by the Organization of Economic Development (OECD) as eligible for official development assistance may also be added to Schedule 4, on a case-by-case basis.

All other jurisdictions that have implemented the WTO waiver have similarly broadened the scope of the WTO waiver to include non-WTO Members. In each case, and in keeping with the WTO waiver, all eligible importing countries are required to make the appropriate notifications to either the WTO or the government of the exporting country as part of the application process.

Questions

1. NGOs may purchase products when "permitted by" an eligible importing country. Should CAMR provide guidance on the meaning of "permitted by" in this context?

2. The WTO waiver also allows the export and distribution of licenced products to developing and least-developed countries that are party to a regional trade agreement.[9] Does CAMR accommodate the purchase and distribution of licenced products by and amongst regional trade groups?

5.0 Eligible Pharmaceutical Products

The WTO waiver defines "pharmaceutical product" as "any patented product, or product manufactured through a patented process, needed to address the public health problems afflicting many developing and least-developed countries, such as HIV/AIDS, tuberculosis, malaria and other epidemics."[10] This definition expressly includes active ingredients and diagnostic kits.

The stated purpose of CAMR is to facilitate access to pharmaceutical products, as defined by the WTO waiver.[11] The products that are eligible for export are listed in Schedule 1 to the *Patent* Act.[12] Schedule 1 was initially composed of all pharmaceutical products on the World Health Organization's (WHO) Model List of Essential Medicines that are patented in Canada. If a product is not patented in Canada, CAMR does not apply and a Canadian pharmaceutical manufacturer is free to export the product as it sees fit.[13]

One of the objectives of Schedule 1 is to provide clarity and transparency to what products are eligible for export under the regime. The inclusion of a pre-approved list of eligible drugs also minimizes the discretion required of the Commissioner in deciding whether to issue a compulsory licence**,** thereby limiting the degree to which that decision may be challenged in court.

Schedule 1 may be amended by Order-in-Council to reflect the evolving public health needs of developing countries. Since the coming into force of CAMR, Schedule 1 has been amended twice. The first amendment was in response to a request from an NGO and a Canadian pharmaceutical manufacturer to add a fixed-dose combination (FDC) HIV/AIDS therapy. The second amendment added an antiviral drug used for the prevention and treatment of the influenza virus, also at the request of a Canadian pharmaceutical manufacturer and an NGO.

CAMR requires the Ministers of Industry and Health to establish an expert committee to advise them on the recommendations they may make to the Governor-in-Council regarding any changes to Schedule 1. This committee must be established by May 2008.[14]

Other jurisdictions that have implemented the WTO waiver have not relied on a pre-approved list of eligible products similar to Schedule 1, opting instead to adopt the WTO's definition of pharmaceutical product without providing additional guidance on the matter.[15]

Questions

3. Is Schedule 1 an appropriate mechanism to define the products that are eligible for export under CAMR?

4. Is Schedule 1 necessary to avoid delays due to litigation?

5. Should the government review Schedule 1 at regularly scheduled intervals to consider amendments that are in addition to requests received from interested manufacturers, importing countries and NGOs?

6. What criteria should be considered when amending Schedule 1?

7. Schedule 1 does not currently contain any active pharmaceutical ingredients (API). Should CAMR allow for the export of APIs?

6.0 Notification

The WTO imposes a number of requirements and conditions that must be met by an eligible importer in order to avail itself of the waiver.[16] The Member must specify the names and expected quantities of the product needed, confirm that it is either a least-developed country or that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the product in question, and confirm that it has granted or intends to grant a compulsory licence in instances where the product is patented in the importing country. Notifications containing this information will be posted on the WTO's website (or on a website maintained by the Government of Canada, in the case of non-WTO Members).[17]

CAMR incorporates these requirements and conditions by stipulating that the Canadian pharmaceutical manufacturer include in its application for a compulsory licence a certified copy of the intended importing country's requisite notice to the WTO or to the Government of Canada, as described above.[18]

Questions

8. Is the requirement that a certified copy of the importing country's notification be included in the application for a compulsory licence necessary to comply with the WTO waiver?

9. CAMR requires non-WTO member developing countries (those listed on Schedule 4) to: declare a national emergency or other circumstance of extreme urgency; agree that the imported product will not be used for commercial purposes; and undertake to adopt anti-diversionary measures.[19] Are these requirements unduly burdensome on non-WTO developing member countries that wish to participate in CAMR?

7.0 Health Canada's Drug Review

Although not specifically required by the WTO waiver, partly at the request of Canadian generic pharmaceutical manufacturers, CAMR requires that all pharmaceutical products intended for export be reviewed by Health Canada in accordance with the standards prescribed by the *Food and Drugs Act* and its regulations.[20] This is also intended to provide eligible importing countries with an assurance that products exported under CAMR are of the same safety, efficacy and quality as those available to Canadians.

Health Canada reviews product submissions under CAMR on a priority basis. A Canadian pharmaceutical manufacturer may file its submission with Health Canada at any time and is not required to await the negotiation of a supply agreement with an importing country or for the importing country to send the required notification to the WTO or the Government of Canada.

