Africa: Contested Compromise on Generic Drugs
(Reposted from sources cited below)

A last-minute World Trade Organization compromise in Geneva on intellectual property protection and access to medicines is being heralded by some as finally opening the doors to imports of generic medicines by poor countries without a manufacturing capability. In intense negotiations in recent months, the U.S. reached behind-the-scenes agreements with key countries such as Brazil, India, South Africa, and Kenya. The U.S. and the international pharmaceutical industry made some concessions after blocking an agreement for almost two years. However, the compromise also imposes extremely complicated procedures designed to protect patent rights, which leave enormous obstacles to overcome before affordable medicines are actually made available.

The World Health Organization and treatment access activists stress that the real test will be whether affected countries and international agencies take full advantage of their right to put public health before patent rights. In a speech in Johannesburg on September 1, Dr. Lee Jong-wook, Director-General of the World Health Organization (WHO), proposed a response strategy called "3 by 5" which aims to provide 3 million people living with AIDS with antiretroviral medicines by the end of 2005. For this to happen, rich countries would also have to provide new financial resources for expanded purchase of generic drugs. UNAIDS estimates that approximately 480,000 people could be treated immediately if resources were available, such as through additional funding for the Global Fund to Fight AIDS, TB, and Malaria.

This posting contains several statements and background analyses on the decision, which came less than two weeks before the beginning of the World Trade Organization ministerial summit in Cancun, Mexico.

Additional related resources:

"African HIV/AIDS Patients Show Better Adherence to Antiretroviral Drug Regimens Than U.S. Counterparts"
651 [type URL on one line or go to http://www.nytimes.com [3] for full story]


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(1) World Trade Organization Statements - August 30, 2003

DECISION REMOVES FINAL PATENT OBSTACLE TO CHEAP DRUG IMPORTS
WTO member governments broke their deadlock over intellectual property protection and public health today (30 August 2003). They agreed on legal changes that will make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

Press release:

Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health:
[full 6-page decision with 11 points and 9 notes]

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Statement of the World Health Organization on WTO access to medicines decision

1 September 2003 -- The World Health Organization (WHO) is encouraged by the consensus reached by Members of the World Trade Organization (WTO) on the issue of access to medicines by countries with little or insufficient capacity for pharmaceutical production.

The agreement covers all medicines. Among the diseases that could be more effectively tackled as a result of this decision are AIDS, tuberculosis and malaria.

WHO will work with the countries which could make use of the new arrangements to assist them to achieve the full public health benefit from the lower prices. Given the urgency of the health needs in the poorest countries, the work to implement this agreement must proceed as quickly as possible. The full impact of the agreement will depend on how effectively it can be implemented in countries.

For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers, when making purchasing decisions.

WHO continues to urge Member States to consider using to the full the TRIPS flexibilities with regard to the protection of public health.

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(3) Oxfam Statement

Oxfam: WTO patent rules will still deny medicines to the poor

August 30, 2003

After two years of intense wrangling, the World Trade Organisation (WTO) appears to have reached an agreement on drug patents.

The deal was apparently brokered tonight at an informal meeting and could be officially confirmed tomorrow morning. If this deal is confirmed, the result would be a severe disappointment, says international agency, Oxfam.

It was hoped that the deal would secure developing countries greater access to low-cost copies of medicines. But thanks to the intransigence of the US and pharmaceutical giants, poor countries would still not have the same legal rights to affordable medicines as industrialised countries.

Oxfam's Head of Advocacy in Geneva, Celine Charveriat said: "If agreed by the WTO, developed countries will trumpet this change to WTO patent rules as a big concession, but the proposed deal is largely cosmetic and will not make a significant difference to the millions of sick people who die unnecessarily in the Third World every year."

Developing countries successfully stopped the US and the pharmaceutical lobby from excluding many diseases from the deal - an important achievement. However, the proposed deal still contains serious flaws. No matter how desperate the health need, a developing country without the capacity to produce a needed drug (which is virtually all of them) will have to ask another government to suspend the relevant patent and license a local company to produce and export it. Few countries, if any, will be prepared to help other countries in this way, as it would provoke retaliation by the US which fiercely defends the commercial interests of the pharmaceutical corporations.

Furthermore, the agreement is wrapped in so much red tape that it becomes largely unworkable - it amends a clause of only 20 words, yet runs to more than seven whole pages. In practice, most poor countries will end up paying the high price for patented medicines or, most probably, doing without.

The change in patent rules was promised by the WTO Ministerial Conference in Doha in 2001 in its landmark Declaration on TRIPS and Public Health.

