



TO WHOM IT MAY CONCERN

LEGAL POSSIBILITIES TO IMPORT GENERIC ARVs and OIs

The following distinction in countries can be made, based on the legal complexities:

- Ø Countries where the required generic ARVs and OIs are not patented/ patents are not valid. An example can be found in Peru.
- Ø A least developed (LDC) member of the WTO has two principal options with respect to avoiding interference by a patent holder. First, an LDC may decide that it will not enforce patents granted within its territory with respect to pharmaceutical products. As an alternative, an LDC can declare an emergency and authorize a government use license. An example of this can be found in Zimbabwe. For an overview of the WTO LDC's please refer to: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm . Non-WTO LDC's can in principle also make use of these two options.
- Ø Non-LDC WTO Members can grant government use licenses under Article 31 of the TRIPS Agreement. Non-WTO members can in principle also grant these government use licenses. An example can be found in Guinée.

Another possibility is to discuss with the Originator Companies whether they are willing to waive their patent rights (compulsory license) for certain LDC's where the emergency situation is dramatic, this would avoid the risk of legal prosecution for these countries altogether. This exercise can be discussed separately when all other possibilities have been exhausted.

For the 3 options discussed above, one of the following documents needs to be provided as written proof to IDA HIV/AIDS Group:

- Ø A written statement from the local authorities (e.g. the Minister of Health) that none of the required generic drugs or active ingredients are patented in the importing country or;
- Ø A written statement from the local authorities of the importing country that they declare an emergency situation and/or authorize a government use license.

Please note however that different documents can be asked for as proof depending on the legal situation on a case-by-case basis.

Find on the next pages examples of Peru, Zimbabwe and Guinée.

For more information you can contact IDA HIV/AIDS Group via info@ida-arv.nl

OFICINA DE INVENCIONES Y NUEVAS TECNOLOGÍAS

CERTIFICADO DE ANTECEDENTES N° 137 / 2004 INDECOPI-OINT

SOLICITANTE : CARE Perú
BÚSQUEDA DE : ESTAVUDINA

MODALIDAD DE BÚSQUEDA:

PAT. INV. (X) MOD.UTIL. () DIS. IND. ()

CRITERIO DE BÚSQUEDA:

La búsqueda se realizó basándose en la información obtenida del Index Merck(*) para el compuesto ESTAVUDINA tal como: Fórmula química, nombre químico, números de prioridad, nombre(s) de inventor(es), etc.

ESTRATEGIA DE BÚSQUEDA:

En la base de datos nacional, se utilizaron las siguientes palabras como estrategia de búsqueda:

Estavudina; D4T; BMY-27857; Zerit	C07H 17/00;
3'-deoxy-2'-timidinina; dideoxy (y)	Bristol-Myers Company
timidin;	Starret; Muzammil Mansuri
nucleosid (y) inhibidor (y)	Martin; Fuller; Howell;
transcriptasa (y) inversa;	441,023; 1989.11.24;
NRTIs	173,473; 1988.03.24
Antiviral	697,512; 1991.04.21;

RESULTADO :

En la Oficina Nacional no existe la patente equivalente a la patente Americana **US 5130421 (EP 334368)** la cual protege el compuesto **ESTAVUDINA**.

IMPORTANTE:

Lo informado no cubre las solicitudes que se encuentran en etapa de confidencialidad al momento de realizar la búsqueda, puesto que estas tienen carácter secreto en virtud de la Decisión 486 de la Comisión de la Comunidad Andina.

