Special Committee Q94: GATT/WTO

Report on

Survey based on Questionnaire no 4: Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health

on behalf of Committee Q94

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1. INTRODUCTION

The Terms of Reference of the Special Committee Q94 include the monitoring of developments in regard to the TRIPS Agreement, and determining the extent of compliance with the provisions of TRIPS by the national laws of National Groups of AIPPI.

An important development in the context of TRIPS and the provisions of Articles 8 and 31 thereof occurred in 2001 in regard to the issue of Public Health. The worldwide debate on the need (particularly of developing and least-developed countries) to have access to affordable medicines to deal with the escalating problems posed by pandemic illnesses such as HIV/AIDS, tuberculosis and malaria, and the perceived relevance of Intellectual Property rights (particularly patent rights) in this connection, resulted in the Declaration on the TRIPS Agreement and Public Health (the so-called Doha Declaration), issued by the Ministerial Conference after its Fourth Session in Doha, Qatar, from 9-14 November 2001. A copy of the Doha Declaration is attached as Appendix A.

In the Doha Declaration the importance of Intellectual Property protection for the development of new medicines was recognised, as well as the concerns about the effect of such protection on medicine

prices (par. 3). The Doha Declaration also recognised (par. 5(b)) that compulsory licences may provide a mechanism for countries to use in their efforts to provide greater access to medicines, but at the same time recognised (par. 6) that member countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making use of the compulsory licensing mechanism provided for in the TRIPS Agreement (Article 31) in order to address the problem effectively.

The Council for TRIPS was accordingly instructed (par. 6) to find an expeditious solution to this problem and to report to the General Council by the end of 2002.

On 30 August 2003 the General Council reached a decision on the 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (hereinafter the WTO Decision). The WTO Decision forms part of the bundle attached as Appendix B. The WTO Decision provides for a compulsory licence model on the basis of which an 'eligible importing Member' country can acquire a 'pharmaceutical product' from an 'exporting Member' country on the basis of compulsory licences issued in the exporting country (under a waiver of Article 31(f) of TRIPS in terms of clause 2) and if necessary in the importing country (under a waiver of Article 31(h) of TRIPS in terms of clause 3).

The compulsory licensing model entails a number of safeguards, for example a prohibition on re-exportation and diversion of products from an eligible importing country (clause 4), except in certain specific circumstances (clause 6(i). The specific circumstances contemplated by clause 6(i) relate to the position in which a developing or least-developed country is a party to a regional trade agreement within the meaning of Article XXIV of GATT 1994, where at least half of the membership is made up of countries on the UN list of least-developed countries. A pharmaceutical product imported into that country may in certain circumstances be exported to other developing or least-developed countries of the regional trade agreement. Provision is also made for technical and financial cooperation by developed countries (clause 4), and for technology transfer and capacity building initiatives in the pharmaceutical sector (clause 7).

The WTO Decision expressly provides (clause 10) that member countries shall not challenge any measures taken 'in conformity with the provisions of the waivers' contained in the Decision, but states

(clause 11) that the waivers shall terminate in respect of each member on the date that an amendment of the TRIPS Agreement takes effect.

The purpose of the Questionnaire prepared by Special Committee Q94 of AIPPI was to determine the extent to which the compulsory licensing model set out in the WTO Decision of 30 August 2003 has been recognised and/or implemented in AIPPI member countries, including by way of legislative amendments, statements of intention, granting of concessions, or other initiatives. It is important to note that the results of the survey as set out in this report naturally reflect the position in the different countries at the time when the responses by National Groups were submitted (see Appendix B). Further developments may have taken place in the meantime.

2. CONDUCT OF THE SURVEY

Following the 2004 AIPPI Congress in Geneva, the Q94 Questionnaire no. 4 (together with supporting documentation, including the WTO General Council Decision of 30 August 2003 and the simultaneous statement by the General Council Chairperson) was distributed to the Presidents and Secretaries of National and Regional Groups of AIPPI under cover of a letter dated 13 September 2004 from Committee Q94 Chairman Mr Ivan Hjertman and Reporter General Mr Luis-Alfonso Durán.

A copy of the covering letter and the Questionnaire no. 4 bundle is attached as Appendix B.

Responses were received from 35 countries; a schedule reflecting the responses received is attached as Appendix C, and an analysis of the numbers of responses which could furnish information in response to the different questions is contained in Appendix D..

