

TO: HONOURABLE MINISTER OF HEALTH

CC: HONOURABLE MINISTER OF JUSTICE
CC: HONOURABLE MINISTER OF STATE FOR TRADE
CC: REGISTRAR GENERAL
CC: DIRECTOR GENERAL UGANDA AIDS COMMISSION

**FROM: UGANDA COALITION ON ACCESS TO ESSENTIAL
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**RE: LEGAL MECHANISMS FOR EXPANDING ACCESS TO
GENERIC MEDICINES IN UGANDA**

This memorandum outlines mechanisms for legally authorising the use of generic versions of patented medicines for Uganda's public treatment programmes (including through designated non-governmental organizations).

We focus here on access to AIDS medicines, given the recent declarations of government that it intends to purchase generic forms of these medicines, many of which are under patent in Uganda. The mechanisms discussed in this memorandum, however, are available to ensure access to generic versions of any essential health product under patent in Uganda, including medicines for opportunistic infections and diagnostics.

The Uganda Coalition on Access to Essential Medicines¹ has been working in partnership with the Consumer Project on Technology (CPTech)² on patent law and access to affordable medicines. The Coalition and CPTech are strongly supportive of the government's efforts to purchase affordable medications. We are committed to working with government to utilise provisions of Uganda's patent law, in compliance with the World Trade Organisation agreements, that allow manufacture or purchase of generic medicines in cases where a patent is held on that medicine.

¹ The Uganda Access to Essential Medicines Coalition includes HEPS UGANDA, Church of Uganda (CHUSA), Health Action International HAI-Africa, Uganda National Health Consumer's Organisations (UNHCO), Joint Clinical Research Centre (JCRC), Medecins Sans Frontierer (MSF-F), National Council of Women Living with AIDS, Uganda Network of AIDS Service Organisations (UNASO), Uganda Consumer Protection Association (UCPA), Uganda Media Women Association (UMWA), Uganda Red Cross Society, Oxfam GB- Uganda, Pharmaceutical Society of Uganda, The AIDS Support Organisations (TASO), Uganda Joint Christian Council (UJCC), Uganda Debt Network (UDN), THETA, Foundation for Human Rights Initiative (FHRI), AIDS Information Centre (AIC), Disabled Women's Network and Resource Organisation (DWNRO), Consumer Education Trust (CONSENT), Panos Eastern Africa Uganda Aids Commission.

² A Washington D.C. based non-governmental organisation specialising in intellectual property law and policy.

Problem statement: The need for legal access to AIDS medicines

The Minister of Health has announced that Uganda intends to purchase generic AIDS medicines (known as antiretrovirals or ARVs) for its treatment programmes. Many important ARVs are covered by patents in Uganda.³ To purchase generic versions of these medicines legally, the government may be required to take certain steps. Ensuring that generic medicines are legally procured may be a condition of donors, such as the good procurement practices of the Global Fund to Fight AIDS, Tuberculosis and Malaria.⁴

Declaration of non-enforcement of patents

The World Trade Organisation agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) requires member states to recognise patents on pharmaceuticals. The Doha Declaration on TRIPS and Public Health, however, instructed that least-developed country members, such as Uganda, are not obliged to enforce patent rights with respect to pharmaceuticals until 1 January 2016.⁵

One option to increase and ensure access to generic medicines may be to issue a declaration that patents will not be enforced on any essential medicines until 2016, that the government decides it needs to address a public health concern (using medicines) that would not otherwise be affordable or available in sufficient quantities. We are not, however, aware of a specific authorisation for such a declaration in Uganda law.

Request that patent holder surrender their patents

Under Section 36 of the Patents Statute, the owner of a patent may “surrender some or all of the claims in respect of a patent.” The Ministry of Health could request that the patent holders (see table below) utilize this section to surrender their rights to enforce their patents in Uganda until 2016.

Section 30 of the Uganda Patent Act

Section 30 of the Patent Act authorises the Minister of Justice to allow use of a patent by any person if “it is in the vital public interest to do so”. The term “vital public interest” is

³ The following medicines are covered by patents filed with the African Regional Intellectual Property Organisation (ARIPO), which are generally recognized by Uganda: Abacavir (patented by GlaxoSmithKline); Lamivudine, 3TC (GSK); Nevirapine (Boehringer Ingelheim); Zidovudine, AZT (GSK); and AZT+3TC (GSK).

⁴ The Global Fund “encourages Recipients to apply national laws and applicable international obligations in the field of intellectual property . . . in a manner that achieves the lowest possible price for products of assured quality.”

⁵ Paragraph 7 of the Doha Declaration states:

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.

defined in subsection (3) as including public health. The Minister is required to authorise the payment of “adequate remuneration” in any order.⁶ This provision complies with Article 31 of TRIPS, which applies to government authorisations of use of patents without permission of the patent holder.

Section 30 procedure for issuing a government use order

There is no process specified for how a government agency or other person should request the Minister of Justice to issue a government use directive. In practical terms, where the purpose of the order is to authorise the purchase of medicines by the Ministry of Health or its designees, it may make a written request to the Ministry of Justice for such an order.