Health Canada has recently reached an understanding with the WHO whereby the WHO will accept the results of Health Canada's review of CAMR products for the purposes of its Procurement, Quality and Sourcing Project (known as the Prequalification Project (PQP)). The objective of the PQP is to assess the acceptability, in principle, of drugs for the treatment of HIV/AIDS, malaria and tuberculosis for procurement by United Nations (UN) Agencies. The assessment procedure is aimed at identifying products and suppliers meeting WHO standards, thus facilitating the procurement of drugs of acceptable quality. Although the PQP is aimed at facilitating procurement by UN agencies, developing countries often look to it as an assurance of product quality when making purchasing decisions. The WHO recently added the above mentioned FDC HIV/AIDS therapy to the PQP on the basis of Health Canada's approval of the product.

The EU and Switzerland are the only other jurisdictions to provide for the regulatory review of products exported under the terms of the WTO waiver**.** That review is voluntary in the EU but mandatory in Switzerland.[21]

Questions

10. Does the requirement that pharmaceutical products be reviewed for safety, efficacy and quality promote or discourage Canadian pharmaceutical manufacturers and eligible importing countries from participating in CAMR?

11. Would manufacturers and countries be more or less likely to participate in CAMR if this review were optional?

12. Are there alternatives to a mandatory/optional Health Canada review process that would be acceptable to Canadian pharmaceutical manufacturers while providing safety, efficacy and quality assurance to eligible importing countries?

8.0 The Application Process

Pursuant to Article 31(b) of TRIPS, a compulsory licence may only be granted by a Member if the applicant first attempted to obtain the permission of the patentee for the use of the patented invention on reasonable commercial terms and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.[22] In the context of the waiver, some have construed this to mean that the requirement can be waived in the exporting country when there is a national emergency or extreme urgency in the importing country.[23]

CAMR requires that the applicant include with its application for a compulsory licence a declaration stating that it had, at least 30 days prior, unsuccessfully sought a voluntary licence on reasonable terms from the patentee.[24] A request for a voluntary licence may be made concurrent to Health Canada's review or to any other step in the process.

An application must identify, among other things, the pharmaceutical product for which the licence is sought, the quantity to be manufactured, the patents which protect it, the country to which it will be exported and the identity of the purchaser. The application must also be accompanied by a copy of the notification the importing country provided to the WTO or the Government of Canada, as the case may be.[25]

If the application meets each of the content requirements described above and the Minister of Health has confirmed that the product has met all of the health, safety**,** quality and distinguishability requirements, the Commissioner must grant the applicant a compulsory licence.

Most other jurisdictions that have implemented the WTO waiver also require a compulsory licence applicant to first seek a voluntary licence from the patentee.[26] Of these jurisdictions, the EU, Switzerland, the Netherlands and Norway explicitly waive this requirement in circumstances of national emergency or extreme urgency but without specifying their locus.

Questions

13. Does the type of information that must be provided to the patentee in the request for a voluntary licence pose a barrier for the licence applicant?

14. How might the application process be simplified?

15. Should "reasonable terms" be defined? If so, how?

9.0 Duration of the Licence

TRIPS requires that the scope and duration of a compulsory licence be limited to the purposes for which it was authorized.[27]

To give effect to this requirement, a compulsory licence granted under CAMR is valid for two years.[28] However, in the event that a licencee is unable to ship the entirety of the licenced product within that time frame, the licence may be renewed for an additional two-year period.[29] The renewal process requires the licencee to submit a form to the Commissioner certifying that a quantity of the product remains to be exported and that it has complied with the terms and conditions of the licence.

The EU, Switzerland and Korea contemplate the granting of compulsory licences for a finite period but a specific upper or lower time limit is not prescribed.[30]

Questions

16. Is a two-year, once-renewable licence term an appropriate duration for a compulsory licence granted under CAMR?

17. Should CAMR provide for a simplified procedure for the renewal of a compulsory licence where the conditions that gave rise to the original licence persist?

10.0 Royalties

The WTO waiver requires that "adequate remuneration" be paid to the patentee on a case-by-case basis, taking into account the economic value to the importing Member of the use authorized in the exporting Member.[31] In addition, TRIPS requires that decisions relating to remuneration be reviewable judicially or independently by a distinct higher authority.[32]

Under CAMR, the remuneration, or royalty fee, to be paid by the licencee to the patentee is calculated by multiplying the monetary value of the supply contract by an amount that fluctuates on the basis of the importing country's standing on the UN Human Development Index.[33] According to this formula, the lowest country on the index would pay a royalty of approximately 0.02 percent, and the highest 3.5 percent. Where a patentee is of the view that the royalty resulting from the application of the formula is inadequate, it may apply to the Federal Court for an order setting a higher amount.[34] In considering the merits of such an application, the Court must take into account the economic value of the use of the licenced product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the licence.[35]

Whereas Switzerland has adopted Canada's formula for calculating the remuneration payable to the patentee[36], other jurisdictions have simply opted to track the language of the WTO waiver by imposing a duty on the licencee to pay "adequate remuneration".[37] The EU has limited the royalty payment to 4% of the value of the supply agreement in situations of extreme urgency.[38]

Questions

18. Is there an alternative to the CAMR formula for calculating remuneration that would better encourage uptake of the regime while remaining compliant with the WTO waiver and TRIPS?

