Trade And Access To Medicines: Things The WTO Should Consider

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Some pending thorny issues linked with trade and access to medicines in developing countries did not come up at the September Public Forum of the World Trade Organization. As unsolved matters closely joining together trade and equitable access to medicines, they might serve as things the WTO should consider to help keep itself relevant and interesting, writes Daniele Dionisio.

Over 1500 delegates, from civil society, academia, business, government and the media, crowded the 19-21 September 2011 Public Forum hosted by the World Trade Organization (WTO) in Geneva. Against a backdrop of an ailing global economy and a deadlocked Doha Round trade deal, the Forum was organized around the theme "Seeking answers to global trade challenges", and included over forty sessions distributed into four sub-themes: food security, made-in-the-world and value added trade, trade in natural resources, and the future of the multilateral trading system.

Remarkably, some thorny issues and pending points closely joining together trade and access to medicines in developing countries did not come up at the Forum. Might these be things for the WTO to consider as a way to help make itself relevant and interesting? In other words, would it be appropriate for the WTO to pick up matters involving trade and access to medicines and take them into account while pushing for non-discriminatory solutions?

These questions are seemingly to the point at a time when key medicines are under prolonged patent regimes, further exacerbated by free trade agreements and governments' choices turning intellectual property (IP) agendas into policies which protect monopolistic interests at the expense of unbiased access to lifesaving medicines. Thinking in this area would probably increase once inherent questions overlooked at the Forum are examined. Some of these issues are highlighted below.

Sustainable Financing Mechanisms

This is the case for sustainable financing mechanisms as the foundation for operational proposals to ensure long-term access to medicines. Adding to the patent pool model, other proposals (including, though not limited to, prizes, advance market commitments, health impact fund, and priority review vouchers) are currently pending as regards suitability for complementing IP regimes and channelling open source schemes, sustainable financing mechanisms, and needs-driven rather than market-driven rules.

As a closely pertaining resource, a Financial Transaction Tax (FTT) is presently under international debate while being recently endorsed by the EU Commission. Should an FTT be introduced, enforced and implemented at a global level worldwide, the generated revenues would reportedly be sufficient to finance development priorities, including access to medicines as part of global health funding.

An FTT would fit the mandate of the World Health Organization while being instrumental to the spirit and resolutions of latest WHO Health Assemblies. Reasonably, it should be up to WTO and WHO to take the lead and push that FTT be introduced and enforced at a global level worldwide, while insisting on health priorities and non-discriminatory access to medicines becoming a substantial objective for subsequent revenues.

WTO 2003 Waiver and Canadian Bill C-393

This is also the case for a WTO 2003 waiver acknowledged as a crucial issue for the needs of millions of the worst-off people needing medicines in resource-limited countries. Indeed, the WTO in November 2001 recognized that Article 31(f) of the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement limited the use of compulsory licences (CLs) “predominantly” for the purpose of supplying the domestic market of the country where the licence was issued (Doha Declaration on TRIPS and Public Health). Allowance for export was then agreed upon through a WTO 2003 temporary waiver (the “August 30th Decision”, voted as permanent amendment on 6 December 2005 and still awaiting ratification by members), that permits export under CL to countries unable to manufacture the medicines themselves.

As an implementation of the WTO 2003 waiver, the Canadian government enforced in 2005 Canada’s Access to Medicines Regime (CAMR) as a federal law aimed at helping get medicines for public health needs to the developing countries. While a few other countries also have introduced laws to implement the waiver, Canada is the only country till now that has really translated legislation into action. Unfortunately, CAMR is a lengthy and cumbersome process with restrictions going beyond the minimum standards in the WTO 2003 waiver. As a priority measure, this regime should urgently be streamlined into a “one-licence solution” that would authorize a

company to produce the same medicine for export to any country that submits notifications to WTO regardless of the quantity of medicine.

Accordingly, proposed legislation Bill C-393, which aims to make CAMR expeditious and easier to use while complying with obligations under WTO's trade rules, is now under examination by the new Canadian Parliament. In addition to the one-licence solution its contents include the removal of unnecessary limits on medicines that can be supplied under CAMR, and the transformation of a motion of four-year duration limit for CAMR reforms into a four-year review, instead of an automatic repeal of them.

On the grounds that amending CAMR is a non-partisan humanitarian issue, there is hope that Bill C-393 will attract new support from members of all Parties in the Canadian Parliament. But, if Bill C-393 is to be passed and make headway on fair access to medicines, this issue should be transparently tackled in any relevant forums and event discussions worldwide.

Defective Anti-Counterfeit, Anti-Substandard Medicine Legislations

No debate was introduced at the Public Forum around the pitfall of misplaced legislations against counterfeit and substandard medicines, wherein misleading definitions unduly jeopardize the legitimate trade in generic medicines. This trade is the only inexpensive lifeline for treatment in resource-limited countries. Indeed, millions of people are benefiting from cheap, high-quality medicines supplied by generics producers based in Brazil, Thailand, South Africa and, mainly, India (see here, and here).

