International Chamber of Commerce
The world business organization

Department of Policy and Business Practices

Further views on cross border compulsory licensing

Prepared by the Commission on Intellectual Property

ICC, the world business organization, promotes international trade, investment and open market economies. ICC firmly believes that the protection of intellectual property stimulates international trade, creates a favourable environment for foreign direct investment, and encourages innovation, transfer of technology, and the development of local industry, all of which are essential for sustainable economic growth.

ICC has always supported the need for a proper balance among different interests. In the field of patents, for example, the system should allow those who innovate to obtain and enforce rights protecting their technological innovations, but should also ensure that society as a whole benefits from disclosure of inventions and the dissemination of knowledge. In the view of ICC, maintaining adequate balances is necessary for the continued successful operation and, hence, acceptance of intellectual property protection systems.

ICC fully shares WTO members' concern that adequate measures should be taken so that serious epidemics of infectious diseases such as HIV/AIDS, tuberculosis and malaria in the developing world can be effectively treated. However, it is clear that many factors other than patented drugs play a role in a successful health strategy - including living conditions, medical facilities, nutrition, and means for the distribution and administration of medicine. It is also clear that many pharmaceuticals which are effective in combating diseases in the developing world are not subject to patent rights (see attached table). It has been pointed out that the availability of health services adapted to local needs, efficient distribution systems and tariff and tax free treatment for drugs play an equally important role in ensuring access to medicines[1]. In the current negotiations on paragraph 6 of the Doha Declaration on TRIPS and Public Health, it is therefore important to remember that the issue of access to medicines calls for measures and policies that are entirely unrelated to intellectual property, and which will not be resolved by eroding the strength of intellectual property rights.

[1] *Workshop on Differential Pricing and Financing of Essential Drugs* organised by WHO and WTO, 8-11 April 2001 in Norway.

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Where a country does need medicines to fight a major disease and cannot afford their market price, the real question to be considered is how to finance that country's access to these drugs, whether patented or not. The current discussions in the TRIPS Council concerning cross border compulsory licensing appear to be premised on the assumption that the companies or institutions which develop such drugs should essentially bear the financial burden of supplying these drugs to countries which cannot afford them.

Research and development in all innovative sectors, including pharmaceuticals, can be funded through grants or, as is the case of the private sector and some academic institutions, through revenues generated by the sale of the resulting products. These revenues in turn are largely dependent on the exclusive rights afforded by patent protection, which is of a limited duration. Cutting off these revenues will deprive entities carrying out research and development of the funds necessary to continue their work. In addition, without the guarantees of effective patent protection, innovative industries and research institutions cannot take the risk of investing in the R&D necessary to the development of new products; indeed, a company's financial viability may depend on the strength of its patents given the sensitivity of share prices to a firm's patent portfolio in certain industries. Innovative companies whose revenues are reduced in certain markets may also be obliged to raise their prices in other markets to recoup their R&D costs.

ICC submits that the problem of access to medicines is essentially one of financing, both of the R&D to produce the necessary drugs and of the infrastructure necessary to administer them effectively. ICC also submits that this financing should be the responsibility of the entire international community, including industry and governments. The private sector is already working with governments and non-governmental organizations to develop and deliver drugs, as well as to build the infrastructure necessary to combat diseases prevalent in developing countries, such as malaria, tuberculosis and HIV/AIDS (see attached table for examples of initiatives). ICC therefore urges governments to give priority to voluntary initiatives and partnerships with the private sector to resolve the problem of access to medicines rather than resorting to a system of unrestrained cross border compulsory licensing which imposes the burden of financing primarily on innovative organizations.

Working with the private sector through voluntary mechanisms will also help reduce the risk that products being manufactured and distributed are of substandard quality, which in the case of pharmaceuticals, can have dangerous and even lethal consequences (see table for proportion of drugs failing quality control tests in developing countries). This risk can spread into other markets if drugs produced under a cross border compulsory licence, not subject to the quality control standards of the patent holder, are diverted into other markets, as has recently occured in Europe. [2]

[2] *The Financial Times.* 3 October 2002, Section Europe Pg. 8, DYER, Geoff "Netherlands acts against re-sold Aids drugs Africa illegal re-exports uncovered:" ; *The Guardian,* 4 October 2002, Boseley and Carroll.

