Introduction

EFPIA fully supports the European Commission’s “Europe 2020” strategy for smart and sustainable growth, and we consider the protection of Intellectual Property Rights (IPR) as an essential pillar for drawing the full benefits from research, innovation, and creative activities. The sustainable growth of a knowledge economy can only be guaranteed if such rights are properly protected and enforced across the whole of Europe's economic area and elsewhere. In respect of this, IPR infringements and the global trade of infringing goods are of great concern to us and our members are committed to working with customs authorities, within their area of competence, to protect patients from the potential dangers of such goods. Hence, EFPIA fully supports the current customs plan developed to tackle four main challenges: dangerous counterfeit goods, organized crime, globalization of counterfeiting, and the sale of counterfeits over the Internet.

QUESTIONS SUBMITTED TO THE PUBLIC AND TO INTERESTED PARTIES

1. Scope of the Regulation: situations in which customs authorities should be competent to take action.

Question

Concerning the competence of customs authorities for IPR enforcement, what should be the situations of infringing goods in which customs authorities should take action?

EFPIA Reply

EFPIA supports (EC) Regulation N° 1383/2003 and believes that Customs should retain their current powers to act against goods suspected of infringing an IPR in all situations in which infringing goods are under customs supervision (including in particular exportation, transit, transhipment, temporary deposit, customs warehousing procedures, placement in free zones or free warehouses), and not just in situations when infringing goods are declared for import. Customs should have the competence to make inspections, detain and suspend release of goods if they are suspected of infringing IPR, i.e., counterfeiting, piracy or patent infringement.
EFPIA members have made two specific Statements on 13 March 2009 and 14 September 2009, the latter jointly with DG TAXUD, around how they would voluntarily utilise the processes available under the Regulation for the specific case of goods in transit that are detained by customs as patent infringing goods where the goods are in transit from one non-EU country to another non-EU country. In particular in March 2009 the EFPIA membership indicated that they would not take action under the Regulation in cases where goods were detained by customs as a suspected patent infringement and the goods were in transit from a country of origin which was outside of the EU to a country of destination which was outside the EU and there was no IPR covering the goods in the country of origin and no IPR covering the goods in the country of destination. The EFPIA membership stands behind these Statements which are annexed to this reply.

EFPIA fully agree that the application of the Regulation by customs should never “unduly hinder the trade in legitimate goods through the territory of the European Union”. It is neither the policy nor practice of its members to encourage Member States to use the powers of detention available to them to prevent the flow of legitimate goods from manufacturer to customer outside the EU. Nor is it the intention of EFPIA members to restrict access to medicines in developing countries or to undermine the Doha Declaration. However the European Union (EU) cannot and should not facilitate or ignore the transit of illegitimate goods. Customs play a key role in preventing the EU from becoming a free platform for transit of illegitimate goods.

2. Scope of the Regulation: range of IPR the Regulation should cover and possible derogations.

Question

What should be the range of IPR covered by the Regulation?

EFPIA Reply

EFPIA believe that the scope of the Regulation should cover the infringement of any IPR, as is the case with the current powers. There is no legitimate reason or interest for the exclusion of certain IPR. On the contrary, and practically, exclusion would only serve to add complexity in the situation where detained goods are suspected of infringing several types of IPR. We consider trade marks to be of particular importance.

A trade mark is by definition and indicator and guarantor of origin and quality of products emanating from a certain legitimate source. The improper use of a trade mark on a product from another – illegitimate - source conveys a false statement about the origin and quality of that product and will inevitably mislead consumers wherever this product reaches the market. In order to remain faithful to the commitment of protecting public health and safety and to reconcile the reality and challenges of a globalized economy with the territorial nature of the trade mark registration, European Customs authorities need to retain the ability to stop potentially counterfeit goods, as defined in Art. 2, § 1 (a) of Council Regulation (EC) 1383/2003. If a consignment in transit through Europe appears to be counterfeit, customs authorities must have the legal means to temporarily detain these products to determine their legal status. In order to determine the authenticity of the suspected medicines in a timely manner, the Regulation should

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1 Infringement action by the right holder can only be taken if the passage through customs areas is an infringement under Member State law. For trade marks, the law on infringement is largely harmonised through EU legislation. For patents, the law is not harmonised and Member States laws vary. Netherlands law deems passage on in transit goods potentially infringing.
develop a procedure under which customs authorities work closely with the manufacturer of the authentic medicine to permit them to inspect and examine the suspected products, while allowing sufficient time for the chemical analysis of a sample of the suspected medicine if the manufacturer determines that such analysis is required. Customs authorities and right holders should cooperate and offer mutual administrative assistance to allow rapid decision making, and, whenever possible, accelerate the release of goods found, contrary to the initial assumption, not to be counterfeit.

