AIPPI

AIPPI

INTERNATIONAL ASSOCIATION FOR THE PROTECTION

OF INTELLECTUAL PROPERTY

SPECIAL COMMITTEE Q94

QUESTIONNAIRE NO. 4

on the

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

GENERAL REMARKS AND INSTRUCTIONS

I. The Terms of Reference of the Special Committee Q94 is to monitor developments in regard to the TRIPS Agreement, and to determine the extent of compliance with the provisions of TRIPS by the national laws of National and Regional Groups of AIPPI.

II. This is the fourth Questionnaire circulated by Committee Q94 to National and Regional Groups. It follows on and is closely related to the third Questionnaire of October 2002 in regard to the Doha Health Declaration. Committee Q94 records its appreciation for the participation of National and Regional Groups to provide the requested information by completing the Questionnaire and returning it to the AIPPI General Secretariat: **mail@aippi.org**

III. It would be most helpful if National and Regional Groups could return the completed Questionnaire by **November 8, 2004**.

IV. If there are any questions with regard to the Questionnaire, please contact:

(i) Chairman of Q94: Mr Ivan Hjertman
email: ivan.hjertman@telia.com
fax: +46 8 510 105 27

(ii) Co-Chair of Q94: Ms Esmé du Plessis
email: edp@adamsadams.co.za
fax: +27 12 362 6440

PURPOSE OF THE QUESTIONNAIRE

The purpose of the Questionnaire is to determine the extent to which the compulsory licensing model set out in the WTO General Council decision of 30 August 2003 has been implemented in WTO member countries, including by way of legislative amendments, statements of intention, granting of concessions, or other initiatives.

To assist National and Regional Groups with their responses, a copy of the WTO decision is attached as Annexure A, as well as a copy of the Statement by the Chairperson of the General Council, marked Annexure B.

1. **QUESTION 1**

Steps to implement the WTO decision

In the preamble to the WTO General Council decision, reference is made to the instruction of the Ministerial Conference in Doha, 2001 that an expeditious solution is to be found for the difficulties in some WTO member countries in regard to access to pharmaceutical products.

1.1 Are you aware of any actual or impending legislative amendments in your country, including,

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

with a view to implementing any or all of the features of the WTO Council decision?

☐ Yes ☐ No

If yes, please provide details such as

- Government Act, Regulation, Proclamation or Bill no.
- Proposal or Policy Paper details
- Website information for text
- Other details

_____

_____

_____

_____

1.2 Has your country made any changes to your laws to provide for importation licences in respect of pharmaceutical products? If so, please provide details.

☐ Yes ☐ No

- Act / Regulation / Proclamation no.
- Website information for text
- Other details

_____
_____
_____
_____

1.3 Has your country made any changes to your laws to provide for exportation licences in respect of pharmaceutical products? If so, please provide details.

☐ Yes ☐ No

- Act / Regulation / Proclamation no.
- Website information for text
- Other details

_____
_____
_____
_____

2. **QUESTION 2**

Identification of 'eligible importing countries'

Clause 2(a) of the WTO decision requires 'eligible importing Member' countries to make a notification to the TRIPS Council recording certain information. (Note: the countries specified in Note 3 of the decision have already indicated that they will not use the compulsory licensing system as importing countries).

2.1 Are you aware -

Whether your own country has filed a notification as an 'eligible importing Member country', and if so, when?

☐ Yes ☐ No

Date:

2.2 Whether any other country/countries have filed such a notification, and if so, which countries?
Countries and dates:
_____
_____
_____
_____
_____

2.3 If your answer to 2.1 is Yes, are you aware of any compulsory licences granted in your country for the importation of pharmaceutical products, and if so, do you have any details as regard licensor, licensee, products covered, etc?
☐ Yes ☐ No
Details:
_____
_____
_____
_____
_____

3. **QUESTION 3**
Granting, notification and information of export licences
Clause 2(b) of the WTO decision deals with compulsory licences granted in 'exporting Member' countries for the exportation of pharmaceutical products in terms of the waiver of TRIPS Art 31(f).

3.1 Are you aware of any compulsory licences which have been granted in your country for the exportation of pharmaceutical products to eligible importing member countries? If so, please provide details of which you are aware, such as licensor, licensee, products covered, etc.
☐ Yes ☐ No
Details:
_____
_____
_____
_____
_____

3.2 Clause 2(c) of the WTO decision requires notification to the TRIPS Council by an exporting member country of the grant of any such compulsory licences. Are you aware of such a notification having been made, and if so, when?

☐ Yes ☐ No
Date(s):

3.3 Clause 2(b) requires a licensee under such a compulsory licence to post certain information on a website. Are you aware of any such website? and if so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

4. **QUESTION 4**

Prevention of re-exportation/diversion of imported products

Clauses 4 and 5 of the WTO decision deal with the need to prevent re-exportation of products imported into eligible importing countries under the licensing system.

Are you aware –

4.1 Whether special measures (in laws or otherwise) have been introduced in your country to prevent re-exportation of products? If so, please provide details, such as Government Act, Proclamation, export restriction, etc

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

4.2 Whether any technical or financial cooperation or assistance has been provided to developing or least-developed countries to prevent trade diversion and re-exploitation? If so, please provide details, such as type of assistance, receiving country, etc.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

5. **QUESTION 5**

Waiver of TRIPS Art 31(f): domestic market supply

Clause 6 provides for the waiver of TRIPS Art 31(f), ie the restriction to use predominantly for the supply of the domestic market, in respect of developing and least-developed member countries which are parties to a regional trade agreement, to permit exportation to other parties of the regional trade agreement of products imported or manufactured under compulsory licences.

Are you aware –

5.1 In the event that your country falls within the provisions of Clause 6, whether use has been made of the exportation provisions of Clause 6? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

5.2 In the event of exportation from your country in terms of a compulsory licence to a country/countries falling within the provisions of Clause 6, whether use has been made of the exportation provisions of Clause 6? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

6. **QUESTION 6**

Technology transfer and capacity building

Clause 7 provides for the promotion of technology transfer and capacity building in the pharmaceutical sector by using the compulsory licensing system of the WTO decision.

Are you aware of any such technology transfer or capacity building initiatives, in your own country or elsewhere? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____