Misleading definitions make no distinction between the wilful infringement of trademark on a commercial scale (the only targeted counterfeiting case in the WTO TRIPS Agreement) and the non-fraudulent civil trademark infringement wherein the names or packages of medicines look accidentally similar.

Worse, misleading definitions divert resources from medicine quality. This is the case for the Anti-Counterfeiting Trade Agreement or ACTA, (negotiated by, among others, the US, EU, Australia, Canada and Japan) that lacks measures to seriously tackle the quality problems posed by substandard medicines.

This backdrop highlights the US President's order this year to apply exacerbated criminal procedures and penalties against counterfeiters, and a concurrent US government initiative (supported by the governments of Kenya, Morocco and the Philippines) aimed to better inform people of the dangers of counterfeit products.

These circumstances are likely paving the way for the expeditious enforcement of an unchanged ACTA in the US, while indirectly acting in favor of defective anti-counterfeit legislations pending in some African countries.

With respect to medicines, ACTA was barely mentioned at the Public Forum. Consequently, while ACTA is now open for signature until May 2013 so that compatibility issues with EU and other negotiating governments can be ironed out, no information was shared on the conclusions of recent studies that ACTA falls short of European standards, does not comply with Parliament orders to exclude TRIPS-plus provisions for medicines, and increases the risk of wrongful seizures, lawsuits and other enforcement actions against legitimate suppliers of generic medicines.

And there's more.

Trans-Pacific Partnership Agreement (TPP)

The debate at the Forum only addressed the different economic levels and needs of the nine countries involved in negotiations for a Trans-Pacific Partnership agreement (Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the US, and Vietnam), together with forecasts on implications for the multilateral trade system.

No information was provided about a plan for medicines, known as Trade Enhancing Access to Medicines (TEAM), introduced by US negotiators at the eighth round of talks in Chicago on 9-15 September 2011. While the US Administration did not disclose the texts of the current plan, a 12 September 2011 US white paper outlining the plan's goals and TPP aims was made publicly available. As per its terms, "….the TPP is a key initiative through which the Administration seeks to advance the United States' multi-faceted trade and investment interests in the Asia-Pacific region……This region includes some of the world's most robust economies and accounts for more than 40 percent of global trade."

This paper flaunts that TEAM would set up a "TPP access window" to accelerate access to medicines, get rid of tariffs on medicines and medical devices, and step up legal certainty for manufacturers of generic medicines. The paper also urges that TPP parties reaffirm their commitment to the Doha Declaration on the TRIPS Agreement and Public Health.

However, reactions from public interest groups and non-governmental organizations are opposing the TEAM initiative, also in the light of a leaked draft of the US position whose contents led to the allegation in the Huffington Post online on 14 September 2011 that the US "…is pushing provisions to tighten intellectual property laws that will make price-busting generic competition impossible. …to make it impossible to challenge a patent before it is

granted; to lower the bar required to get a patent (so that even drugs that are merely new forms of existing medicines, and don't show a therapeutic improvement, can be protected by monopolies); and to push for new forms of intellectual property enforcement that give customs officials excessive powers to impound generic medicines suspected of breaching IP…. The US will also reportedly introduce measures to make it harder and more expensive for generic drugs to get regulatory approval, and to lengthen patent monopolies for pharmaceutical firms so that they keep generics out and prop up drug prices for longer. All of these measures are known to hit the availability of affordable medicines in developing countries hard …".

As regards the white paper, concerns also refer to the lack of specifics, wherein exacerbated customs and criminal measures are enforced to curb trade in counterfeit medicines, and no measures are tabled to help national regulatory frameworks seriously tackle the quality problems posed by substandard medicines.

Taken together, the non-transparent dynamics bound up with TEAM compound fear that this initiative would be something that backs big pharma rather than making headway on non-discriminatory access to medicines in developing countries. This is particularly worrying owing to the fact that TEAM will probably play as the basis for future agreements between the US and other developing and developed countries. This concern seemingly harmonizes with a swipe taken by the US rep on 14 September at the WTO trade policy review of India, maintaining that India's IP trade policy is out of sync with international best practices.

Fodder for the Eighth WTO Ministerial

The questions highlighted here were not brought forth at the Public Forum, though they closely join together trade and access to medicines. But they could now serve as issues for the WTO to take into account in debates towards non-discriminatory solutions, including at the eighth WTO Ministerial Conference to be held 15-17 December 2011 in Geneva. Indeed, the WTO's guiding principles comprise, among other things, open borders, non-discriminatory treatment by and among members, improved public welfare, reduced poverty, and commitment to transparency in the conduct of its activities. Otherwise, are the utmost opportunities for fair trade and access to be given up?

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