Although ICC urges governments to give priority to voluntary solutions for the reasons stated above, it recognizes that negotiations are underway in the TRIPS Council to decide on a mechanism to allow a country to issue compulsory licences for the purpose of exporting to other countries that do not have sufficient manufacturing capacity in the pharmaceutical sector. ICC is concerned that sight of the initial objective has been lost during the course of these discussions. The genesis of the Doha Declaration on TRIPS and Public Health was the debate on how to help populations in certain low income countries to access medicines for HIV/AIDS, malaria and TB. Some of the solutions being proposed are far wider than necessary to tackle this issue and will erode the patent system without any corresponding contribution to resolving the original problem. ICC urges the TRIPS Council to keep its focus on diseases of the degree of seriousness of HIV/AIDS, malaria and TB and on access by countries that cannot afford drugs for such diseases.

To limit unneccessary erosion of the patent system, which could in turn discourage research into drugs for the diseases falling within the scope of any mechanism eventually agreed, any solution to the cross-border compulsory licensing problem must include adequate safeguards to protect the patent holder's interests. ICC urges that the TRIPS Council clarify the following critical issues:

- That the field of use of cross border compulsory licensing be strictly limited.
- That the solution should not apply to products other than pharmaceuticals.
- That safeguards be put into place to protect the rights of the innovator from re-exportation of the drug out of the receiving country and from diversion of the drug either within the manufacturing country or to other countries.
- That safeguards be put in place to limit which countries will be eligible as a receiving country, and which countries will be eligible as a manufacturing country.
- That the duration of a cross border compulsory licence be limited in time and that the cross border compulsory licence itself be reviewed periodically by the TRIPS Council.
- That the exporting and importing countries issue cross border compulsory licences that comply with each provision of TRIPS Article 31, excepting Article 31 (f) but including prior notice to the right holder in conformity with Article 31 (b) and with particular emphasis on Article 31 (c) as to limiting the scope of the cross border compulsory licence to the purpose for which the use was authorized.

Attached is a table of facts and figures which ICC hopes will contribute to the debate by setting the discussions in a factual context.

DISCUSSION ON ACCESS TO MEDICINES AND CROSS BORDER COMPULSORY LICENSING: BACKGROUND FACTS

A/ Prevalence of TB, malaria, HIV/AIDS and existence of drug patents

Table I provides information concerning the prevalence, in the developing world, of the diseases specifically mentioned in the Doha Declaration on TRIPS and Public Health. Table II provides general information concerning the existence of patents on drugs for treating these diseases, and Table III details patent coverage in Africa for antiretroviral drugs. The combination of these facts suggests that the existence of patents alone is not responsible for the lack of access to such drugs.

Table I Prevalence of TB, malaria and HIV/AIDS in developing countries

Disease	Deaths w-wide	New Cases	Prevalence in Developing World
TB[3]	2 million per year	>8 million per year	2 million in sub-Saharan Africa; 3 million in South East Asia, 0.25 million in Eastern Europe (per year)
Malaria[4]	>1 million per year	300 million per year	90% of deaths w-wide in Sub-Saharan Africa
HIV/AIDS	3 million[5] in 2001	5 million[6] in 2001	95% in developing world[7]; 40 million HIV cases w-wide; 28.5 million (71%) in Sub-Saharan Africa[8]

[3] WHO fact sheet on tuberculosis no 104, revised August 2002, see website. http://www.who.int/mediacentre/factsheets/who104/en.
[4] Roll Back Malaria, see WHO website fact sheet on malaria no 94, http://www.who.int/inf-fs/en/InformationSheet01.pdf.
[5] UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.
[6] UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.
[7] "Patent Protection and Access to HIV/AIDS Pharmaceutical in Sub-Saharan Africa", A Report Prepared for the World Intellectual Property Organization (WIPO), International Intellectual Property Institute, 2000.
[8] UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.

