Hazel Tau and Others v GlaxoSmithKline SA (Pty) Ltd and Others: Submission of the Canadian HIV/AIDS Legal Network

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Introduction

The Canadian HIV/AIDS Legal Network (the Network) is a national, community-based, charitable organization working exclusively in the area of policy and legal issues raised by HIV/AIDS. It was formed in November 1992 and has over 200 members across Canada and internationally. Engaged in education, legal and ethical analysis, and policy development, the Network promotes responses to HIV/AIDS that:

- Implement the International Guidelines on HIV/AIDS and Human Rights;
- Respect the rights of people with HIV/AIDS and of those affected by the disease;
- Facilitate HIV prevention efforts;
- Facilitate care, treatment, and support of people with HIV/AIDS;
- Minimize the adverse impact of HIV/AIDS on individuals and communities; and
- Address the social and economic factors that increase vulnerability to HIV/AIDS and to human rights abuses.

The Network produces, and facilitates access to, accurate and up-to-date information and analysis on legal, ethical, and policy issues related to HIV/AIDS, in Canada and internationally. We consult, and give voice to, Network members and a wide range of participants, in particular communities of people with HIV/AIDS and those affected by HIV/AIDS, in identifying, analysing, and addressing legal, ethical, and policy issues related to HIV/AIDS. We link people working on or concerned by these issues. We recognise the global implications of the epidemic and incorporate that perspective in our work. The Network is a non-governmental organization in Special Consultative Status with the Economic and Social Council of the United Nations.

I have been the Network's Director of Policy & Research since January 1999. Before joining the staff of the Legal Network, I practised law in Toronto, Canada. I have been researching and writing on HIV/AIDS-related legal and human rights issues for many years, in addition to my involvement with several community-based organisations serving people living with HIV/AIDS and with other human rights organisations. Since June 2001, I have been a member of the Ministerial Council on HIV/AIDS, a body of independent experts that advises Canada's federal Minister of Health on the country's national strategy on HIV/AIDS.[1]

On behalf of the Canadian HIV/AIDS Legal Network, I served as Secretary to the Third International Consultation on HIV/AIDS and Human Rights in July 2002, which produced the Revised Guideline 6 ("Access to Prevention, Care, Treatment and Support") of the *International Guidelines on HIV/AIDS and Human Rights* issued by the Office of the UN High Commissioner for Human Rights

[1] This submission is made solely on behalf of the Canadian HIV/AIDS Legal Network, and any reference herein to other entities does not indicate any affiliation with this submission.

(OHCHR) and the Joint UN Programme on HIV/AIDS (UNAIDS). For the consultation, I prepared both a background paper reviewing key developments related to access to HIV/AIDS treatment, care and support and a draft proposed text for the revised Guideline and related commentary. Following the expert consultation, I prepared the final text of the revised Guideline and commentary for submission to UNAIDS and the OHCHR.

Purpose of this submission

The purpose of this submission is three-fold. First, the Network would like to express its support for the complaint lodged on 19 September 2002 by Hazel Tau and ten others, including people living openly with HIV/AIDS, health care workers treating people with HIV/AIDS, the Congress of South African Trade Unions (COSATU), the Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union (CEPPWAWU) and the Treatment Action Campaign (TAC). I have read the Statement of Complaint and supporting affidavits, and come to the same *prima facie* conclusion that GlaxoSmithKline SA (Pty) Ltd and Boehringer Ingelheim (Pty) Ltd and/or their related companies in South Africa and abroad have engaged in the excessive pricing of antiretroviral medicines to the detriment of consumers.

Second, the Network would like to place before the Commission the recent judgment of the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*,[2] in which the history of the development of the antiretroviral drug zidovudine (AZT) is set out in some detail. I understand that in terms of section 49B(2)(a) of the Competition Act, 89 of 1998, "[a]ny person may … submit information concerning an alleged prohibited practice to the Competition Commission, in any manner or form". We submit that the judgment is of significant relevance in determining whether the prices charged to the private sector in South Africa for Retrovir® and Combivir® bear "reasonable relation[s] to the economic value" of AZT and AZT/lamivudine respectively. This, we understand, is the central question to be determined in this matter.

