WORLD TRADE ORGANIZATION

TRIPS and Health: Frequently Asked Questions
Compulsory Licensing of Pharmaceuticals and TRIPS (From www.wto.org[1])

A certain amount of confusion exists about the TRIPS Agreement's provisions and compulsory licensing for medicines. These are some answers to questions that are frequently asked.

What is compulsory licensing?

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

Are these flexibilities new?

No. They always existed in the TRIPS Agreement, ever since it took effect in January 1995.

But what about the November 2001 Doha Ministerial Declaration on TRIPS and Public Health? Didn't that change the rules?

Not in general. Two provisions to do with **least-developed countries** and **countries that do not have production capacity** directly involved changes to the rules of the TRIPS Agreement. For the main part the declaration was important for clarifying the TRIPS Agreement's flexibilities and assuring governments that they can use the flexibilities, because some governments were unsure about how the flexibilities would be interpreted. Let's focus on the general case first.

OK. What is the general case?

For compulsory licensing, it's when the generic copy is produced mainly for the domestic market, not for export.

Is this the same as tearing up the patent?

No. The patent owner still has rights over the patent, including a right to be paid for the authorized copies of the products.

Does there have to be an emergency?

Not necessarily. This is a common misunderstanding. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences.

The TRIPS Agreement does list a number of conditions for issuing compulsory licences, in Article 31. In particular:

- normally the person or company applying for a licence has to have tried to negotiate a **voluntary licence** with the patent holder on reasonable commercial terms. Only if that fails can a compulsory licence be issued, and
- even when a compulsory licence has been issued, the patent owner has to receive payment; the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the

[1] http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

circumstances of each case, taking into account the economic value of the authorization", but it does not define "adequate remuneration" or "economic value".

There's more. Compulsory licensing must meet certain additional requirements: it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and it should be subject to legal review in the country.

You said "normally" …

Yes, this is where the confusion about emergencies arises. For "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try first for a voluntary licence. It's the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing: the purpose is to say that the first step of negotiating a voluntary licence can be bypassed in order to save time. But the patent owner still has to be paid.

Who decides whether the payment is "adequate"?

The authorities in the country concerned. The TRIPS Agreement says the patent owner must be given the right to appeal in that country as well.

And that's always been the case under the TRIPS Agreement? What has changed?

Yes, it's always been the case. What has changed is a provision that used to say that compulsory licences must be granted mainly to supply the domestic market (paragraph (f) of Article 31). The 2001 Doha Ministerial Conference decided that this should be changed so that countries unable to manufacture the pharmaceuticals could obtain cheaper copies elsewhere if necessary.
The legal means of making the change was agreed on 30 August 2003 when the General Council decided to waive the provision, allowing generic copies made under compulsory licences to be exported to countries that lack production capacity, provided certain conditions and procedures are followed.

All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US. Since they joined the EU, the list now includes 10 more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

As recorded in a separate statement that is not part of the waiver, 11 other members announced voluntarily that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

So all obstacles have been removed?

Not entirely. The WTO waiver on its own is not enough. To use the system, potential exporting countries probably have to change their laws too. This is where their laws complied with the original TRIPS provision by requiring production under compulsory licensing to be predominantly for the domestic market. So far Norway, Canada, India and the EU have formally informed the TRIPS Council that they have done so.

And least-developed countries?

They can now delay protecting pharmaceutical patents until 2016. So long as a medicine is not patented in a least-developed country, the government does not need to issue a compulsory licence to import. But the supplying country would have to issue a compulsory licence to export a generic copy of a medicine that is patented in that country.

Just to be clear, if a compulsory licence is issued it could be under the original TRIPS Agreement and not under the newer 2003 decision?

Correct. The 2003 decision (sometimes called the “Paragraph 6” decision because it refers to that that paragraph of the Doha declaration) only deals with compulsory licences to produce for export. Many news stories are about the possibility of issuing compulsory licences to supply domestic markets. That was always possible.