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**Guidelines of the European Commission
concerning the enforcement by
EU customs authorities of
intellectual property rights with regard
to goods, in particular medicines,
in transit through the EU**

1. Introduction

On 11 and 12 May 2010 India (WT/DS408/1) and Brazil (WT/DS409/1) respectively requested consultations with the EU at the World Trade Organization (WTO) regarding certain detentions of medicines in mere transit through the EU. The medicines in question were generic medicines in the countries of provenance and destination and covered by a patent right in the EU. The EU held constructive consultations with India and Brazil in Geneva on 7-8 July 2010 and on 13-14 September 2010.

The concerns raised by India and Brazil during the WTO consultations, as well as the specific incidents of detentions which triggered the WTO disputes against the EU, have shown that the relevant EU legislation for intellectual property enforcement by customs authorities could benefit from further clarification to increase legal certainty.

Preventing IPR-infringing medicines from entering the EU market is a priority. However, customs enforcement of IPR should not result in restricting legitimate international trade in medicines in the course of genuine transit through the EU.

These Guidelines aim to address the specific concerns raised by India and Brazil with regard to medicines in genuine transit through the EU which are covered by a patent right in the EU. In order to ensure the smooth flow of these medicines, they provide elements of clarification of the rules governing the enforcement of intellectual property rights at EU borders set out in Council Regulation 1383/2003¹ and its implementing Regulation 1891/2004².

On 1 December 2011 the Court of Justice issued the judgment related to the joined cases C-446/09 (Philips) and C-495/09 (Nokia). In essence, the judgment addresses the question of whether goods coming from a non-member State, which are imitations of goods protected in the European Union by a trade mark right or copies of goods protected in the European Union by copyright, a related right or a design, may be classified as 'counterfeit goods' or 'pirated goods' within the meaning of Regulation No 1383/2003 and, before the entry into force of that Regulation, within the meaning of Regulation No 3295/94 merely on the basis of the fact that they are brought into the customs territory of the European Union, without being released for free circulation there. Nevertheless, the

¹ Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights OJ L 196, 2.8.2003, p. 7-14.

² Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights OJ L 328, 30.10.2004, p. 16-49.

findings of the Court go beyond this scope and are applicable to other intellectual property rights, such as patents.

These Guidelines therefore aim, in addition, to clarify the scope for the customs control of any goods in transit through the territory of the EU in the light of the findings in the Nokia-Philips judgment.

2. Principles

Council Regulation No 1383/2003 and its implementing Regulation No 1891/2004 set out the conditions and procedures for action by the customs authorities in the EU when goods are suspected of infringing intellectual property rights, as well as the measures to be taken when the relevant goods are found to infringe intellectual property rights. EU customs authorities have the right to control all goods in any of the situations referred to in Article 1(1) of the Regulation.

At international level, the EU and its Member States, as regards matters within their competence, are required to act in accordance with their rights and obligations under the WTO Agreements, in particular those pursuant to Article V of the General Agreement on Tariffs and Trade (GATT) and Article 41 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Goods in transit through the territory of the EU in the sense of Article V.1 of the GATT 1994 may find themselves in several of the situations referred to in Article 1(1) of Council Regulation No 1383/2003. For the purposes of these Guidelines, goods shall only be deemed to be in transit across the customs territory of the EU when the passage across EU territory, with or without warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the EU. Such transit constitutes a situation in which customs authorities may act, in accordance with Article 1 of the Regulation.

Council Regulation No 1383/2003 and its implementing Regulation No 1891/2004 do not contain any substantive rules (or any interpretation of substantive rules) defining the conditions under which goods in transit infringe intellectual property rights, other than by reference to the relevant substantive intellectual property laws. None of the recitals or the provisions of Council Regulation No 1383/2003 set out a new criterion for the purposes of ascertaining the existence of an infringement of the law applicable in the Member State of transit or of determining whether there is an act liable to be prohibited because it infringes that law. It follows that only infringements of intellectual property rights as conferred by European Union law and the national law of the Member States are covered by those Regulations. The final determination of whether goods in transit constitute "goods infringing an intellectual property right" for the purpose of Council Regulation 1383/2003 thus belongs to the authorities competent to decide on the case in accordance with the relevant

substantive intellectual property laws referred to in Article 2 of Regulation 1383/2003.

When applying Council Regulation No 1383/2003, the Customs authorities must take into account that goods placed under a suspensive customs procedure cannot, merely by the fact of being so placed, infringe intellectual property rights applicable in the European Union, as the European Court of Justice has repeatedly stated. This is also applicable to goods placed in other customs situations such as temporary storage, entry into free zones or free warehouses, or those related to their transshipment.

The mere fact that non-Community goods remain non-Community goods throughout the applicable customs procedure does not in itself preclude measures to protect intellectual property rights.

Those rights may be infringed when, during their presence within the customs territory of the European Union without being released to free circulation (for instance, placed under a suspensive procedure), or even before their arrival in that territory, goods coming from non-Member States are the subject of a commercial act directed at the European Union market, such as a sale, offer for sale or advertising, or where it is apparent from documents (e.g. instruction manuals) or correspondence concerning the goods that their diversion to the European Union market is envisaged. In addition to the existence of a commercial act already targeted at the European Union market, other circumstances can also lead to suspicion of infringement of intellectual property rights and consequently to temporary detention by the customs authorities of the Member States such as, for instance, the existence of indications showing a concrete risk of fraudulent diversion to the European Union market. Therefore, the customs authority to which an application for action is made must, as soon as there are indications available to it giving grounds for suspecting that such an infringement exists, suspend the release of or detain those goods. Those indications, as illustrated in the above-mentioned Court's judgment, may include, inter alia, the fact that the destination of the goods is not declared whereas the suspensive procedure requested requires such a declaration; the lack of precise or reliable information as to the identity or address of the manufacturer or consignor of the goods whereas the customs legislation requires to provide such information, a lack of cooperation with the customs authorities or the discovery of documents or correspondence concerning the goods in question suggesting that there is liable to be a diversion of those goods to the European Union market. Such a suspicion must, in all cases, be based on the facts of the case.

In particular with regard to medicines in transit, under the 'Declaration on the TRIPS Agreement and Public Health' adopted by the Doha WTO Ministerial Conference on 14 November 2001, the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, especially, to promote access

to medicines for all. The EU and its Member States are fully committed to all the efforts made to facilitate access to medicines for countries in need in accordance with the Declaration.

Consequently, and in the light of certain cases of customs detentions on the grounds of patent infringement of shipments of medicines originating in a third country, it is understood that the mere fact that medicines are in transit through the EU territory, and there is a patent right applicable to such medicines in the EU territory, does not in itself constitute enough grounds for customs authorities in any Member State to suspect that the medicines at stake infringe patent rights.³ It is further understood that a situation in which medicines are in transit through EU territory, and there is adequate evidence that satisfies the customs authorities that there is a substantial likelihood of diversion of such medicines onto the EU market, may constitute enough grounds for customs authorities to suspect that the medicines at stake infringe patent rights.

³ For purposes of these Guidelines, the term "patent" includes a supplemental protection certificate.