3. Scope of the regulation: possible derogations for which customs authorities will not be competent to take action in the light of the regulation.

Questions
- Should the derogation concerning small quantities of goods of a non-commercial nature contained in travellers’ personal luggage be kept or should it be withdrawn?
- Should the derogation concerning overruns be kept or should it be withdrawn?
- Should the derogation concerning parallel trade be kept or should it be withdrawn?

EFPIA Reply
- a. derogation concerning personal traveller’s allowance:
  In a pharmaceutical context: derogation concerning small quantities of counterfeit goods should be withdrawn in its entirety, as this is in the interest of the individual’s personal health and also a public health obligation (exceptions may apply for medicines that have been legitimately purchased in the country of residence or port of departure where a health risk from counterfeiting for the traveller himself can be ruled out); in a non-pharmaceutical context, this should apply to all products that present a potential health or safety threat. Seizure of articles may also be useful to obtain evidence in the context of further investigation.

- b. derogation concerning so-called “overruns”:
  The derogation concerning overruns should also be withdrawn. Overruns fulfill the definition of “counterfeit goods” if these goods bear - without authorization - the trade mark which is identical to the trade mark validly registered. Additionally it would be practically impossible to distinguish between goods in the legitimate supply chain and counterfeit goods; the derogation for overruns is in practice an invitation to circumvent the Regulation.

- c. derogation concerning parallel trade:
  The derogation concerning parallel trade should be withdrawn partially; only legitimate parallel imports between EU Member States should be derogated; parallel imports into the EU originating from non-EU States remain illegal by any means². Those goods put on the market in countries where the IPR are not exhausted are infringing goods.

4. Simplified procedure enabling customs authorities to have infringing goods abandoned for destruction under customs control, without there being any need to determine whether an intellectual property right has been infringed.

Questions

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² Cases C-355/96 (Silhouette), C-173/98 (Sebago) and C-414/99 - C-416/99 (Davidoff)
Should the implementation of the simplified procedure as described in Article 11 of Council Regulation (EC) N° 1383/2003 be kept as optional for Members States? Or should it be compulsory and directly applicable by all Member States? Or should it be deleted?

**EFPIA Reply**

The simplified procedure pursuant to Article 11 of the Regulation should be compulsory and directly applicable in all Member States. It has been a successful tool in the practical management and handling of “clear cases” of infringing and therefore illegitimate goods found by Customs. The procedure would be more effective as it would not enable infringers to choose the country of import or transit so as to escape the risk of the simplified procedure. It must also be borne in mind that shipments of clearly illegal goods are not likely to be reclaimed by the infringers and, lacking a counterpart, the obligation of going through a full legal case might further deter the legitimate fight against IPR infringers including counterfeiters.

IPR holders are, in practice, frequently faced with non responsive consignees, incomplete, or even false, information/contact details for consignees and shipping/freight forwarding companies who do not wish to disclose the identity of their customers (the true goods owners) making consent impossible. In such circumstances without the simplified procedure even the most clear-cut of IPR infringement cases must go to court. Not only is this a waste of resources for the IPR holder, in the event that there is no appearance of the goods owner, there is no way for the IPR holder to recover any of the legal cost spent preparing and bringing the legal action or for storing the goods.

Making the simplified procedure compulsory would also be in line with the general character of Regulation (EC) N°1383/2003 which is, for most parts, uniformly and directly applicable in all Member States. Continuing the optional implementation of the simplified procedure would lead to different levels of legal protection of both IPR holders (and in a pharmaceutical context also of consumers) which is contrary to the “acquis communautaire”. The review of the simplified procedure should therefore take into account the above mentioned realities and practicalities of enforcement activities against IPR infringers.

5. Small consignments and sales via the internet

**Questions**

Should a new procedure be envisaged to deal with small consignments? What should be the concept of small consignment?