11.0 The Good Faith Clause

The WTO waiver was adopted by the WTO General Council in light of the General Council Chairperson's statement stipulating that it must be used in good faith in order to deal with public health problems and not for commercial policy objectives.

CAMR gives effect to this statement by providing the patentee with the right to challenge a licence in court where there is cause to believe that the licence is commercial in nature.[39] To challenge the licence, the patentee must first establish that the average price of the licenced drug is 25 percent or more of the average price of the equivalent patented brand name drug in Canada. If this test is met, the Court is mandated to look to the merits of the application and determine, based on a number of statutory considerations, whether the licence is commercial in nature.

Notwithstanding the relative price of the licenced drug and the Court's assessment of the merits, an application will be dismissed where the licencee can establish that the drug's price remains less than its cost of production plus 15 percent.[40]

If, however, the patentee prevails on its application, the Court can either terminate the licence or allow it to continue on the payment of compensation by the licencee for the commercial use of the patent. A termination order can also be accompanied by either: 1) an order requiring the licencee to deliver any remaining licenced product in its possession to the patentee, or 2) with the consent of the patentee, an order requiring the licencee to export any remaining product to the purchasing country.

Other jurisdictions, such as the EU, Netherlands and Norway, have made varying references to the text of the Chairperson's Statement, or to the principles underlying it, in either regulatory language or supporting documentation.[41] However, to date, Canada is alone in fashioning specific measures to give effect to this aspect of the waiver.

Questions

19. Does the prospect of litigation under the good faith clause discourage Canadian pharmaceutical manufacturers from participating in CAMR?

20. Is the good faith clause necessary to implement the Chairperson's Statement?

21. What alternative measures might be employed to ensure that CAMR is not used for commercial purposes?

12.0 Quantities Exported Under Licence

As part of the notification requirements described earlier, the WTO waiver requires an eligible importing country to indicate to the WTO both the name and the quantity of the pharmaceutical product it intends to import.[42] Compulsory licences granted under the terms of the WTO waiver must be limited to this notified amount.[43]

To give effect to these provisions, CAMR requires that the quantity of product authorized to be manufactured and exported under compulsory licence not exceed the lesser of either the quantity set out in the manufacturer's licence application, and the quantity indicated in the importing country's notification to the WTO or to the Government of Canada.[44]

The laws of the EU, Switzerland and Netherlands also provide that the amount authorized for export will be limited by the terms of the compulsory licence.[45] In addition, the EU has established an accelerated procedure for modifying the original authorized quantity where it does not meet the importing country's ongoing needs.[46]

Questions

22. How does the limit on authorized quantity impact participation in CAMR?

23. Should CAMR include a simplified procedure for amending the authorized quantity of a compulsory licence after it has been granted?

13.0 Anti-Diversion Measures

According to the WTO waiver, products produced under compulsory licence should be distinguishable through special packaging and/or special colouring/shaping provided that such distinction is feasible and does not have a significant impact on price.[47] The licencee is also required to post information on a website describing these distinguishing features, as well as information regarding the quantities being shipped to each destination.[48]

In keeping with the WTO waiver, CAMR requires that products exported under licence bear the mark "XCL" (for solid oral dosage forms), be of a colour that is significantly different from the patented version sold in Canada and include certain information on all labelling to distinguish them from the patented versions available on the Canadian market.[49] Products are also issued an export tracking number by Health Canada which must be printed on the product label.[50]

Before a pharmaceutical product may be exported under CAMR, the licencee must also establish a website disclosing the name of the licenced product, its distinguishing characteristics, the identity of the importing country and the amount to be manufactured and sold for export, as well as information identifying every known party that will be

handling the product while it is in transit from Canada to the importing country.[51] To further promote transparency and prevent the diversion of the product, the licencee must provide to the patentee, the importing country and the purchaser, within 15-days before the product is exported, a notice specifying the quantity to be exported and the identity of every known party that will be handling the product while it is in transit.[52]

The EU, Netherlands, Norway, Switzerland, and Korea track the language of the WTO waiver and require all products to be identifiable as being produced under compulsory licence and distinguishable from the patentee's product through packaging, colouring and/or shaping.[53] These jurisdictions also require the licencee to establish a website disclosing the product's identifying features.[54]

Questions

24. Are the safeguards in CAMR sufficient to prevent the diversion of exported pharmaceutical products?

25. Do the anti-diversion provisions extend beyond the requirements of the WTO waiver in a manner that negatively impacts participation in CAMR? If so, what alternatives should be considered?

