

We comment on the European Commission's Preliminary Report in the Pharmaceutical Sector Inquiry that was published on 28<sup>th</sup> November 2008 (hereinafter referred to as "**the Preliminary Report**"). In the Preliminary Report, the Commission names various methods and strategies that are employed by originator companies with the purpose of delaying market entry of generic competition. In this respect, the Preliminary Report names various aspects related to the regulatory framework of patents and market authorisations. We would like to draw the European Commission's attention to another regulatory measure that needs to be mentioned in this connection: "Council Regulation (EC) No. 1383/2003 of 22<sup>nd</sup> July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights" (hereinafter referred to as "**Regulation 1383/2003**").

Regulation 1383/2003 has proven to be a constant threat to imports of pharmaceutical products that are produced outside the European Community. This applies even in cases in which the products do not infringe any third-party patents. It will be demonstrated that Regulation 1383/2003 enables originator companies to unjustifiedly delay and impede imports of generic pharmaceuticals into the European Community. This causes damages to the producers and importers of the pharmaceuticals and restricts competition in the Common Market.

We will structure our comments as follows. We will give an overview of Regulation 1383/2003 (I.). We will then identify the aspects of Regulation 1383/2003 that can be misused by originator companies in order to achieve anticompetitive effects (II.).

## **I. Overview of Regulation 1383/2003**

Regulation 1383/2003 enables anyone who holds an intellectual property right ("**IPR**") to prevent goods infringing this IPR from being traded from outside the territory of the European Community into this territory. By applying to the competent customs authority identifying the goods that allegedly infringe the applicant's IPR, the applicant can ask the customs authorities to suspend the release of the relevant goods or detain them (Art. 9 sec. 1). If the application is granted and the authorities are able to identify the goods, then they will detain them or suspend their release and notify the applicant accordingly. The applicant

then has 10 working days to initiate proceedings against the person infringing its IPR (Art. 13 sec. 1, subsec. 1 and 2). This period of 10 working days can, in accordance with the last paragraph of Art. 13 sec. 1, be extended for up to another 10 working days. Whether an extension is granted or not is purely within the authority's discretion. Experience shows that in practice, in most of the cases extensions are granted by the authorities.

The authorities will release the goods if the applicant fails to initiate proceedings within the above mentioned period of 10 to 20 working days. Otherwise, the goods will remain in the authority's custody until the proceedings have been completed. The importer may only ask the authority to release the goods before that time on the basis of Art. 14 of Regulation 1383/2003. However, such an early release will only be granted if the importer provides a security that, according to Art. 14 sec. 2, "*must be sufficient to protect the interest of the right-holder*".

## **II. Deficiencies of Regulation 1383/2003 in cases of alleged patent infringements**

Regulation 1383/2003 applies to infringements of various kinds of IPRs. This includes trademarks, trademark symbols, copyrights and related rights, design rights, national plant varieties, designation of origins or geographic indications, geographical designations, patents and supplementary protection certificates (Art. 2). It provides for the same rules for all of these IPRs. No matter which one of the IPRs is the subject-matter of the application, the same authorities are competent to decide on the application, the same requirements must be met by the holder's application and (with only few exceptions) the same procedural rules apply. Whilst these rules may be suitable for an efficient protection of e.g. trademark infringements, they have proven to be too far-reaching in cases of alleged patent infringements. This is apparent in particular from the following considerations.

**1. No obligation of customs authorities to assess whether an infringement exists/is plausible**

Regulation 1383/2003 sets out the conditions for action by the customs authorities when goods are suspected of infringing an intellectual property right (Art. 1 sec. 1). However, the Regulation does not contain any explicit obligation on the authorities to assess whether an infringement exists or at least is plausible. Therefore, it is not entirely clear what the preconditions of the customs authorities' actions are, in particular whether the authorities may reject an application on the grounds that an infringement has not been demonstrated by the applicant. Art. 5 sec. 5 supports the view, that the customs authorities do not have to make an own assessment since the information to be provided by the applicant needs to contain only the information that is needed to identify the relevant goods. It is not necessary for the applicants to set out the details of the infringement. Therefore, there is a lack of objective control whether the applicant's claim is justified or not.

**2. Customs authorities will usually not be able to assess whether a patent infringement exists**

Even if one was of the opinion that Regulation 1383/2003 obliges the customs authorities to assess the justification of the claim and to reject unjustified applications, this would not improve the application of Regulation 1383/2003 in cases concerning patents. Patents relate to technical inventions that usually are only understandable to specialists in the respective field. Customs authorities will not have the staff and the resources that are necessary in order to make an informed assessment. Furthermore, as regards chemical substances like pharmaceuticals, the patents often relate to chemical characteristics of the substance in question. Therefore, in order to assess whether an infringement exists, a chemical analysis of the products may be necessary. The customs authorities do not have the equipment, the know-how, the personnel and the resources to conduct such an analysis.