Third, the Network would like to draw particular attention to the *International Guidelines on HIV/AIDS and Human Rights* (issued in 1998 by the Office of the High Commissioner for Human Rights (OHCHR) and the Joint United Nations Programme on HIV/AIDS (UNAIDS)), which have recently been amended insofar as the regulation of HIV-related goods, services and information is concerned.[3] These amendments update the *International Guidelines* to reflect developments in international law and policy regarding access to HIV/AIDS-related prevention, treatment, care and support, as well as greater governmental commitments regarding human rights related to HIV/AIDS, including improved access to health care services. We submit that Revised Guideline 6, which deals expressly with states' obligations in regulating HIV-related medicines to ensure affordability and accessibility, is of particular significance in providing guidance on the interpretation and application of the prohibitions against excessive pricing.

Interest of the Network in supporting the complaint

The Network's mission is to promote responses to HIV/AIDS that respect, protect and fulfil the human rights of people living with HIV/AIDS and those affected. From the outset, a global perspective and a commitment to working with, and learning from, colleagues in other countries have guided the Network. This is reflected in, *inter alia*, our commitment to promote access to treatment in developing

[2] 2002 SCC 77.

[3] *HIV/AIDS and Human Rights International Guidelines: Revised Guideline 6* (Geneva: OHCHR and UNAIDS 2002), available online at <www.unaids.org/publications/documents/human/HIVAIDSHumanRights_Guideline6.pdf>. The Guidelines are attached to the complainants' Statement of Complaint marked Annexure O.

countries, including joint activities with the AIDS Law Project (South Africa) which is heavily involved in ongoing advocacy campaigns and litigation regarding drug pricing and treatment access. As a result of these partnerships, the Network helped create in Canada the Global Treatment Access Group, a loose affiliation of a dozen Canadian civil society organizations addressing Canadian government policy as it affects access to medicines and the realization of the human right to health generally in developing countries.

I have read the Competition Act and note that the Commission is authorized to use particularly strong powers in any investigation into a prohibited practice. Of particular interest to the Network are the powers in section 49A of the Act dealing with the summonsing of "any person who is believed to be able to furnish any information on the subject of the investigation, or to have possession or control of any book, document or other object that has a bearing on that subject". In our treatment access work, we have been frustrated by the difficulty in accessing relevant information within the possession and/or control of multinational pharmaceutical companies, particularly insofar as pricing practices and research and development costs are concerned. We believe that a proper investigation into the Hazel Tau complaint will require that the Commission use the full extent of its powers of search and summons to gain access to such relevant information.

Implications of the AZT judgment of the Supreme Court of Canada

On 5 December 2002, the Supreme Court of Canada released its judgment in *Apotex Inc.* v. *Wellcome Foundation Ltd.*,[4] concerning the validity of the Canadian patent on AZT held by Glaxo. While the judgment deals primarily with the requirements under Canadian patent law for obtaining a patent on an invention "in the context of a new use for an old chemical compound",[5] it provides important information regarding the role played by the respondents in that matter in the development of AZT as a treatment for HIV/AIDS. Such information, in my opinion, complements the detailed affidavit of James Packard Love (Expert Annexure JPL), which is relied upon by the complainants in the matter currently before the Competition Commission.[6]

In particular, paragraphs 7-21, 35, 52 and 101 of the Supreme Court of Canada's judgment summarise the following relevant findings of fact from the judicial proceedings in Canadian courts on the validity of Glaxo's AZT patent:

- At the time that Glaxo scientists started their work that lead to the patenting of a new use for the existing chemical compound AZT, it was already known that:
    - HIV attacks T-cells which are crucial to the functioning of the human immune system;[7] and

[4] 2002 SCC 77. A copy of the judgment of the Supreme Court of Canada is attached to the original of this submission (sent to the Commission by mail); an electronic copy of the judgment may be found on-line at http://www.lexum.umontreal.ca/csc-scc/en/rec/html/novopha2.en.html. A copy of the original trial decision of the Federal Court of Canada (Trial Division) from 1998 is also attached to the original of this submission; an electronic copy may be found on-line at http://decisions.fct-cf.gc.ca/fct/1998/t-3197-90.html and may be cited as *Apotex Inc.* v. *Wellcome Foundation Ltd.*, (1998) 145 F.T.R. 161.

[5] *Supra* note 3, at para 2.

[6] See in particular paragraphs 16-44 of the affidavit of James Packard Love (Expert Annexure JPL).

[7] *Supra* note 3, at paragraph 7.