Table II Patents on drugs for TB, malaria and HIV/AIDS

Disease	Patents on relevant drugs
TB and malaria	Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drugs List are now "off patent", that is, no longer protected by patents[9]. This list includes 9 anti-tuberculosis drugs and 8 drugs against malaria[10].
HIV/AIDS	Most anti-retroviral drugs not protected by patents in majority of developing countries.[11] Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drug List - which includes many drugs used to treat various aspects and side effects of HIV/AIDS - are now "off patent", that is, no longer protected by patents[12]. This list includes 12 antiretrovirals.[13]

[9] WIPO *Emerging issues in IP: Patents & access to drugs and health care.* "Striking a Balance: Patents and Access to Drugs and Health Care". http://www.wipo.org/about-ip/en/studies/publications/health_care.htm

[10] WHO Essential Medicines Model List (Revised April 2002) Core List. http://www.who.int/medicines/organization/par/edl/eml.shtml

[11] "Patent Protection and Access to HIV/AIDS Pharmaceutical in Sub-Saharan Africa", page 36, Report Prepared for The World Intellectual Property Organization (WIPO), International Intellectual Property Institute, 1996, 2000.

[12] WIPO *Emerging issues in IP: Patents & access to drugs and health care.* "Striking a Balance: Patents and Access to Drugs and Health Care". http://www.wipo.org/about-ip/en/studies/publications/health_care.htm

[13] WHO Essential Medicines Model List (Revised April 2002) Core List. http://www.who.int/medicines/organization/par/edl/eml.shtml

Table III ***Patent coverage in Africa for antiretroviral drugs for HIV/AIDS, by country***[14]

	NRTIs*							NNRTIs*			Protease Inhibitors					
	Combivir [GSK*]	Epivir [GSK]	Hivid [Roche]	Retrovir [GSK]	Videx [BMS*]	Zerit [BMS]	Ziagen [GSK]	Rescriptor [Pharmacia]	Stocrin [Merck]	Viramune [BI*]	Agenerase [GSK]	Crixivan [Merck]	Fortovase [Roche]	Norvir [Abbot]	Viracept [Agouron]	Total
Algeria																0
Angola																0
Benin	X	X								X					X	4
Botswana	X	X		X			X			X	X					6
Burkina Faso	X	X								X					X	4
Burundi	X			X												2
Cameroon	X	X								X					X	4
Cape Verde																0
Central African Republic	X	X								X					X	4
Chad	X	X								X					X	4
Comoros	X	X		X												3
Congo (Republic)	X	X					X			X					X	5
Congo (Democratic Republic)	X											X				2
Côte d'Ivoire	X	X								X						3
Djibouti																0
Egypt	X	X														2
Equatorial Guinea																0
Eritrea																0
Ethiopia																0
Gabon	X	X								X					X	4
Gambia	X	X		X			X			X	X				X	7

[14] Table III was taken from a study completed by Amir Attaran and Lee Gillespie-White in October 2001. ATTARAN, Amir and GILLESPIE-WHITE, Lee. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa". *Journal of the American Medical Association.* October 17, 2001-Vol. 286, No. 15, Pg. 1888.

Ghana	X	X		X			X			X					X	6
Guinea										X					X	2
Guinea Bissau															X	1
Kenya	X	X		X			X			X	X				X	7
Lesotho	X	X					X			X	X				X	6
Liberia																0
Libya																0
Madagascar	X	X														2
Malawi	X	X		X						X	X				X	6
Mali	X	X								X					X	4
Mauritania	X	X								X					X	4
Mauritus																0
Morocco	X	X														2
Mozambique																0
Namibia																0
Niger	X	X													X	3
Nigeria	X	X		X									X			4
Rwanda	X			X												2
Sao Tome and Principe																0
Senegal	X	X								X					X	4
Seychelles	X	X		X			X									4
Sierra Leone	X			X			X									3
Somalia										X						1
South Africa	X	X		X	X	X	X	X	X	X	X	X	X		X	13
Sudan	X	X		X			X			X	X				X	7
Swaziland	X	X					X			X	X				X	6
Tanzania	X	X		X			X			X						5
Togo	X	X													X	3
Tunisia	X	X														2
Uganda	X	X		X			X			X	X				X	7
Zambia	X	X		X			X			X	X					6
Zimbabwe	X	X		X			X			X	X		X		X	8
Total	37	33	0	17	1	1	15	1	1	25	12	2	3	0	24	172

* NRTI indicates necleoside reverse transcriptor; NNRTI, non-NRTI; GSK, GlaxoSmithKline; BMS, Bristol Myers Squibb; BI, Boehringer Ingelheim.