The primary intention when the survey was initiated, was that the results of the survey would be made available for discussion at the AIPPI ExCo Conference in Berlin during September 2005.

At the 2004 AIPPI Congress in Geneva, the Bureau set up a communication platform between AIPPI and its Committee Q94 and representatives of the TRIPS Directorate of the WTO, with a view to facilitating regular meetings and/or communications in regard to developments pertaining to TRIPS-related issues. It is envisaged that the survey results would also be of interest to the TRIPS Directorate, and that some of the findings of the survey should be communicated to

and discussed with the representatives of the TRIPS Directorate at the scheduled meetings. At a meeting with the TRIPS Directorate on 17 February 2005 the TRIPS Directorate representatives did indeed indicate that they would be interested in the outcome of the survey.

3. RESULTS OF THE SURVEY

3.1 Question 1

Question 1 of the Questionnaire dealt with the implementation of the WTO General Council Decision of 30 August 2003. Question 1.1 requested National and Regional Groups to provide information on steps taken or contemplated in their respective countries to implement any of the features of the Decision, by way of actual or impending legislative amendments, including

- statements of intention to introduce amendments,
- consultation processes with a view to legislative amendments,
- proposals for new or amended legislation
- already enacted legislation.

Question 1.2 requested information on legislative changes specifically to provide for **importation** licences in respect of pharmaceutical products, and Question 1.3 asked the same about **exportation** licences.

Of the 35 responses received, 19 countries indicated that no steps have been taken to implement any of the features of the WTO Decision, 13 countries indicated that some measures have been introduced or are under consideration, while 3 countries indicated that they were not prepared or in a position to respond to the questions.

Summary of information received on Question 1

3.1.1 Question 1.1

Of the 13 countries which indicated that measures have been introduced or are under consideration to implement the WTO Decision, 5 countries within the EU referred to the European Commission proposed Regulation of 29 October 2004, generally indicating that finalisation of that proposal was being awaited before implementation steps would be taken on a national level. The EU proposal will provide a harmonised system of compulsory licensing in the area contemplated by the WTO Decision, together with safeguards against diversion of products back into the EU. A copy of the EU proposed Regulation is attached as Appendix E. It was further indicated by

- the French Group that, in addition to the EU proposed Regulation, a proposal for an amendment of the French Code of Intellectual Property in regard to compulsory licences was being considered;
- the Swedish Group that the Swedish Ministry for Justice has commenced preparations for national implementation in parallel with the work in the European Commission, of a proposal for appropriate regulation. However, it was also indicated that the Swedish government may not proceed with the preparation for national implementation depending on the timing and content of the European Commission proposal.

Further,

- the Norwegian Group indicated that legislative amendments to their Patents Act, 1967 and Patent Regulations, 1996 have been effected as from 1 June 2004 (namely §49 no.5 of the Patents Act (1967-12-15 no 0009), and §§ 107, 108, 109 of the Patent Regulations (1996-12-20 no 1162). Information is available from the WTO website as document IP/C/W/427; and
- the Swiss Group indicated that a proposal for a revision of the Swiss Patent Law (232.14) in the form of a so-called pre-draft of June/July 2004 has been tabled.

The responses for countries outside Europe indicated that

- in Canada an Act has been enacted (the Jean Chrétien Pledge to Africa, S.C. 2004, c.23) to amend the Patent Act, R.S.C.1985,c.P-4, and the Food and Drugs Act, R.S.C. 1985 c.F-27, to allow the Commissioner of Patents to authorise the production, sale and export of patented medicines in accordance with the WTO Decision. The Act was assented to on 14 May 2004 and will come into force on a date to be proclaimed, once, proposed regulations under the amendment Act, which were published for comment on 2 October 2004, have been finalised and published. It is expected that the Act will be proclaimed during February/ March 2005. The text of the Act can be found at www.parl.gc.ca/PDF/37/3/parlbus/chambus/house/bills/goverment/c-9.PDF .
- in Indonesia a draft for a Government Regulation on Patent Licensing has been prepared, which will provide for compulsory importation and exportation licences for pharmaceutical patents;
- in Korea the National Assembly has been presented with a proposal for amended legislation (of the Patent Act) relating to compulsory licensing for the exportation of pharmaceutical products to countries with public health problems;

