



# FICPI INFORMATION DOCUMENT

## 29 AUGUST 2013

### CET INFORMATION DOCUMENT

<p>TITLE: <i>Report of FICPI meeting with the World Trade Organisation (WTO) 29 August 2013, Geneva, Switzerland</i></p> <p>DRAWN UP BY: <i>Commission d'Etude et de Travail (CET) Work &amp; Study Commission) Roberto Pistolessi, CET 5 sub-Chair, Life Science</i></p> <p>PURPOSE: For information and publication in the library section of FICPI's website</p>	
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A FICPI delegation consisting of Bastiaan Koster (President), Eric Le Forestier (President of CET) and Roberto Pistolessi (Sub-Chair of CET 5, Life Science) visited the WTO on 29 August 2013. At the 2012 meeting the WTO was represented by Antony Taubman, Director of the Intellectual Property Division and Competition Policy government Procurement, and Roger Kampf, Thu-Lang Tran Wasescha and Pierre Arhel, Counselors for the Intellectual Property Division. At the 2013 meeting, the FICPI delegation was met by Hannu Wager, Raymundo M. Valdes, Thu Lang Tran Wasescha, Jayashree Watal, Pierre Arhel, Counselors for the Intellectual Property Division.

#### General state of play at WTO in IP matters

Hannu Wager informed about the Council's decision of June 11, 2013, further extending the transition period under Article 66.1 of the TRIPS. For the time being, this transition period has been extended twice for all LDC<sup>1</sup> members in response to a specific request by LDCs:

- in its decision of November 29, 2005, the TRIPS Council extended the period until July 1, 2013;
- on June 11, 2013 this period was further extended until July 1, 2021 (or when a particular country ceases to be in the LDC category if that happens before that date); despite such an extension, LDCs must however preserve and continue the progress towards implementation of the TRIPS.

Although this new extension is independent from that originally provided for by the Doha declaration, which extended the implementation of patent and test data protection by LDCs to January 1, 2016, the Doha deadline is now also implicitly extended to July 1, 2021. We have been however informed that LDCs are already negotiating a further extension of the Doha declaration deadline beyond July 1, 2021.

Pierre Arhel handed a copy of the June 11, 2013 decision to the delegation, available on line at: [http://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/7\\_1\\_ipc64\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf)

#### Patents & health: Outcomes of the July 2013, WHO, WIPO, WTO Symposium

A joint Symposium having title *Medical Innovation - Changing Business Models* was hosted by the three organizations on July 5, 2013. IP was addressed only marginally by the speakers. The Symposium was also attended by Alfred Köpf on behalf of FICPI. The various presentations, including videos, are available on line at:

[http://www.wipo.int/meetings/en/2013/who\\_wipo\\_ip\\_med\\_ge\\_13/program.html](http://www.wipo.int/meetings/en/2013/who_wipo_ip_med_ge_13/program.html)

#### Custom enforcement and goods in transit

WTO's understanding of the dispute settlement proceedings initiated by Brazil and India against the EU custom measures (i.e. the detention of in-transit generic medicines by customs authorities at different EU ports on the basis of Council Regulation (EC) No 1383/2003) is that the two countries would now appear to be satisfied with the (alleged) agreement reached with the EU. However, WTO has not

<sup>1</sup>Least-developed country



received any official notification in this sense from the parties and it does not exclude that similar situations may happen again in the future. A possible inconsistency between the draft legislation on Community Trademark and the EU policy on goods in transit was further mentioned.

### Paragraph 6 system update

About one third of WTO member states have formally accepted the proposed amendment to the TRIPS which allowing generic medicines to be made under “compulsory licences” exclusively for export to countries that cannot produce the medicines themselves.

Once two thirds of members have formally accepted it, the proposed amendment will take effect in those members and will replace the 2003 waiver<sup>2</sup> for them. For each of the remaining members, the waiver will continue to apply until that member accepts the amendment and it takes effect.

Although reaching the 2/3 thresholds is a challenging goal, WTO is confident that it will happen soon. Disappointment was however expressed by WTO about the fact that only one compulsory licence has been granted to date (the licence was used by a Canadian company, i.e. Apotex, to ship medicines to Rwanda). In particular, WTO complains that possible users of the system are alleging that the system itself is complicated; however, none has been able to provide a practical example showing that the system is indeed complicated.

### Tobacco plain packaging

Plain packaging: four complaints have been filed against Australia by Ukraine, Honduras, Dominican Republic and Cuba. There are also legal actions between tobacco companies and states. WTO is aware of the concern raised by several parties that plain packaging criteria may be extended to other products (alcohol, food, etc.).

### Technical co-operation – working with developing countries

WTO would be willing to receive assistance from FICPI in order to educate developing countries to better understand IP and related implications and also to provide them with legal advice. Eric Le Forestier explained that offering free legal advice to developing countries might be a difficult task since this is the normal activity of FICPI members.

Jayashree Watal expressed the desire to have FICPI speakers in its events and workshops (WTO would not however be available to pay the cost); first possibility being a workshop in Mauritius from November 5 to 7. Eric Le Forestier expressed FICPI’s general availability in this sense, to be evaluated on a case-by-case basis, and indicated that FICPI would normally need at least 2-month advance notice. Jayashree Watal will provide more information about the Mauritius workshop.

### General

Jayashree Watal asked for FICPI’s view on the Myriad decision. Roberto Pistolessi explained that the Myriad decision is discussed in an article, which will be published, soon in FICPI’s newsletter. The decision is not so terrible as it may appear, since it only applies to isolated DNA as such and not to cDNA (which is used by the industry to produce proteins by means of DNA recombinant technology). Furthermore, the decision does not deal with the patentability of the possible uses of isolated DNA. Nevertheless, the Myriad decision is a step back for the US system, in particular if compared to the EU where, according to the Biotech Directive, an element isolated from the human body, including the sequence or partial sequence of a gene, may constitute a patentable invention, provided that its function is expressly disclosed in the patent application. Jayashree Watal requested to receive FICPI’s newsletters in the future.

*[End of document: prepared by Roberto Pistolessi]*

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<sup>2</sup>On August 30, 2003, member states decided to waive countries’ obligations provided by article 31(f) of the TRIPS (stating that production under compulsory licensing must be predominantly for the domestic market) until the article is amended.