



NEWSLETTER

/ Border Seizure Procedures / Opinion of the Enlarged Board of Appeal issued on 16.12.2005 on case G 01/04

April 2006

Border Seizure Procedures

Border seizure procedures in the European Union are an effective tool in enforcing intellectual property rights.

Goods which infringe property rights are manufactured primarily in Asia - especially in China (see diagram 1). Between 1998 and 2004, the quantity of counterfeit and pirated goods seized by EU customs authorities increased by around 1000%. It is estimated that EU customs authorities seize counterfeit and pirated goods to the value of 1 to 2 billion Euros every year⁽¹⁾. In order to counter this alarming development, that is to both drastically reduce worldwide trade of counterfeit and pirated goods manufactured without permission as well as combat international networks operating in this field, a series of legal instruments have recently been brought into force by the Council and Commission of the European Union.

The most important instrument as far as customs law is concerned is EU Council Regulation (EC) No. 1383/2003 of July 22, 2003 which came into force on July 1, 2004. This regulation deals with 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⁽²⁾. Commission Regulation (EC) No. 1891/2004 lays down provisions for the implementation of Council Regulation (EC) No. 1383/2003 and has been effective since October 21, 2004⁽³⁾.

Some of the major innovations regulated by Council Regulation (EC) No. 1383/2003 regarding border seizure procedures are:

- checks in categories not formerly included such as plant variety rights, protected designations of origin and protected geographical designations,
 - simplified procedures,
 - Member States are given the right to destroy counterfeit or pirated goods with as little administrative effort as possible.
- Those most benefited by the Council Regulation are holders of industrial property rights.

Border seizure procedures are started either as a result of a granted application for action – which is free of charge for the right-holder or by the customs authorities themselves in the case of goods incurring suspicion. An application for border seizure can be made by the right-holder, by any other person authorised to use the property right, by a representative or by a collecting society and must contain the following in order for the customs authorities to be able to proceed:



Diagram 1

(1) „Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee“, Commission of the European Union, Brussels, 11.10.2005

(2) Official Journal of the EU, L 196 of 2.8.2003

(3) Official Journal of the EU, L 328 of 30.10.2004

- information such as a technical description, scheduled arrival date, country of origin and routes used to distribute the goods, means of transport used, etc. so that the goods in question can be readily recognised by the customs authorities, and proof that the applicant holds the right for the goods in question
- proof that the applicant holds the right for the goods in question.

The application form for action should be handed in to the "Zentralstelle Gewerblicher Rechtsschutz (ZGR)" (= central industrial property office) at the "Oberfinanzdirektion Nürnberg" (= regional finance office in Nuremberg)⁽⁴⁾. The ZGR has been coordinating border impoundment proceedings since 1995 and furthermore provides advisory services to companies in Germany regarding steps to be taken in border impoundment proceedings and also in the enforcement of industrial rights. Applications made to the ZGR can refer to border impoundment proceedings in all EU Member States. The competent customs department subsequently processes the application and notifies the applicant of its decision on the allowability of his application within 30 working days. If the application is accepted, the ZGR forwards its decision to the competent customs authorities of the other EU Member States named in the application.

Diagram 2 depicts the border impoundment procedure chronologically.