Charveriat added: "If confirmed, the deal would be a betrayal of the pledge made in the Doha Declaration to put public health
before patent rights. It is profoundly unfair to create fresh legal obstacles for developing countries trying to obtain affordable generic medicines, purely in the interests of an industry that in the US alone made US$37 billion in profit last year. This decision would raise questions about who really makes policy in the WTO, and is a bad omen for the upcoming WTO summit in Cancun”.

The international agency insisted that if the deal goes ahead it would not put a stop to efforts by developing countries and pressure groups to build on the important gains of recent years, such as the Doha Declaration and the reductions in the price of AIDS drugs. Indeed, this outcome would strengthen the need for a thorough revision of the TRIPS Agreement with a view to taking developing countries out of the TRIPS straightjacket altogether.

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For more information please contact Amy Barry in Oxfam's press office on 0044-7980664397 or abarry@oxfam.org.uk [11] or Celine Charveriat in the Geneva office at 0041-79-668-6477.

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(4) Healthgap Background Analysis
HealthGap Listserv (sign-up at http://www.healthgap.org [12])

The incredible shrinking Doha Declaration

Brook K. Baker, Health GAP, August 26, 2003

With the new Chairman's Statement on Paragraph 6, dated August 21, 2003, it is easy to discern the U.S.'s latest plan to shrink the Doha Declaration to a totally ineffectual platitude with no real capacity to deliver cheaper, standard-quality generic medicines to countries that lack the same capacity to produce medicines efficiently as the U.S. does. In essence, the U.S. has engaged in a two-part squeeze play creating "the incredible shrinking Doha Declaration."

On one end of the vise, the U.S. has tried to limit countries that are permitted to import generic medicines pursuant to a compulsory license to address a public health need in four ways. First, the U.S. brokered an absolute agreement from 23 relatively rich countries that they would not issue compulsory licenses for importation under any circumstances. Obviously, many of these countries are large enough and have sufficiently robust generic industries to issue a compulsory license for domestic production. But still the U.S. has succeeded in shrinking the richest part of the international market, essentially engaging in protectionism at a historic level. Second, the U.S. convinced some other, generally smaller or poorer countries (12 in all [note: China was listed twice!]) to agree to issue compulsory licenses for import only in order to address national emergencies or other circumstances of extreme urgency. Another piece of the potential market for generic medicines was thereby lopped off, certainly including some countries that don't need to import (China) but also including countries that have no domestic capacity whatsoever (Qatar). Third, the U.S., and presumably the E.U., forced the E.U.
accession countries, 10 in all, to import only on an emergency or urgency basis and to relinquish even this right upon accession into the E.U. This will certainly have a devastating impact on the costs of medicines in some very poor Eastern European countries, including some that are facing an escalating HIV/AIDS crisis.

To this total of 45 countries that have expressly relinquished their sovereign right to import generic medicines for public health purposes pursuant to a compulsory license, the U.S. has imposed a fourth condition that threatens importation for many other middle-income developing countries. Basically, the U.S. has set up a notification-and-review process whereby countries that say that they need to import generics because of incapacity in their pharmaceutical sector will be forced to prove and then defend such determinations. The standard for proving "insufficient capacity" is already terribly uncertain. Accordingly, the reporting-and-review process will, as a practical matter, deter countries from risking involvement in a damaging and costly WTO dispute resolution process simply because they could import generic medicines much more cheaply than they could produce them at home. This prove-and-review standard doesn't name countries, but it will certainly have a deterrent effect on countries which might try to import cheaper generics.

Accordingly, this demand-end of the vise is designed to dramatically shrink the potential market for generic drugs and to exclude virtually all markets with meaningful and stable purchasing power.

At the other end of the vise, the supply end, the U.S. is trying to dramatically increase the risks and costs of producing generic medicines for export. In part, the risk factors for generic producers include the shrinking markets mentioned above. In particular, generic producers will be uncertain whether a particular country has properly determined that it lacks sufficient pharmaceutical capacity or that there is a public health emergency - a decision that can not only be reviewed in the WTO, but a decision that might prompt a lawsuit by a patent-holder.

Moreover, the U.S. is also adding to the direct costs of manufacturing generic medicines by its overly stringent anti-diversion standards, which should more accurately be called bloated-pricing standards. As amply described by DG Shah's Comments on the draft Chairman Statement, varying pill size, shape, and color is not cost-free, particularly when moving from round, white tablets or capsules. Although there may well be some sense in not using a proprietary name (a trade mark infringement) or the same packaging, there is virtually no sense in adding dramatically to costs (and potential bio-availability) by changing size and shape. This added and unnecessary cost burden is especially egregious, as DG Shah points out, when you might have to change trade dress, size and shape for multiple small markets.

