

## **EU still pushing data exclusivity through FTA, India stands firm**

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European Union is still pushing India to accept TRIPS-plus data exclusivity provisions through the proposed Free Trade Agreement though India is still firmly against it, if the latest draft chapter on intellectual property rights is any indication.

According to the draft available, India still firmly held on to its known positions on several key IP provisions notwithstanding the strong push, creating wide differences between the two sides, even as authorities claimed that the deal would be closed by March next.

“The Parties recognise the importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the World Trade Organization. In interpreting and implementing the rights and obligations under this Agreement, the Parties shall ensure consistency with this Declaration. The Parties shall contribute to the implementation and respect the Decision of the WTO General Council of 30 August 2003 on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005. Nothing in this Agreement shall be construed as to impair the capacity of the Parties to promote access to medicines and protect public health,” said the consolidated draft prepared after the latest round of talks.

“The Parties shall guarantee the confidentiality, non disclosure and non reliance of data submitted for the purpose of obtaining an authorisation to put a pharmaceutical product on the market. For that purpose, the Parties shall ensure in their respective legislation that any information submitted to obtain an authorisation to put a pharmaceutical product on the market will remain undisclosed to third parties and benefit from a period of at least [...] years of protection against unfair commercial use starting from the date of grant of marketing approval in either of the Parties,” EU has stated in the draft.

“Each Party in its laws and regulations shall provide for protection of undisclosed information in accordance with and subject to the flexibilities in the TRIPS agreement to be further discussed.” India has clarified in the draft about protection of data submitted to obtain a marketing authorization.

Another worry figured in the draft for India is the stand of EU on radical enforcement mechanisms including sterner border measures for in-transit goods. This is incidentally against the assurance by the EU on transit of goods, after India repeatedly took up the

matter of seizure of drugs en route to Africa by the EU authorities. After world wide protests and strong resentment including raising up of the matter at the dispute settlement forum of the World Trade Organisation, EU had assured that it would change laws to allow smooth transit of goods.

According to observers, the WTO, WIPO and World Health Assembly have all opposed data exclusivity provisions. However, both the US and EU being homes to multinational pharma companies have been pushing for the same and it could lead into serious impact on the affordability and access to medicines. Data exclusivity would mean artificial monopoly with the extension of patent and it cannot be challenged as in the case of patents, they point out.