14.0 Termination of Licence

As mentioned, the WTO waiver was adopted in light of the Chairperson's Statement that it must be used in good faith. In keeping with this, CAMR gives the patentee the right to apply to the Federal Court for an order terminating a compulsory licence where it can establish that the application contained materially incorrect information, that the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties, that the product has been re-exported in a manner contrary to the WTO waiver, or that one of the prescribed terms of the licence has not been respected.[55]

The EU, Switzerland, Norway and Korea provide for the termination of a licence in similar circumstances, including where the importing country fails to make the requisite notification to the WTO[56] or where any of the prescribed conditions of the licence are not met.[57]

Questions

26. Are the grounds for the termination of a licence in CAMR sufficiently clear?

27. Are they fair?

28. Does the possibility of having a licence terminated in this manner deter pharmaceutical manufacturers from participating in CAMR?

15.0 Consultation Process/Submissions

Persons interested in making written representations in response to the present paper, or to other aspects of CAMR not mentioned above, are invited to submit their comments to Industry Canada or Health Canada at the below coordinates no later than January 24, 2007. All submissions will be posted publicly on the CAMR Website at www.camr-rcam.gc.ca within 15 days of that date. A report summarizing the submissions, identifying specific features of CAMR commentators believe to be problematic and proposing possible legislative or regulatory alternatives will be posted by the government on the CAMR website and tabled in both Houses of Parliament.

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994 [hereinafter TRIPS]. Least-developed countries have been given an extension until January 1, 2016, to provide protection for patents.
[2] In instances where importation of licenced product also requires the issuance of a compulsory licence in the importing country, the WTO waiver also waived the article 31(h) requirement that remuneration be paid by the importing country to the patent holder. Under the waiver, it is only in the exporting country that remuneration must be paid, taking into account the economic value of the authorization to the importing country.
[3] Canada's Access to Medicines Regime is also known as "Bill C-9" and the "Jean Chrétien Pledge to Africa (JCPA)".
[4] *Patent Act*, R.S. C. 1985, c. P-4, s. 21.2(1) [hereinafter *Patent Act*]. Section 21.2(1) states: A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force. (2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which the House is still sitting after the report has been completed.
[5] European Union, Regulation (EC) No 816/2006 of the European Parliament and the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [hereinafter EC Regulation No 816/2006]; Switzerland, Draft Amendment to Federal Law on Patents for Inventions [hereinafter Swiss Draft Amendment]; Norway, Amendments to Act of 15/12/1967 No. 9 relating to patents by Act of 19/12/2003 no.127/Patent Regulations of 20 December 1996 No. 1162 amended by Royal Decree of 14/05/2004 [hereinafter Norway Amendments]; India, The Patents (Amendments) Act, 2005 No. 15 of 2005; China, State Intellectual Property Order #37 [hereinafter China Order #37]; Korea, Korean Patent Act as revised by Industry and Energy Committee in the National Assembly and effective as of December 1, 2005 [hereinafter Korean Patent Act]; and the Netherlands, Policy Rules for the issuance of a compulsory licence under s. 57 of the Patents Act 1995 [hereinafter Netherlands Policy Rules].
[6] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003), Article 1(b) [hereinafter WTO waiver].
[7] *Patent Act*, *supra* note 4, s. 21.03(b).
[8] *Ibid*., s. 21.04(2)(f).
[9] WTO waiver, *supra* note 6, para 6.
[10] *Ibid*., para 1(a).
[11] *Patent Act*, *supra* note 4, s. 21.01.
[12] *Ibid*., s.21.02. CAMR defines pharmaceutical products as "any patented product listed in Schedule 1, in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product."
[13] *Food and Drugs Act*, R.S., 1985, c. F-27, s. 37 [hereinafter *Food and Drugs Act*].
[14] *Patent Act*, *supra* note 4, s. 21.18.
[15] China's legislation limits eligible products to pharmaceutical products needed to treat an infectious disease. Infectious diseases are defined as HIV/AIDS, tuberculosis, malaria and other infectious diseases listed on China's "PRC Measures in Prevention and Treatment of Infectious Diseases". See China Order, *supra* note 5, article 2.
[16] WTO waiver, *supra* note 6, para 2(a).
[17] TRIPS and public health: dedicated website for notifications, online: <http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm> and *Patent Act*, supra note 4, s. 21.19.
[18] *Patent Act*, *supra* note 4, s. 21.04(3)(d).
[19] *Patent Act*, *supra* note 4, s. 21.04(3)(d)(v).
[20] *Food and Drugs Act*, *supra* note 13; *Food and Drug Regulations*, C.R.C., c. 870, c.07.004 [hereinafter *Food and Drug Regulations*].
[21] EC Regulation No 816/2006, *supra* note 5, article 18, Swiss Draft Amendment, *supra* note 5, article 5.
[22] TRIPS, *supra* note 1, article 31(b).
[23] See Fredrick M. Abbott, appearance before the Standing Committee on Industry, Science and Technology (March 10, 2004), online: <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=75333> (date accessed: October 13, 2006).

