Committee on International Trade

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Subject: Commercial aspects of intellectual property rights for medical products in the context of COVID-19

Dear Commissioner,

The on-going COVID-19 pandemic has presented a wide variety of challenges for international trade, many of which you addressed during your appearance in the INTA Committee last month. On this occasion, I would like to follow up on the discussion we had on the issue commercial aspects of intellectual property rights, in particular how they pertain to medical products in the context of the current crisis.

A well-functioning ecosystem for the protection and enforcement of intellectual property rights in FTAs and at WTO level is crucial for the EU as a leading global producer and exporter of pharmaceuticals, and in particular for innovation, the research and development of new vaccines, medicines and treatments. It is therefore essential to encourage at this stage all means of cooperation to incentivise innovation and investment that can lead to a vaccine, cure or treatment.

With the whole world fighting this pandemic, the general availability of medication able to fight the disease (incl. existing drugs, experimental anti-viral medication, and eventually a future vaccine) is a question of global importance. There is currently no evidence of problems related to the access to new, patented vaccines or medicines as vital preventive measures in the current crisis. The rights of developing countries in particular to get access to any breakthrough drugs, however, need to be guaranteed, while of course ensuring that sufficient incentives remain for such drugs' development.

Depending on the context in which a vaccine is eventually developed, many countries may have no other recourse than compulsory licensing, should the negotiating of voluntary licenses with patent owners not be successful. The EU's recent trade agreements include clear rules on commercial aspects of intellectual property rights, which generally acknowledge the issuing of compulsory licences in line with the TRIPS agreement and make due reference to public health concerns as legitimate grounds for exceptional actions. At the same time, however, provisions such as those for data exclusivity, enhanced patent protection and the protection of trade secrets, could possibly make it more difficult for many countries to invoke such clauses to their fullest

effect. I would be grateful if you could provide us with an assessment of what role the EU free trade agreements and TRIPS will play in such a situation, including whether the Commission is considering any guidelines on the ways in which voluntary licensing could be encouraged over immediate compulsory licensing.

The same questions also affect the EU's and Member States' ability to import a future cure, a vaccine or other needed medicines produced abroad, should efforts for finding a voluntary licensing agreement fail. While stepping up production capacities in Europe is key, all options to ensuring the adequate availability of needed pharmaceuticals should be on the table. The EU and many Member Staves have partially limited their ability to make use of compulsory licensing by opting-out of the system established under the 30 August 2003 Decision of the WTO. Could you elaborate on the current tools available to the EU in this context?

Lastly, there remains the question of counterfeit trade in medical goods and medicines in particular. This has become a concern in the context of the current pandemic, given that many EU Member States have already been affected by the delivery of sub-standard goods or outright fraud. Do the Commission and Member States have plans to strengthen their anti-counterfeiting activities at this critical juncture in order to avoid fraudsters taking advantage of desperate buyers when effective treatments are found?

I am looking forward to receiving your views on these matters.

Yours sincerely,

Bernd Lange

Cc: Adrián Vázquez Lázara, Chair of JURI Committee

Pascal Canfin, Chair of ENVI Committee

Juan Fernando López Aguilar, Chair of LIBE Committee