**EFPIA Reply**

A new (additional) procedure for a simplified procedure dealing with small consignments seized in particular at post or courier level is very desirable, most notably to effectively deal with the increasing role of internet sales of counterfeit, pirated or patent infringing goods. Given the physical characteristics of pharmaceuticals it is possible to send quite large volumes in small packages. Practically the heavy paperwork/bureaucracy involved may discourage customs authorities from detaining / seizing small shipments especially given resource constraint3. A simplified procedure would provide an improved level of efficiency and improve consistency in the Member States. Furthermore, experience shows that the addressees of shipments from

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3 The paperwork related to a seizure can take up to 45 minutes and a busy customs unit such as at, for example, the major European airports can seize hundreds of infringing small consignments per day.
internet pharmacies are aware that such supply is illegal in most cases and that therefore they are likely to agree to destruction.

From a pharmaceutical point of view, such new concept should feature that:
(a) small consignments could be defined as anything capable of being sent by regular mail or regular express carrier service.
(b) there should be presumed consent to destruction as currently provided for under the Art 11 simplified procedure.
(c) The internal customs procedure should be significantly streamlined, for example using a pre-printed tick box notification letter to the consignee, such that it takes no more than 10 minutes.
(d) if the goods owner wishes to oppose destruction he has to make a deposit of, at least, those costs which occur if the respective product is stored for a period of 12 months by the customs authorities;
(e) failure to make this deposit within a given term of 20 days will be deemed as consent for immediate destruction of the respective consignment;
(f) manufacturers should have the right to be informed about the seizure of such consignment and, on request, inspect and analyse the products suspected of being counterfeit (for health reasons, including potential product recalls) but manufacturers are encouraged to waive such right of information and inspection in order to keep administrative burden low.

6. Cost of storage and destruction.

Questions
- What should be the scope of the provisions regarding costs in the IPR customs enforcement regulation? Should it refer to any cost or should it be limited to the costs incurred by customs authorities, leaving other costs to be borne in accordance with the common provisions regarding civil or criminal IPR enforcement applicable in the territory of the Member state where action has been taken?
- What should be the responsibility, regarding costs of storage and destruction, of each of the economic operators involved – voluntarily or involuntarily – in the international trade or IPR infringing goods? In addition to the right holders and the holder of the goods, there are several intermediaries involved, such as shippers, carriers, consignors, customs declarants and holders of customs warehouses.
- Should these provisions be set out without prejudice of the right of the person liable for costs to seek redress through the judicial system from any other party involved according to common provisions in force?

EFPIA Reply
a. The scope of the provisions regarding costs in the IPR customs enforcement should be limited to costs incurred by customs authorities inclusive of storage and destruction costs. All other costs should be borne in accordance with the common provisions regarding civil or criminal IPR enforcement applicable in the territory of the Member State where the action has been taken. However, in theory the infringer should be liable for all costs and we would prefer the Regulation to expressly place primary responsibility for all costs connected to the interception, storage, transport and destruction of infringing goods on the infringer.

b. On the question of the costs of storage and destruction as regards third party intermediaries (such as shippers, carriers, consignors,…), we believe that the intermediaries should also be liable for the costs incurred. Shipping companies, for example, not only participate...
economically in such trade but they are the only ones in a contractual relationship with the sender and may seek compensation within this relationship.

c. The provisions need to be set out without prejudice of the right of the person liable for costs to seek redress through the judicial system from any other party involved (also due to mandatory national law regimes in most Member States).

7. Miscellaneous.

Question

The Commission would be grateful to receive any other comments not yet covered by the previous questions in this paper

EFPIA Reply

Public health and safety: The pharmaceutical industry is greatly concerned that a “laisser-faire” approach should not be promoted in the review of the Customs Regulation, while all indicators, including the Commission’s own seizure statistics, show a great increase in the trade in infringing products, in particular counterfeits. Though IPR are not necessarily the best tools to prevent unsafe medicines from entering into the realms of commerce, they have shown their ability to address the issue. A greater focus on public health and safety considerations would be welcomed, provided that customs and health authorities are empowered to cooperate and jointly tackle this problem.

Information by customs: Our member companies indicate that they would like to be informed by the customs of the number of products seized for each IPR concerned as well as the batch number, so as to check as quickly as possible where the original batch(es) has (have) been distributed, which countries are potentially concerned, all this for safety reasons.

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