[24] See *Patent Act*, *supra* note 4, s. 21.04(3)(c).
[25] *Patent Act*, *supra* note 4, s. 21.04.
[26] The EU, Switzerland, Norway and Korea have explicitly implemented a duty to seek a voluntary licence. See EC Regulation No 816/2006, *supra* note 5, article 9, Swiss Draft Amendment, supra note 5, article 40e.1, Norway Amendments, *supra* note 5, s.49, Netherlands, *Patents Act 1995,* s. 57(1) and Korean Patent Act, *supra* note 5, article 107(1). It is not clear whether the legislation of the other jurisdictions is silent on the matter or a voluntary licence requirement is not contemplated.
[27] TRIPS, *supra* note 1, article 31(c).
[28] *Patent* Act, *supra* note 4, s. 21.09.
[29] *Ibid.,* s. 21.12.
[30] EC Regulation No 816/2006, supra note 5, article 10, Swiss Draft Amendment, supra note 5, article 40e.2, and Korean Patent Act, supra note 5, article 111.
[31] WTO waiver, supra note 6, para 3.
[32] TRIPS, supra note 1, article 31(j).
[33] *Patent Act*, supra note 4, s. 21.08. See also *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R./2005-143, s. 8.
[34] *Patent Act*, supra note 4, s. 21.08(4).
[35] *Ibid*., s. 21.08(7).
[36] Swiss Draft Amendment, supra note 5, article 40e.5. See also the Preliminary Draft Explanatory Report that accompanies the Swiss Draft Amendment.
[37] For example, Netherlands Policy Rules, supra note 5, article 5 states: The Minister of Economic Affairs shall determine adequate remuneration to be paid by the licencee taking into account the economic value of the product to the importing state.
[38] EC Regulation No 816/2006, supra note 5, preambular paragraph 15.
[39] *Patent Act*, supra note 4, s. 21.17. This provision has come to be known as the "good faith clause".
[40] There is an international precedent for both figures. Under the European Union's Access to Medicines Program, pharmaceutical companies who sell tiered-price products to developing countries enjoy special protection from reimportation on the condition that their medicines are made available either at a price cut of 75 percent off the average ex factory price in OECD countries, or at less than the cost of production plus 15 percent. See Council Regulation (EC) No. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.
[41] See EC Regulation No 816/2006, supra note 5, preambular paragraph 6.
[42] WTO waiver, supra note 6, para 2(a).
[43] *Ibid*., para 2(b)(i).
[44] *Patent Act*, supra note 4, s. 21.05(2).
[45] EC Regulation No 816/2006, supra note 5, article 10(2), Swiss Draft Amendment, supra note 5, article 40d.3, and Netherlands Policy Rules, supra note 5, article 2(2).
[46] EC Regulation No 816/2006, supra note 5, article 16(4).
[47] WTO waiver, supra note 6, para 2(b)(ii).
[48] *Ibid*., para 2(b)(iii).
[49] Food and Drug Regulations, supra note 20, C.07.008.
[50] *Ibid.* C.07.009.
[51] *Patent Act*, supra note 4, s. 21.06.
[52] *Ibid*., s. 21.07.
[53] EC Regulation No 816/2006, supra note 5, article 10, Swiss Draft Amendment, supra note 5, article 40d.4, Norway Amendments, supra note 5, s.108(1) and (2), Korean Patent Act, supra note 5, article 110(2)(iii), and Netherland Policy Rules, supra note 5, article 3(4).
[54] EC Regulation No 816/2006, supra note 5, article 10, Norway Amendments, supra note 5, s.109, Korean Patent Act, supra note 5, article 110(iii) and Netherlands Policy Rules, supra note 5, article 3(4).
[55] *Patent Act*, supra note 4, s. 21.14.
[56] EC Regulation No 816/2006, supra note 5, article 5, Swiss Draft Amendment, supra note 5, article 40e.6, Norway Amendments, supra note 5, s.108, Korean Patent Act, supra note 5, article 114.
[57] EC Regulation No 816/2006, supra note 5, article 16.

ANNEX A

WORLD TRADE ORGANIZATION

WT/L/540
2 September 2003
(03-4582)

implementation of paragraph 6 of the doha declaration on the trips agreement and public health

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

Decides as follows:

1. For the purposes of this Decision:

   (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1];

   (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

   (c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

   (a) the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that:

[1] This subparagraph is without prejudice to subparagraph 1(b).
[2] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
[3] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.
[4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

(i) specifies the names and expected quantities of the product(s) needed[5];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[6];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licencee shall post on a website[7] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

[5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.
[6] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.
[7] The licencee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licencee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