  - HIV infects the T-cell by "insinuating and integrating a DNA copy of its RNA genome into the genome of the T-cell using reverse transcriptase, an enzyme common to all retroviruses."[8]

- Believing that the reverse transcriptase stage offered the best target for a drug, Glaxo scientists began to screen various compounds, including a compound later to be known as AZT that had been synthesized and tested by Dr. Jerome Horwitz of the Detroit Institute of Cancer Research in 1964.[9]

- Having identified suitable compounds for testing, the Glaxo scientists tested them against two mouse retroviruses "because they were readily reproducible, predictable, reliable and easy to use". In November 1984, AZT appeared "to eradicate completely the retrovirus in the mouse T-cells".[10]

- At that time, scientists at Glaxo recognized that the "immune systems of humans and mice are sufficiently different that it is not possible to predict from studies in mouse cells how a drug would work, if at all, in humans."[11]

- Being unable and ill equipped to complete the more sophisticated testing required, Glaxo turned to outside bodies for assistance. The critical testing of the compound was completed by scientists at the publicly-funded National Institutes of Health (NIH) who "had developed a human cell line … that could propagate *in vitro*, be infected with HIV *in vitro*, and provide information relevant to the ability of candidate compounds to inhibit the replication of HIV in the T-cells of living patients." At that time, scientists had struggled to grow human T-cells *in vitro*.[12]

- "[T]he only contribution made by Glaxo/Wellcome in the case of AZT was to identify a new use."[13]

- The sophisticated scientific research conducted at the NIH provided "crucial evidence on which the 'sound prediction' of AZT's utility depended".[14] In other words, but for the testing that Glaxo necessarily relied upon the NIH to conduct, Glaxo would have been unable to make a "sound prediction" of AZT's utility in treating HIV and would have been unable to continue with the development of AZT.

I understand that the extent to which a pharmaceutical manufacturer was responsible for—and invested its own resources in—the development of any particular product is relevant insofar as the price charged for that product is compared to its economic value. Quite clearly, greater involvement and investment in the development of a particular pharmaceutical product would justify a greater discrepancy between these two values.

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[8] Ibid.
[9] Ibid, at paragraphs 8-10.
[10] Ibid, at paragraph 11.
[11] Ibid, at paragraph 12.
[12] Ibid, at paragraphs 15-17.
[13] Ibid, at paragraph 52.
[14] Ibid, at paragraph 101.

Implications of Revised Guideline 6 for excessive pricing analysis

The *International Guidelines on HIV/AIDS and Human Rights* were first issued in 1998 by the Office of the UN High Commissioner for Human Rights (OHCHR) and the Joint UN Programme on HIV/AIDS (UNAIDS). The Guidelines, requested by the UN Commission on Human Rights, were the product of an international expert consultation convened by these bodies in 1996, and their stated purpose is to assist States in translating international human rights norms into practical observance in the context of HIV/AIDS. The UN Commission on Human Rights has, by consensus, urged States to ensure their laws, policies and practices comply with the Guidelines, and has invited States to "take all necessary steps to ensure the respect, protection and fulfilment of HIV-related human rights as contained in the Guidelines".[15]

Since the Guidelines were originally published and received this endorsement by the UN Commission on Human Rights, significant developments have occurred with regard to human rights related to health in general, and with regard to the issue of access to HIV/AIDS-related treatments in particular. In the light of these developments, the OHCHR and UNAIDS convened another international consultation of experts in July 2002 to update Guideline 6; it now provides up-to-date policy guidance to States based on current international law and best practice experiences. The Revised Guideline 6, dealing with "Access to Prevention, Treatment, Care and Support", was released in September 2002 by UNAIDS and the OHCHR, and reads in part as follows:

> "States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure … safe and effective medication at an affordable price…. States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods … including antiretroviral and other safe and effective medicines…."

As explained in the accompanying commentary and recommendations to States, this means, *inter alia*, that States should establish national plans to realise universal access to HIV/AIDS-related treatment. These plans must make resources available, set timelines for the realisation of these plans, and ensure equal and universal access to HIV/AIDS-related treatment over a reasonable time. In addition, States must ensure that HIV-related medicines are regulated to ensure affordability and accessibility. In short, Revised Guideline 6 calls for the development of an appropriate regulatory framework to ensure access to essential medicines.

This guidance to States is based on their obligations under international law to take legislative and other measures to realise human rights such as the right to health, for those States which are party to the *International Covenant on Economic, Social & Cultural Rights* (ICESCR, Articles 2 and 12) or regional human rights instruments containing similar provisions (such as the *African Charter of Human and Peoples' Rights*). It is further based on direction provided by various UN bodies with jurisdiction and competence in this area.

For example, the UN Commission on Human Rights has, by consensus, declared that access to medications in the context of pandemics such as HIV/AIDS is fundamental to realising the right to health.

[15] Resolutions 2001/51 and 1999/49. Copies of such resolutions referred to herein are attached to the original of this submission (sent to the Competition Commission by mail); electronic copies of these resolutions may be found on-line via http://www.unhchr.ch.