The Minister of Justice, Legal and Parliamentary Affairs, in terms of section 34 as read with section 35 of the Patents Act [Chapter 26:03], hereby makes the following notice:—

1. This notice may be cited as the Declaration of Period of Emergency on (HIV/AIDS), Notice, 2003.

2. The Minister hereby declares an emergency for a period of five years with effect from 1 st January, 2003 to 31 st December, 2008 for the purpose of enabling the State or a person authorised in writing by the Minister under section 34 of the Act—

- (a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions;
- (b) to import generic drugs used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

All correspondence should be addressed to
"THE SECRETARY"

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Facsimile: 704116/723765/729311
E-mail: minind02@samara.co.zw
Telegrams: "TRADEMIN", Harare
Private Bag 7708, Causeway, Zimbabwe



Reference: G14-142/894

**MINISTRY OF INDUSTRY
AND INTERNATIONAL TRADE**
Mukwati Building
4th Street/Livingstone Avenue
Harare
Zimbabwe

10 March 2004

Secretary for health and Child
Welfare

Attention: Ms. Nhekairo

Drug Control council

The Chief Executive
Varichem Laboratories

The Chief Executive
Confederation of Zimbabwe Industries

The Chairman
Pharmaceutical Manufacturers Association
c/o Graniteside Chemicals

**RE: WTO TRADE RELATED INTELLECTUAL PROPERTY TRIPS AGREEMENT
(TRIPS)**

The WTO TRIPS agreement protects patent rights of manufacturers. Article 31(f) of the TRIPS agreement says that production under compulsory licence must be predominantly for the domestic market. This effectively limited the ability of countries that cannot manufacture pharmaceutical products from importing cheaper generic drugs from countries where pharmaceuticals are patented. Companies manufacturing drugs under compulsory licence could not export these generic drugs.

Following heated debates on how the TRIPS agreement negatively impacted on the poorer countries ability to procure drugs for AIDS and other chronic diseases WTO member states agreed to grant a waiver on the export of generic drugs that are manufactured under compulsory licence. The waiver, which expires in 2016 allows cross boarder trade of generic drugs manufactured under compulsory licence.

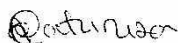
The decision was granted to minimise public health problems that affect many developing and least developed countries (LDCs) especially those arising from HIV/AIDS tuberculosis, Malaria among other drues.

Implications that arise as a result of the press release are as follows:-

- 1) Varichem Laboratories, which manufacture ARV drugs under compulsory licence can, subject to them meeting domestic demand, produce and export excess ARV drugs.
- 2) Pharmaceutical companies and other organisations can import generic ARV drugs that are manufactured

Stakeholders are hereby advised to disseminate this information so that the country can benefit from the waiver.

Yours Sincerely


A. Katuruza

FOR: SECRETARY FOR INDUSTRY AND INTERNATIONAL TRADE

trips.dma



8 AVR. 2005

Conakry, le -----2005

REPUBLIQUE DE GUINEE
Travail – Justice - Solidarité

MINISTRE DE LA SANTE

N° 0613 /MS/CAB

**Pour: IDA ARV Procurement Services BV
P.O. Box 37348
1030 AH Amsterdam
Les Pays-Bas**

Le Ministre de la Santé de la République de Guinée après avoir attentivement examiné les textes juridiques et résolutions pertinents de l'OMC, à savoir l'Accord sur les ADPIC, la Déclaration de Doha sur les ADPIC et la Santé publique, et la décision du Conseil des ADPIC du 27 juin 2002, relativement à la question des brevets des médicaments pour le VIH/SIDA et de leur obtention dans le cadre du programme national VIH/SIDA, vous notifie par la présente que :

La République de Guinée en tant que pays en développement Membre de l'OMC déclare une situation d'urgence relative au VIH/SIDA et décide qu'elle n'appliquera pas les brevets en ce qui concerne les traitements médicaux pour le VIH/SIDA et les conditions qui s'ensuivent. Des médicaments génériques pour le VIH/SIDA pourront donc être importés en République de Guinée sur la base de la déclaration et de la décision susmentionnées. Le ministre de la Santé suggère par le présent avis que des mesures soient prises pour accélérer l'accès aux médicaments précités dans le but de poursuivre un programme de traitement global du SIDA en République de Guinée.

Nom : Dr. Harirata BAH, Directrice Nationale de la Pharmacie et du Laboratoire

Signature :

Date : 18 avril 2005