[8] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

   (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

   (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the

Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

Annex

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

ANNEX B

	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Implementing Instrument	*Patent Act*, s.21.01-21.2	*Regulation 816/2006*	Draft Amendment to *Federal Law on Patents for Inventions*	Amendments to Act of 15/12/1967 No.9 relating to patents by Act of 19/12/2003 no. 127/Patent Regulations of 20 December 1996 No. 1162 amended by Royal Decree of 14/05/2004	*The Patents (Amendments) Act*, 2005 No. 15 of 2005	*State Intellectual Property Order #37*	*Korean Patent Act*	Policy Rules for the issuance of a compulsory licence under s. 57 of the *Patents Act* 1995
Date in Effect	May 14, 2005 (Royal Assent May 14, 2004)	June 29, 2006	Draft amendment dated November 23, 2005, not enacted.	June 1, 2004: *Regulations* Dec. 2003: *Patent Act*	January 1, 2005	January 1, 2006	December 1, 2005	December 23, 2004
Eligible Importers/ Permitted Purchasers	**S.21.03**: WTO and non-WTO Members who have notified the WTO or Canada of intent to use the Decision and have insufficient manufacturing capacity. Also, any country recognized by the UN as being a LDC. Eligible countries are listed on Schedules 2-3-4 of the *Patent Act.* Schedule 2: Least developed WTO and non-WTO Members. Schedule 3: Developing country WTO Members. Schedule 4: WTO Members that have signalled their intention to rely on the Decision in cases of national emergency and non WTO-Members eligible for OECD development assistance. **S.21.04(2)(f)**: NGOs may purchase products with the permission of an eligible importing country.	**Art.4:** WTO and non-WTO Members with insufficient manufacturing capacity and any country recognized by the UN as being a LDC. **Art.4**: Non-WTO members eligible for OECD development assistance who have notified the Commission of their intention to use the system in a whole or limited way. **Art. 8**: All importers except LDCs must establish that they have insufficient or no manufacturing capacity.	**Art. 40 d.1**: WTO and non-WTO developing Members and LDCs with insufficient manufacturing capacity. LDCs do not need to establish lack of manufacturing capacity. Notifications to WTO or Swiss government required.	**S. 107.1** *Regulations*: WTO and non-WTO Members with insufficient manufacturing capacity and countries designated as LDCs by the UN. **S. 107** *Regulations*: Notifications to WTO or Norwegian Ministry of Foreign Affairs for States that are not party to the WTO Agreement.	**Art. 92A.(1)**: Any country having insufficient manufacturing capacity in the pharmaceutical sector for the required product.	**Art.9**: WTO members who have notified the WTO and non-WTO LDCs who have notified the government of China through diplomatic channels.	**Art. 107(7)**: Countries that have given notice to the WTO or the government of Korea. **Art. 107 (7) (ii)**: All except LDCs must establish that they have insufficient or no manufacturing capacity. **Art. 107(7) (iii)**: Where applicable, the notice must include a confirmation that the importing country intends to grant a licence for the import of the product.	**Art. 3**: Any LDC or WTO Member that has made a notification as required by the WTO Decision. **Art. 3(3)**: Non-WTO Member LDC must include the following with its application: a declaration that the country has insufficient or no manufacturing capacity, and a description of the anti-diversionary measures that will be taken. Permitted purchasers include importing states, groups of importing states, regional organizations and NGOs.

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	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Eligible products	**S.21.01:** "…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." **S.21.02**: "pharmaceutical product" means any patented product listed in Schedule 1. **Schedule 1** lists the products that are eligible for export under the regime. The list can be amended by Order-in-Council.	**Art. 1**: For the manufacture and sale of pharmaceutical products intended for export to eligible importing countries to address public health problems. **Art. 2**: Pharmaceutical products defined as any product of the pharmaceutical sector, active ingredients and diagnostic kits.	**Art. 40 d.1**: Products needed to fight public health problems, in particular those resulting from HIV/AIDS, malaria and tuberculosis. ***Preliminary draft explanatory report***: it is suggested to interpret the Decision of 30 August 2003 broadly and include active ingredients, diagnostic kits and vaccines.	**S. 108** *Regulations*: Pharmaceutical products as defined in para 1(a) of the Decision.	**Art. 92A.(1)**: Compulsory licences available for the manufacture and export of patented pharmaceutical products to address public health problems. **Art. 92A. *in fine***: Pharmaceutical products defined as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.	**Art.2**: Infectious diseases - defined as HIV/AIDS, tuberculosis, malaria and other infectious diseases (as listed in a document called "PRC Measures in Prevention and Treatment of Infectious Diseases) that have led to public health problems. **Art.2**: Pharmaceutical products defined as any patented product, or products manufactured through a patented process, of the pharmaceutical sector needed to treat an infectious disease. This includes active ingredients and diagnostic kits.	**Art. 107(1)(v)**: "...where working the patented invention is necessary to export a pharmaceutical product for the purpose of curing diseases for a number of patients in an importing country." **Art. 107(8):** "Pharmaceutical product" means any patented pharmaceutical product, any pharmaceutical product manufactured through a patented process, any patented active ingredient needed for manufacturing the pharmaceutical product and any diagnostic kits needed for the use of the pharmaceutical product.	**Art.1**: "Pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, including active ingredients for the manufacturing of these products and diagnostic kits to use the product.
Health and Safety Review	**S. 21.04 (3)(b)** of the *Patent Act* and **C.07.004** of the *Food and Drug Regulations* provide for a mandatory review by Health Canada to ensure exports are of the same safety, efficacy and quality as drugs approved for sale in Canada.	**Art. 18** provides for a voluntary review: Where the application for a compulsory licence concerns a medicinal product, the applicant may avail himself of the scientific option procedure or any similar procedures under national law.	**Art.5 (1)** *Law on Therapeutic Products***:** Licencee must obtain authorization for the production of the licenced products to ensure their high quality from the Swiss Institute of Therapeutical Products. **Art. 7** *Law on Therapeutic Products*: licencee must guarantee that the products will be produced in conformity with standards of Good Laboratory Practice.	Not required.	Not required.	Not required.	Not required.	Not required.