B/ Healthcare infrastructure

The following data puts into perspective other identified factors contributing to the lack of available drugs to treat TB, malaria and HIV/AIDS. These include insufficient public funding for the purchase of drugs and the lack of an adequate medical infrastructure to properly deliver medicines to the target patient population.

- Public health expenditures
  - Western Europe and North America upwards of USD 1,500 per person annually.
  - Africa frequently under USD 20 per person.[15]

- World Health Organization insights into factors contributing to lack of access to essential drugs in the developing world[16]:
  - Over one-third of the world's population lacks access to essential drugs, mainly in poorest parts of Africa and Asia ;
  - 50-90% of drugs in developing and transitional economies are paid for out-of-pocket;
  - Up to 75% of antibiotics are prescribed inappropriately; worldwide average of patients who take their medicines correctly is 50%;
  - Less than one in three developing countries have fully functioning drug regulatory authorities; and
  - 10-20 % of sampled drugs fail quality control test in many developing countries. Failure in good manufacturing practices too often results in toxic, sometimes lethal products.

[15] "Beyond Our Means? The Cost of Treating HIV/AIDS in the Developing World", Martin Foreman, The Panos Institute (London, 2000). See www.panos.org.uk.

[16] WHO Essential Drugs and Medicines Policy, see www.who.int/medicines, "The Rationale of Essential Medicines" (updated 8 November 2002)

C/ Public-private partnerships and private sector initiatives for supplying needed drugs

Table IV provides a non-exhaustive listing of certain public-private partnerships and private sector initiatives working to provide access to drugs to treat HIV/AIDS, TB and malaria in developing countries. Some of these initiatives provide outright grants to developing countries or international organizations to allow for the purchase of needed drugs, while others provide needed drugs directly to the developing countries or international organizations. Other programs conduct research into targeted diseases.

Table IV[17] Public-private partnerships and private sector initiatives for supplying needed drugs

HIV/AIDS, TB and malaria

Initiative	Participants	Goals
The Global Fund	Government, philanthropic organizations, industry and individuals	Attracts, manages and distributes financial resources to combat HIV/AIDS, tuberculosis and malaria

HIV/AIDS

Initiative	Participants	Goals
Accelerating Access Initiative	UNAIDS, WHO, UNFPA, World Bank, Merck & Co. Inc., Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffmann-La Roche, GlaxoSmithKline and Abbott Laboratories	Finds ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS-related illnesses

[17] Information used for Table IV was taken from the International Federation of Pharmaceutical Manufacturers Association website at www.ifpma.org .

HIV/AIDS *(continued)*

Initiative	Participants	Goals
African Comprehensive HIV/AIDS Partnership (ACHAP)	Government of Botswana, the Bill and Melinda Gates Foundation, Merck & Co., Inc./The Merck Foundation	Helps prevent HIV infection, increase rates of diagnosis and treatment of HIV/AIDS in Botswana. Merck & Co., Inc. Donates antiretroviral medicines
Enhancing Care Initiative	Merck & Co., Inc., Harvard AIDS Institute Francois-Xavier Bagnoud Center for Health & Human Rights at the Harvard School of Public Health, Brazil, Senegal, KwaZulu Natal province in South Africa and Thailand	Helps advance the quality of and access to comprehensive education, care, and treatment for individuals living with HIV/AIDS in developing countries
International AIDS Vaccine Initiative (IAVI)	Developing countries, governments and international agencies, GlaxoSmithKline, Merck & Co., Inc., Boehringer Ingelheim, Bristol-Myers Squibb, Roche Holding, Rockefeller Foundation, World Bank, USAID, the Bill and Melinda Gates Foundation.	Collaborates with developing countries, governments and international agencies dedicated to accelerating the development of a vaccine to halt the AIDS epidemic.
Viramune Donation Program	Boehringer Ingelheim	Viramune offered free of charge for a period of 5 years to developing countries