- in Mexico an amendment to the Industrial Property Law was approved by Congress and became effective on 27 January 2004, although **not** as a direct result of the Doha Declaration, to provide that 'serious illness' can constitute a national emergency and can thus be relied upon within the specified parameters for the grant of compulsory licences;
- in New Zealand, where the Patents Act, 1953 is being reviewed, government agencies have indicated that there will be no amendments to address the Doha Declaration issues until such time as the TRIPS Agreement has been formally amended, although the New Zealand government supported the Doha Declaration and actively follows the process;
- in South Africa consultation has commenced within technical committees in regard to the possible introduction of legislative amendments of IP laws, while a regulatory amendment under the Medicines and Related Substances Act, 1965 has introduced an importation licensing model for the parallel importation of medicines which have been put onto the market outside the country;
- in the USA, although no legislation has been identified to amend US laws to reflect the provisions of the Doha Declaration, the Free Trade Agreements (FTAs) between the US and other countries in some instances have addressed the issues reflected in the Doha Declaration and WTO Decision.

3.1.2 **Question 1.2**

In reply to Question 1.2 (provision for **importation** licences), only South Africa indicated that legislative provision has been made for importation licences, although not as a result of or on the basis of the Doha Declaration or the WTO Decision.

Note: The following countries are listed in note 3 to the WTO Decision as countries which have indicated that they will **not** make use of the licensing system as **importing** countries:
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

3.1.3 **Question 1.3**

In reply to Question 1.3 (provision for **exportation** licences), 3 countries (Canada, Norway and Switzerland) indicated that their legislative amendments will provide for exportation licences in terms of the WTO Decision. The EU proposed Regulation will also provide for exportation licences.

3.2 **Question 2**

Question 2 endeavoured to determine the extent to which notification of countries as 'eligible importing Members' has taken place in terms of clause 2(a) of the WTO Decision, and to find out whether any compulsory licences for the **importation** of pharmaceutical products have been granted.

Most of the 35 responses received (namely 29) indicated that the Groups were not aware of any notifications by countries in terms of clause 2(a), nor of the grant of any compulsory importation licences. A few (namely 6) of the responses from the Groups in developed countries confirmed that their countries have indicated in terms of clause 1(b) of the WTO Decision that they will **not** use the system as importing countries. (See the note to paragraph 3.1.2 above.)

Summary of information received on Question 2

Some further useful explanatory material was provided, for example:

- The Canadian Group explained that section 21.04(3(d) of the Canadian amendment Act inserted section 21.04(3)(d) into the Patent Act, which section requires compliance with the terms of clause 2(a) of the WTO Decision before the Commissioner of Patents will authorise use of the patented invention. Further, the amendment Act sets out, in Schedules 2, 3 and 4, lists of eligible importing countries; to be so listed a country must fulfil the requirements stipulated by section 1 of the amendment Act, which provides for the addition of section 21.03 to the Patent Act. This section requires that for a country to be included in a Schedule, such country must notify the TRIPS Council in writing that it intends to import pharmaceutical products in accordance with the WTO Decision.
- The Japanese Group pointed out that no countries have as yet filed formal notifications with WTO in terms of clause 2(a) of the Doha Decision.
- The Malaysian Group confirmed the point made by the Japanese Group. It further recorded that the Malaysian Government has granted a compulsory licence to Cipla, a Mumbai-based

manufacturer of anti-retroviral drugs. The Malaysian licence holder is Syarikat Megah Pharma & Vaccines (M) Sdn BhD (Company no. 552048-H) and the licence is for the importation of the following drugs: Didanosine 100mg, Didanosine 25mg, Zidovudine 100mg, Lamivudine 150mg, and Zidovudine 300mg. Compensation is to be paid to Bristol-Myers Squibb and GlaxoSmithKline. The drugs will be used exclusive to supply the government hospitals of Malaysia for two years.

- The South African Group recorded that, although no compulsory licences for the importation of pharmaceutical products in terms of clause 2(a) of the WTO Decision have been granted, GlaxoSmithKline and Boehringer Ingelheim were compelled to grant licences to South African generic manufacturer Aspen Pharmacare, in respect of Combivir and Viramune anti-retroviral products. This was done as a result of intervention by the South African Competition Commission.
- The US Group also confirmed that countries that have filed notification (as contemplated in clauses 1(b) or 2(a)) are to be listed on the WTO website.

3.3 **Question 3**

Question 3 was framed to obtain information in regard to the granting of compulsory licences in terms of clause 2(b) of the WTO Decision in 'exporting Member' countries for the **exportation** of pharmaceutical products.

Nearly all of the responses received indicated that the Groups were not aware of the granting of any such licences.