ANNEX B

	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Application Process	**S.21.04(2)**: applicant submits application to Commissioner of Patents, application must contain: - name of product, version -maximum quantity of product to be manufactured and sold -patentee -importing country -name of governmental person/entity to which the product is to be sold.	**Art. 6(3)**: The application shall set out the following: - name and contact details of applicant - name and quantity of product - importing country - where applicable, evidence of prior negotiation with patentee - evidence of request (indicating quantity required) from representative of importing country, NGO, UN body or other international health organization acting with formal authorization of the importing country.	**Art. 40 d.5**: Federal Council specifies the conditions for granting licences (i.e., defines the information or notification required). Application must include declaration that importing country will grant a compulsory licence.	Federal Court grants licences. Form and content of application not specified.	**Art. 92A.(2)**: The Controller grants licence "Controller" means the Controller General of Patents, Designs and Trade Marks (s. 2(1)b. of the Patents Act 1970).	**Art. 9**: Chinese State Council can request that the State Intellectual Property Office grant a compulsory licence to allow a third party to produce and export the needed product.	Not specified.	**Art. 3**: Application must be accompanied by an order addressed to the applicant from a permitted purchaser.
Notice to Patentee	**S. 21.15**: The Commissioner will notify the patentee of the grant of a compulsory licence. **S 21.16**: The licencee must provide a copy of the sales agreement with the importing country to the Commissioner of Patents and the patentee.	**Art.7**: Patent holder will be notified of each application and will have an opportunity to comment to the competent authority. "Competent authority" is defined in Art. 2(4) as the national authority having competence to grant compulsory licences under this Regulation in a given Member State.	Not specified.	Not specified.	Not specified.	Not specified.	**Art.107**: Applicant must first seek a voluntary licence.	Not specified.
Duty to seek voluntary licence	**S. 21.04 (3)(c)**: applicant must provide the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least 30 days before filing the application, sought from the patentee a licence to manufacture and sell the pharmaceutical product for export	**Art. 9**: Applicant must provide evidence that it attempted to seek a voluntary licence 30 days prior to submitting application - except in situations of extreme urgency.	**Art. 40 e.1**: Applicant must seek voluntary licence on reasonable terms within a reasonable time (30 days). This requirement is waived in emergency situations.	**S. 49** *Patent Act* & **Art. 108** *Regulations*: Applicant must first seek a voluntary licence on reasonable commercial terms within a reasonable period of time. Reasonable is defined with reference to the economic value of the use of the invention to the importing country. This requirement is waived in emergency situations.	Not specified.	Not specified.	**Art. 107**: Applicant can apply for a compulsory licence if consultations with patent holder are unsuccessful.	**S.57 (1)** *Patents Act 1995,* the Minister of Economic Affairs must make certain that the patent holder is unwilling to issue a voluntary licence before issuing a compulsory licence. In urgent cases, the Minister may refrain from making such an investigation.

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	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Duration of licence	**S.21.09**: licence is valid for 2 years.	**Art. 10(3)**: duration of the licence will be indicated on the licence by the competent authority.	**Art. 40 e.2**: limited to the purpose for which it was granted.	Not specified.	**Art. 92A. (2)**: licence limited to terms and conditions specified and published by Controller.	Not specified.	**Art. 111**: term of licence is set by Commissioner of Korean IP Office. Licencee may request a modification to the licence.	Not specified.
Royalties	**S. 21.08** *Patent Act*, to be paid by licencee taking into account the humanitarian and non-commercial reasons underlying the issuance of the licence. **S. 8** *Use of Patented Products for International Humanitarian Purposes Regulations*: prescribes formula for determining royalty rate: [(1+number of countries on UNHDI - importing country's rank) / number of countries on UNHDI] x 0.04.	**Art.10(9)**: To be paid by licencee. In situations of extreme urgency the royalty shall not exceed 4% of supply agreement. In all other cases, the royalty is to be determined by taking into account the economic value of the use to the importing country as well as humanitarian circumstances.	**Art. 40 e.5**: determined considering the economic value of the licence in the importing country and the development level of that country; the Federal Council clarifies the manner of calculation. ***Preliminary draft explanatory report***: adopts Canada's royalty rate formula	**S.50.2** *Act* & **S. 108** *Regulations*: remuneration shall be determined with reference to the economic value of the use of the invention to the importing country.	Not specified.	**Art. 7 & 11**: Adequate remuneration to be paid to patent holder.	**Art. 106**: Reasonable remuneration.	**Art. 5**: The Minister of Economic Affairs shall determine adequate remuneration to be paid by the licencee taking into account the economic value of the product to the importing state.
Good Faith Clause	**S. 21.17**: If the average price of the licenced drug is 25% or more of the average price of the equivalent patent brand name drug in Canada, the patentee may apply to the Federal Court for a number of legal remedies on the grounds that the essence of the agreement is commercial in nature.	**Preamble, par. 6**: The system is to be used in good faith and not for industrial or commercial policy objectives.	Not specified.	**S.108** *Regulations*: Manufacture and export shall cease if the licencee learns that the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence.	Not specified.	Not specified.	Not specified.	Not codified in the policy rules but the accompanying explanatory notes repeat the Chairperson's Statement.