Shrink the market, increase costs, and add burdensome procedural requirements - is that the simple and efficient solution promised at Doha? The answer is obviously no. And the answer is no because the U.S. remains more committed to maximizing profits for the most profitable industry in the world, Big Pharma, than it is to the million of lives at stake.
Activists are accused of rhetorical excess when we talk about trade barriers, intellectual property barriers, and lives hanging in the balance. To bureaucrats in the USTR these lives are literally and casually traded for profit - profit for the pharmaceutical puppet masters who hide behind the scene and pull the strings. Unfortunately, for reasons that cannot be fathomed, certain developing countries, including some in leadership positions and that face escalating public health dilemmas, are content to trade their citizens' health for minor reductions in farm export subsidies or for temporary access to textile markets (before an even cheaper producer arrives on the scene). In other words, the responsibility for the incredible shrinking Doha Declaration certainly rests primarily with the U.S. (and secondarily with the E.U. and Japan), but developing countries are becoming complicit in their own destruction.

When unified in the aftermath of the Anthrax scare, developing countries succeeded in overpowering the U.S. bully-boys and producing the Doha Declaration. Now, they are letting the world's biggest bully talk them and conditionalize them to death. Not only should they reject the Chairman's draft statement, they should reject the Motta text of December 2002. It too contained too many compromises of vital interests. Developing countries would do better to rely on the text of the Doha Declaration and the flexibilities of the TRIPS Agreement. Then willing generic producers could export under Article 30 (permitting limited exceptions to patent rights) to willing importers that have issued compulsory licenses. People living with diseases need a full-size, fully operational Doha Declaration, not a shrunken pale imitation ghost-written by the U.S. pharmaceutical industry.

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(5) Statement from Consumer Project on Technology

CPTech Statement on WTO deal on exports of medicines

August 30, 2003

Consumer Project on Technology
http://www.cptech.org/ip/health [14]

"Today's decision on the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health puts the WTO into unchartered waters. The WTO secretariat, the TRIPS Council and the Chair of the TRIPS council will now begin to routinely review the issuance of individual licenses, and the WTO will now as a matter of expected practice, oversee the use of compulsory licensing in the most intimate terms, looking at the terms of individual licenses, evaluating the basis for deciding manufacturing capacity is insufficient, or reviewing or second guessing any of the new terms and obligations that the new implementation language introduces into the regulation of compulsory licensing of patents on medicines.

The persons who have negotiated this agreement have given the
world a new model for explicitly endorsing protectionism. The United States, Europe, Canada, Australia, Japan and other developed economies will be allowed to bar imports from developing country generic suppliers -- under completely irrational protectionist measures that are defended by the WTO Secretariat and its most powerful members as a humanitarian gesture.

"The European Commission's DG-Trade has engineered this agreement as an attack on a position endorsed by its own parliament that was a far more elegant and rational solution to the export issue.

The EU Parliament Amendment 196 was 52 words. The new WTO deal is more than 3,200 words. The extra 3,150 words were not needed and will create a morass of uncertainty and gamesmanship. The new deal will predictably be used to prejudice other more useful export strategies under Articles 30 or 31.k of the TRIPS agreement.

"The new agreement has very modest benefits, and it has very substantial costs, risks and uncertainties.

"On the positive side, the new agreement completely rejects the efforts of the US, Japan, the European Union and the WTO Secretariat to limit the scope of diseases for compulsory licensing, and it also does not require high standards such as epidemics or emergencies. Routine public health problems can be addressed in the new agreement. The developing countries did hold the line on this, under enormous pressure from major pharmaceutical companies and the trade delegates who lobby on behalf of the biggest pharmaceutical companies.

"The next step for public health activists will be to be more pro-active on trade and public health, both locally and globally. Locally it is now time for countries to give effect to paragraph 4 of the Doha Declaration, and actually issue compulsory licenses to promote access to medicine for all. If it can be said at the WTO, it can be done back home.

Globally, it is now time for NGOs to take greater control of the global debate over how best to fund R&D. On the hand, we have scenarios of ever increasing shares of GDP being spent to support a largely non-innovative big pharma system of extremely costly marketing efforts, and a growing police state designed to stop the trade in expensive medicines. On the other hand, there are new ideas on how trade agreements should more efficiently address global support for R&D, and new ideas on how to best fund innovation for new medicinal products. We think the latter agenda is better for everyone."

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Date distributed (ymd): 030903
Region: Continent-Wide
Issue Areas: +health+ +economy/development+

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