The following aspects were referred to:

- The Canadian Group indicated that no such licences have been granted in Canada inasmuch as the Canadian Amendment act has not yet been put into effect, but pointed out that this Act itself does not specifically require notice to the TRIPS Council of the grant of a licence as contemplated in clause 2(c) of the WTO Decisions, although the establishment of a website, containing the prescribed information, is provided for in section 21.09, as required by clause 2(c) of the TWO decision.
- The Czech Group pointed out that information on granted compulsory licences will be posted on the WTO website.

3.4 **Question 4**

Question 4 was aimed at obtaining information regarding the introduction of special measures to prevent re-exportation or diversion of products from importing countries as contemplated in clause 4 of the WTO Decision; and to find out whether any technical or financial cooperation or assistance has been rendered in this regard.

Of the 35 responses received, most indicated that the National Groups were not aware of any such measures or assistance. It must be borne in mind that IP practitioners would not usually have information pertaining to government actions in the context of the WTO processes, nor would they have reason to follow these processes on a continuing basis. WTO requires country reports by September each year, and further information could be obtained from the WTO website.

As set out below, some relevant and useful information was provided by some countries.

Summary of information received on Question 4

The following aspects were referred to in Group Reports, namely:

- The Canadian Group pointed out that the Canadian amendment Act (not yet proclaimed) will insert sections into the Patent Act (ie section 21.14(f) and 21.04(3)(b)) to prevent re-exportation of products produced in Canada.

  Section 21.14(f) will allow the Federal Court, on application by the patentee, to terminate authorisation where:
  … the product exported to the country or WTO Member, as the case may be, under the authorisation has been, with the knowledge of the holder of the authorisation, re-exported in a manner that is contrary to the General Council Decision.

  Section 21.04(3)(b) requires notification by the Minister of Health that the product meets the requirements of the *Food and Drugs Act* and its regulations, including:
  … the requirements under those regulations relating to the marketing, embossing, labeling and packaging that identify that version of the product as having been manufactured
  (i) in Canada as permitted by the General Council Decision
  (ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be.

- The Czech Group referred to existing legislation in their country to avoid trade diversion into the EU of certain key medicines, namely Czech Act no. 191/1999 Coll. on measures concerning the import, export and re-export of products infringing certain intellectual property rights, as amended by the Act no. 260/2002 Coll., and implementation of the Council Regulation (EC) no 1383/2003 of July 2003 and Council Regulation (EC) no. 953/2003 of 26 May 2003.
- The French Group referred to the proposed changes to French law and the proposal for EU regulation.
- The Swedish Group also drew attention to Council Regulation (EC) no 953/2003 of 26 May 2003 to avoid trade diversion into the EU of certain key medicines.
- The Swiss Group pointed out that the Proposal for a Revision of Swiss Patent Law will include a new Article 40c dealing with these aspects.
- The US Group stated that, while no legislation has been introduced or passed in the United States concerning the re-exportation of products under the Doha Declaration and Decision, pre-existing law has prohibited the re-importation of pharmaceutical products that have been made in the United States and initially exported. Such pre-existing law does not address, per se, the question of products made in the United States under a compulsory licence which are subsequently exported. However, the law would prohibit the re-importation of such products, along with existing US patent law, which does not treat a foreign sale, per se, to be an exhaustion of patent rights that exist in a product.

3.5 **Question 5**

Question 5 was aimed at information regarding the re-exportation of pharmaceutical products by developing and least-developed countries to other such countries within the framework of a regional trade agreement, as contemplated in clause 6 of the WTO Decision.

None of the Group responses provided any information in this regard.

3.6 **Question 6**

Question 6 elicited information regarding instances of technology transfer or capacity building in the pharmaceutical sector, as contemplated in clause 7 of the WTO Decision.

Again few countries could offer any information in regard to such initiatives. However, some useful comments were received, as follows:

- The Brazilian Group referred to the requirement for full disclosure in their law, namely Article 5(1) of Presidential Decree 3.201/99 as amended by Presidential Decree 4.830/03 providing for the nullification of a patent where the patent owner fails to disclose manufacturing details for products covered by the claims.
- The Japanese Group pointed out that the Japanese pharmaceutical industry has made many efforts in regard to technology transfer and capacity building, unrelated to the Doha Declaration. However, no further steps have as yet taken place.

April 4, 2005
I. Hjertman: Chair Q94
E. du Plessis: Co-Chair Q94