ANNEX B

	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Quantities exported under licence	**S. 21.05 (2)**: quantity authorized may not exceed the lesser of either the maximum quantity set out in the manufacturer's licence application, or the quantity indicated in the importing country's notification to the WTO or Canada.	**Art. 10(2):** amount of product(s) manufactured under licence shall not exceed what is necessary to meet the needs of the importing country/countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere. **Art. 16(4)**: There is an accelerated procedure for modifications to the amount authorized for manufacture and sale where the importing country's needs were not met by original licence.	**Art. 40 d.3**: Licence limited to quantity necessary to satisfy need, all products produced under licence must be exported.	**S.108(3)** *Regulations*: 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.	**Art. 92A.(2)**: Terms and conditions of licence specified and published by Controller.	**Art. 10**: Not specified. The licence must indicate the conditions required by the Decision.	**Art. 107(4)(ii)**: All products produced under a licence must be exported.	**Art. 2(2)**: The compulsory licence shall state the type and amount of the pharmaceutical product to which the compulsory licence issued for the purposes of the order applies. "Order" is defined in Art. 1(h) as a written order for a pharmaceutical manufacturer to manufacture a specified amount of a pharmaceutical product.

ANNEX B

	Canada	EU	Switzerland	Norway	India	China	Korea	Netherlands
Anti-Diversion Measures	**S.21.06**: requires the licencee to establish a website disclosing the name of the licenced product, its distinguishing characteristics, identity of the importing country and amount to be manufacturer and sold for export. **S.21.07**: export notice provided by the licencee to the patent holder, the importing country and the purchaser. ***Food and Drug Regulations*** **C.07.008**: Exported products must bear the mark "XCL" (for solid dosage forms), be a colour that is significantly different from the version sold in Canada and include certain information on all labelling to distinguish them from the patented versions available on the Canadian market . **C.07.009**: Products are issued an export tracking number by Health Canada which must be printed on the product label.	**Art. 10(5)**: All products must be identifiable as being produced under the Regulation and distinguished from the patentee's product through special packaging and/or special colouring/shaping. **Preamble, par. 11**: To avoid overproduction and diversion, authorities should take into consideration existing licences for the same product and countries. **Art. 10(6)**: The licencee must establish a website prior to export.	**Art. 40 d.4**: Product must be distinguished from patented version by means of packaging, colouring, shape provided no major impact on price.	**S. 108 (1) 1** *Regulations*: Product must be distinguished from patented version by means of packaging. **S. 108 (1) 2** *Regulations*: Product must bear a label indicating it was produced for export. **S. 109** *Regulations*: The licencee must establish a website listing the name and quantity of the product and identify the importing country. The Court may stipulate more detailed requirements.	Not specified.	Not specified.	**Art. 110(2)(iii)**: Product must have packaging or labelling to distinguish it from patented version and website on which appears the matters set by the adjudication must be established.	**Art. 3(4)**: The manufacturer must take measures with regards to packaging, colouring, and/or shaping provided the measures are feasible and there is no impact on price. **Art. 3**: Prior to export, the licencee must post, on either its own website or the WTO webpage, the anti-diversionary measures it has taken and the quantity of the pharmaceutical product being shipped.
Termination of Licence	**S. 21.14**: Federal Court can terminate a licence where the patent holder establishes that the application contained: -incorrect information -the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties -product has been re-exported in a manner contrary to the WTO Decision -one of the prescribed terms of the licence has been violated.	**Article 5**: Licence may be terminated if importing country fails to make proper notifications. **Art. 16**: A licence may be terminated if terms of the licence are not met.	**Art. 40 e.6**: Federal Court may terminate licence when the circumstances that led to its grant no longer exist.	**S.108** *Regulations*: Manufacture and export shall cease if the licencee learns that the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence.	Not specified.	Not specified.	**Art. 114**: Commissioner of Korean IP Office may cancel adjudication, inter alia, where working patented invention is no longer within purpose of adjudication.	Not specified.