It can be concluded that not even a plausibility-check can be performed by the competent authorities in cases of alleged infringements of patents relating to pharmaceutical products. Unlike an alleged infringement of a trademark, such an assessment cannot be made easily by non-specialist staff.

**3. Authorities often can not assess infringements and only *identify* products reported to be infringing**

Since customs authorities lack the know-how, the facilities and the resources to assess whether the application is well-founded, the customs authorities will usually grant protection to the applicant and suspend the release of the goods in question or detain them. Therefore, the realistic risk exists that the practical application of Regulation 1383/2003 leads to an automatism.

**4. There is no legal remedy, not even in clear cases**

There is no way for the importer concerned to prevent the authorities' actions or mitigate their effects, not even if it could prove that the goods do not infringe the patent. Regulation 1383/2003 does not provide for any possibility to oppose the application before or after the authority's actions. Therefore, once the goods have been detained or their release has been suspended, they are removed from the importer's disposal at least for the 10-day time period of Art. 13 sec. 1 subsec. 1 which can be – and in particular in patent cases often is – extended by further 10 working days (Art. 13 sec. 1 subsec. 2). It is not possible for the importer concerned to shorten these time periods. As a result, the importer has to expect a delay of at least 4 weeks, plus the time he needs to provide the requested security.

After these 10 or 20 working days, the importer will get back the goods without security only in case the applicant has not filed proceedings against the importer. However, in the case of pharmaceutical patents, the Commission's investigation has proven that it is very likely that originator companies will employ patent litigation even in cases in which chances are low. In case such proceedings are initiated, Art. 14 of Regulation 1383/2003

provides for the possibility to obtain the release of the goods on provision of a security. Since this security must be “*sufficient to protect the interest of the right-holder*” and therefore will have to take into account the potential loss of market share that the originator has to expect in the case of market entry of a significantly cheaper generic company, it requires large resources on the side of the generic company in order to be able to enter a market with significant quantities. Thus, even if the generic company decides to take the risk and make available the financial resources, this will hamper its sales efforts in the relevant market.

#### **5. There is no sufficient risk/cost for the applicant**

Filing the application for action does not entail any significant cost or risk for the holder of an IPR. As regards costs, this is stipulated expressly in Art. 5 sec. 7 subsec. 2 which states that the “*right-holder shall not be charged a fee to cover the administrative costs occasioned by the processing of the application*”. Besides, the applicant does not necessarily have to expect a significant risk even in case of filing a dubious application. Apparently, when the text of the Regulation was drafted, it was realized that the legal instruments of Regulation 1383/2003 are prone to being misused. From Art. 6 sec. 1, it can be seen that the potential to harm the undertaking concerned by the authorities’ action in result to an unjustified application was anticipated.

However, Art. 6 sec. 1 falls short of a clear and unambiguous stipulation providing compensation that balances the risks of the holder of the IPR and the importer. Art. 6 sec. 1 requires the applicant to declare in the application that liability is accepted in the event that the goods in question “*are subsequently found not to infringe intellectual property rights*”. However, it is not certain whether this declaration affords an own legal basis for claims. Instead, Regulation 1383/2003 expressly refers to the provisions of national legislation (Art. 19). The national legislation in many Member States does not provide for an express legal basis for damage claims or other legal remedies for such cases.

In effect, importers are largely without protection against applications on the basis of Regulation 1383/2003. They cannot prevent the delay caused by the authorities' actions, and the importers often will refrain from filing legal action for damages against the applicant.

### **III. Conclusion**

For the reasons set out in the chapters above, Regulation 1383/2003 enables an originator company to delay and impede the market entry of a generic company whose production facilities are located outside the European Community. This can be done easily and without significant risk. On the other hand, the harm to competition in the relevant market and the damages sustained by the importer resulting from the delayed entry into a newly opened pharmaceutical market are significant.

It is therefore suggested to install effective legal means by which it is safeguarded that customs authorities only suspend the release of allegedly infringing goods or detain them in case the infringement has been sufficiently proven by the applicant. If, due to the complexity or technical nature of the patent, no sufficient evidence for an infringement can be given, customs authorities should not be allowed to order suspension of release or the detention of goods. Also, clear and severe legal consequences for the applicant in the case of unjustified applications should be installed. The applicant must be fully liable for any unjustified application. The legal and financial risk of a decision of a public authority that has no or very low material preconditions may not be carried by one party alone.

Furthermore, it is suggested that the European Commission clarifies in its final report on the sector inquiry that false applications on the basis of Regulation 1383/2003 of a dominant company are seen as an abuse in terms of Art. 82 EC.