The procedure for the Minister of Justice to issue a government use order is implied under section 30 of the Patent Statute. First, the Minister (of Justice) is required to act “in consultation with the Registrar [of patents]”. This can be by ordinary letter, through a meeting or by other means since the law does not provide a specific format.

Second, the minister must offer the owner of the patent “an opportunity to be heard” before the order is made. No specific format for this hearing specified. Therefore, an ordinary letter addressed to the patent holder describing the intended action and grounds, and giving an opportunity to respond within a reasonable time (e.g. 30 days), may suffice.

Third, the Minister is authorised to “direct that a patented invention be exploited by a Government agent or other person designated by the Minister”. No specific format for this directive is specified. A notice published in the Register and Gazette and sent to the patent holders would appear sufficient.

Section 30 public interest grounds

Under Section 30, the lack of access to an essential medicine, combined with the high prices of patented medicines, may be grounds for issuing a government use directive authorising all qualified suppliers to meet the government’s needs. Quality generic versions of a full ARV treatment are now available for under \$200 a year, while patented

⁶ Section 30(1) of the Patents Statute states:

Where the Minister [responsible for the supervision of the Patent Registry] is of the opinion that it is in the vital public interest to do so, he, in consultation with the Registrar, and without the authority of the owner of a patent, may direct that a patented invention be exploited by a Government agent or other person designated by the Minister, on the following conditions –

- (a) that the owner of the patent and any licensee has been given an opportunity to be heard before the direction is made; and
- (b) that the Government provides for the payment of adequate remuneration, as fixed by the Registrar, to the owner of the patent for use of his invention.

Section 30(3) states:

For the purposes of this section “vital public interest” includes matters of paramount importance pertaining to national security, public health, public order and morality and the national economy.

versions cost over \$700. The generic prices, negotiated by the Clinton Foundation, are for three-drug fixed dose combinations that are not available from the patent holders.

Adequate compensation under Section 30

Pharmaceutical companies that have the capacity to research and develop new medicines argue that monopoly prices are necessary for them to recoup those costs and finance the development of new medicines. The government can contribute to meeting the research and development costs for needed medicines without allowing a patent monopoly.

Under Section 30, the Minister is required to authorise the payment of “adequate remuneration” for the patent holder. A royalty payment may be used under this section to contribute to the patent holder’s research and development.

A royalty of 2-3% would be adequate compensation in Uganda, given its status as a least developed country. 3% should be reserved to medicines for which there has not already been significant government contribution (from any government) to research and development.

A 2-3% royalty is supported by a number of considerations. African countries only account for about 1% of the medicine market for the patent holding companies. Only about 3% of net sales by the patent holders is invested in research and development for new innovative medicines, about 10% of which is directed toward conditions that primarily affect developing countries. Compensation under compulsory licences in other countries has ranged from 0%-8% of net generic sales. Canada’s law provided for presumptive compulsory licences for pharmaceuticals until the early 1990s in exchange for 4% royalties. In the Philippines, compulsory licenses have been issued with compensation of 2-3% of net generic sales. The UNDP (2001) recommended royalties for compulsory licences of 2-6% of generic sales.

The payment of a royalty may be made conditional on the patent holder proving, to the satisfaction of the registrar, that they hold valid patents in Uganda under the current law.

Other African examples

South Africa’s Competition Commission recently found that GlaxoSmithKline and Boehringer Ingelheim violated its Competition Act by excessively pricing their products and refusing to licence generic suppliers. The Commission announced that it is seeking a compulsory licence to allow all qualified suppliers to supply public and private markets.

An application has been filed in Kenya to authorise the use of generic ARVs for government use.

Conclusion

The Coalition recommends that the Minister of Health request that the Minister of Justice issue a government use order under Section 30 of the Patents Statute. The order should

authorise the use of the following ARV patents in the government's treatment programmes, to the extent that they are applicable in Uganda.⁷

<u>ARIPO NO.</u>	<u>GENERIC NAME</u>	<u>PATENT HOLDER</u>	<u>DATE FILED</u>
AP 136	lamivudine (3TC)	IAF Biochem International	8 Feb 1990
AP 182	lamivudine (3TC)	IAF Biochem International	2 May 1991
AP 300	lamivudine (3TC)	GlaxoSmithKline (GSK)	2 June 1992
AP 11	zidovudine (AZT)	GSK	unknown
AP 1067	3TC+AZT combination	GSK	29 Oct 1997
AP 101	abacavir (ABC)	GSK	unknown
AP 196	abavavir (ABC)	GSK	unknown
AP 652	ABC+3TC+AZT combo	GSK	unknown
AP 179	nevirapine	Boehringer Ingelheim (BI)	16 Nov 1990
AP 198	nevirapine	BI	28 June 1990

⁷ Some of the patents appear to have been filed after the effective date of Uganda's Patents Statute, 1991, and, therefore, may not be applicable in Uganda. The Coalition is yet to establish their validity.