Tuberculosis

Initiative	Participants		Goals
Action TB	Tuberculosis	GlaxoSmithKline, and Academic Research Groups in South Africa, Gambia, UK, USA	International, coordinated research program aimed at finding new targets for anti-TB therapies, identifying novel vaccine candidates and identifying surrogate markers for use in clinical trials.
Global Alliance for TB Drug Development	Tuberculosis	An alliance of industry, NGO's and foundations from around the world.	Discovery and development of cost-effective new anti-TB drugs.
Stop TB Partnership	Tuberculosis	International Federation of Pharmaceutical Manufacturers Association, WHO	Development and improvement of strategies to control and eliminate TB.

Malaria

Initiative	Participants		Goals
Coartem		Novartis, WHO, Institute for Microbiology and Epidemiology in Beijing	Novartis supplies, through WHO, unlimited quantities of Coartem to public sector agencies of developing countries where malaria is endemic.

Malaria *(continued)*

Initiative	Participants		Goals
JPMW Alliance	Malaria	Japanese pharmaceutical companies, the Ministry of Health, Labor & Welfare, and the Special Program for Research and Training in Tropical Diseases of the WHO, Kitasato Institute, Tokyo	Screens chemical entities from the chemical libraries of the Japanese pharmaceutical companies for antimalarial activity.
LAPDAP Antimalarial Drug Development	Malaria	WHO, UNDP, World Bank, WHO Special Program for Research and Training of Tropical Diseases and GlaxoSmithKline.	Research agreement to develop a new effective oral treatment for uncomplicated malaria, primarily for use in Sub-Saharan Africa, at affordable prices for public health programs.
Malaria Vaccine Initiative	Malaria	Program for Appropriate Technology in Health, the Bill and Melinda Gates Foundation, GlaxoSmithKline.	Develops malaria vaccines and ensures their availability and accessibility in the developing world.
Medicines for Malaria Venture	Malaria	Bayer, GlaxoSmithKline, Roche, the International Federation of Pharmaceutical Manufacturers Associations, WHO, the Rockefeller Foundation, World Bank, Department for International Development, the Swiss Agency for Development Cooperation, the Ministry for Development Cooperation and the Netherlands.	Discovers and develops new anti-malarial drugs suitable for use in developing countries.

Malaria *(continued)*

Initiative	Participants		Goals
Roll Back Malaria Global Partnership	Malaria	WHO, UNDP, UNICEF, World Bank, NGOs, donor agencies, research groups, private sector (eg Exxon Mobil, GlaxoSmithKline, Novartis, Proctor and Gamble, World Alliance for Community Health)	RBM seeks to strengthen health systems to ensure better delivery of health care, especially at district and community levels, and to encourage the development of new and more effective anti-malarial drugs and vaccines.

D/ Impact beyond the private sector

Academic and other non-profit research insitutions also derive revenue from the outlicensing of patents on drugs. Without this revenue, these institutions would have to draw more heavily upon local government support or reduce much needed medical research. Below are figures indicating licensing revenues for over 300 universities, hospitals and other research institutions in the US and Canada in 2000 – these do not relate exclusively to, but include, licensing of drug patents.

Table V ***Data relating to patent filing and licensing activity of academic and other non-profit research institutions in the US and Canada in fiscal year 2000 (July 1, 1999 - June 30, 2000)***[18]

Total inventions disclosed	13,032
US patent applications filed in fiscal year	9,925
Total Adjusted Gross License Income received	USD 1,26 billion
Total U.S. patents issued	3,764
Start-up companies formed around university intellectual property in 2000	454
Start-up companies formed around university intellectual property since 1980	3376

In addition, for US universities that responded to the 2000 AUTM survey:

Percentage increase from 1991 to 2000 in patent filings	256%
Percentage increase from 1993 (earliest year surveyed) to 2000 for patents issued to U.S. universities	131%
Percent increase in gross license revenue from 1991 to 2000	698%

[18] Information extracted from "Association of University Technology Managers (AUTM) Licensing Survey:Fiscal Year 2000" , Copyright 2002, The Association of University Technology Managers,Inc.