Accordingly, the Commission "calls upon States to pursue policies, in accordance with applicable international law, including international agreements acceded to, which would promote: (a) the availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them", and "(b) the accessibility to all without discrimination, including the most vulnerable sectors of the population, of such pharmaceuticals or medical technologies and their affordability for all, including socially disadvantaged groups."[16] In the same resolution, the Commission "calls upon States… to adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties."[17]

The UN Committee on Economic, Social and Cultural Rights is the expert body charged with monitoring States' compliance with their obligations under the ICESCR and with providing guidance on the interpretation and implementation of that treaty's provisions. In one of its "General Comments", the Committee has provided the most detailed articulation to date of the content of the human right to health in the ICESCR. The Committee has indicated that one of the four essential elements of the right to health is the "accessibility" of goods and services, including their "economic accessibility (i.e., affordability)".[18]

In addition, the Committee has observed that, with respect to the right to health under Article 12 of the ICESCR as with other human rights, all States Parties have the tripartite obligation to *respect*, *protect* and *fulfil* the right.

- Importantly, the Committee has advised that "the obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees" – this includes the duties of States "to adopt legislation or take other measures ensuring equal access to health care and health-related services provided by third parties" and "to control the marketing of medical equipment and medicines by third parties".[19]

- Furthermore, "the obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health" – this obligation requires States: (1) "to take positive measures that enable and assist individuals and communities to enjoy the right to health", (2) "to fulfil (provide) a specific right contained in the Covenant when individuals or groups are unable, for reasons beyond their

[16] Resolution 2002/32, paragraph 2(a)-(b).

[17] Resolution 2002/32, paragraph 3(b). The references to "international law, including international agreements acceded to" in this paragraph must necessarily include the international law of human rights, including conventions acceded to by States such as the ICESCR, which obliges States Parties to "take steps" to fully realize human rights, such as the right to health, "by all appropriate means, including particularly the adoption of legislative measures" The UN Committee on Economic, Social and Cultural Rights has pointed out that the adoption of legislative measures, although critically important, does not exhaust states' obligations under the ICESCR. See: Paragraph 4 of the General Comment No. 3: The nature of States parties' obligations (Art. 2, par. 1 of the Covenant). Adopted 1990, contained in U.N. Doc. E/1991/23.

[18] Committee on Economic, Social and Cultural Rights. General Comment No. 14: The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights). Adopted 11 May 2000. U.N. Doc. E/C.12/2000/4, CESCR: paragraph 12. A copy of the Committee's General Comment is attached to the original of this submission (sent to the Commission by mail); an electronic copy may be found on-line at: http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4,+CESCR+General+comment+14.En?OpenDocument.

[19] Ibid, paragraphs 33 and 35.

control, to realize that right themselves by the means at their disposal," and (3) "to undertake actions that create, maintain and restore the health of the population."[20]

I understand that section 27(2) of the Constitution of the Republic of South Africa places a similar obligation on the state as that outlined in general terms under international law and briefly described above. In addition, I understand that when interpreting the Bill of Rights, section 39(1)(b) of the Constitution requires consideration of international law, and that in terms of section 39(2) of the Constitution, all legislation must be interpreted in a manner which "promote[s] the spirit, purport and objects of the Bill of Rights." Simply put, in interpreting and applying the prohibition against excessive pricing in the Competition Act, the Commission must consider the state's positive constitutional obligations regarding access to health care services, and should consider the guidance provided in this regard by Revised Guideline 6 of the International Guidelines on HIV/AIDS and Human Rights. Those Guidelines reflect the positive obligations on the Republic of South Africa under international law to pursue access to affordable medicines for its people as a fundamental element of realising the human right to the highest attainable standard of health. The Guidelines also reflect the direction from authoritative UN bodies with expertise in this field that States are obliged, where necessary, to take measures to this end where the conduct of private actors, such as pharmaceutical companies, may be hindering such access.

Conclusion

The Canadian HIV/AIDS Legal Network thanks the Competition Commission of South Africa for this opportunity to make submissions on a critical issue affecting people living with HIV/AIDS not only in South Africa and other developing countries, but also throughout the world. We trust that these submissions will assist the Commission in conducting its investigation.

Should the Commission wish to contact me for any further information and/or assistance, it can telephone me at +1.416.595-1666, or contact me at +1.416.595-0094 (fax) or relliott@aidslaw.ca (e-mail).

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17 December 2002
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[20] Ibid, paragraphs 33 and 35.