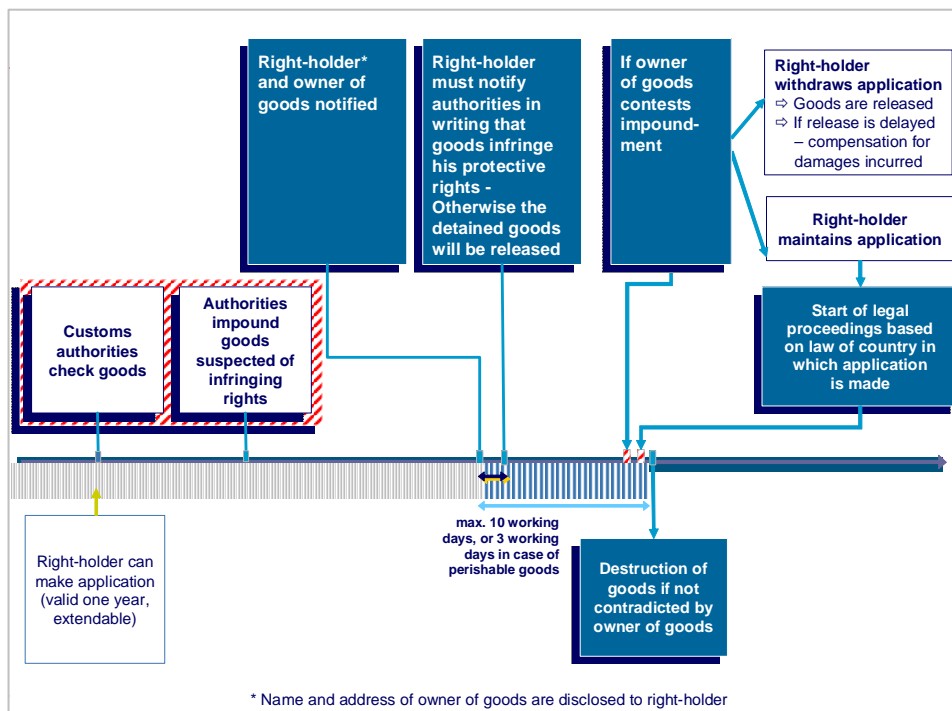


Diagram 2

Goods are examined by the customs authorities following the lodging of an appropriate application (valid for one year, extension possible) or if they are suspected of infringing a property right. In such cases the goods are taken out of circulation by the customs authorities and both the holder of the right as well as the owner of the goods are notified that the goods have been impounded. The name and address of the owner of the goods are disclosed to the holder of the property right. Within 10 days, or 3 days in the case of perishable goods, the right-holder must inform the customs authorities in writing whether in his opinion the goods infringe his property right. Otherwise the detained goods will be released. If the owner of the goods does not contest the impoundment, the goods will be destroyed at the expense of the property right-holder. If the owner of the goods contests the impoundment and the right-holder withdraws his application, the goods will be released and the right-holder held liable for damages incurred as a result of the impoundment. If the right-holder upholds his application for detention of the goods, he must initiate legal proceedings within 10 days of receipt of notification of the impoundment in order to determine whether an intellectual property right has been infringed or not under the national law in force in the Member State within the territory of which the goods have been impounded. The result of such proceedings determines the fate of the impounded goods. The owner can

obtain the release of the detained goods on provision of a security. This is however not possible if the right-holder obtains a temporary restraining order prohibiting the release of the goods by the customs authorities.

Council Regulation (EC) No. 1383/2003 covers approximately 95% of all cases of border impoundment. There are however a few exceptions which fall under German national law as in the case of parallel imports, for example, or in the case of semiconductor protection rights and non-registered trademarks.

A particular advantage of border impoundment procedures, and in particular of the new Council Regulation (EC 1383/2003), lies in the fact that only a single application is required in order to apply for action by customs authorities in

the entire territory of the European Union. This facilitates matters for the right-holder. Furthermore, the right-holder does not incur any expenses as a result of his application. An application is therefore suitable as a means of prevention. Of particular importance is the fact that the EU system of border impoundment can be applied to nearly all types of property rights.

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Opinion of the Enlarged Board of Appeal issued on 16.12.2005 on case G 01/04

1. Comment

Almost two years after referral by the President of the EPO, the Enlarged Board of Appeal issued an Opinion on December 16, 2005 on case G01/04 relating to the patentability of "diagnostic methods". The referral of the President of the EPO was made in the light of two differing Technical Board decisions - T385/86 and T964/99. Both decisions relate to Art. 52(4) EPC according to which "diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application", and are therefore excluded from patent protection.

2. Decision

In decision T385/86, the Technical Board interpreted Art. 52(4) EPC narrowly and decided that procedures which only provide interim results are not diagnostic methods in the strict sense of this Article. This decision became common practice at the EPO, as can be seen in several subsequent decisions by Technical Boards. In contrast to this, Technical Board decision T964/99 even considered methods as inadmissible under Art. 52(4) EPC if one procedural step includes, for example, the taking of a sample from a human or animal body while all other steps are purely technical and only provide interim results.

An answer therefore had to be found as to whether, in order to be excluded from patentability, a diagnostic method has to contain all necessary procedural steps in the preparation of a medical diagnosis – as per decision T385/86 - or whether an essential step in a diagnostic method carried out "on the human or animal body" already excludes this method from patentability as ruled in decision T964/99.

The Enlarged Board of Appeal defined as follows the procedural steps carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes:

- (i) the examination stage involving the collection of data,
- (ii) the comparison of this data with standard values,
- (iii) any significant deviation, i.e. a symptom, is identified in comparison, and
- (iv) the deductive medical or veterinary decision-making stage in which the deviation is attributed to a particular clinical picture.

In this context the deductive medical or veterinary decision-making stage (iv above) is an intellectual exercise unless, as a result of developments in the field of diagnostic technology, a device capable of reaching diagnostic conclusions can be used. As an intellectual exercise the deductive decision-making stage cannot be regarded as an invention.

Under the terms of the EPC an invention must be technical. Art. 52(4) EPC therefore determines that the diagnostic method must encompass procedural steps of a technical nature, thereby making the method as a whole a technical one. Non-technical steps necessary to carry out a diagnostic method must however also be included in the (independent) claim in order to comply with the clarity requirements of Art. 84 EPC. The Opinion further specifies that the classification of a procedure as a diagnostic method is not dependent on the participation of a medical or veterinary practitioner with responsibility, nor on the fact that all procedural steps can also - or even exclusively - be carried out by medical or non-medical support staff, the patient himself or an automated system.

As inventions are only patentable if the methods involve steps of a technical nature, the criterion "based on the human or animal body" only needs to be considered in connection with procedural steps of a technical nature. Emphasis is therefore placed on the criterion that the diagnostic method be practiced on the human or animal body.

A particular type or level of intensity of interaction with the human or animal body is however not required. If some or all of the procedural steps of a technical nature are carried out by a device without involving any interaction with the human or animal body, for instance by using a specific software program, these steps cannot be considered to fulfill the criterion "practiced on the human or animal body", because their implementation does not necessitate the presence of either. Similarly, procedural steps carried out in vitro in a laboratory do not fall under the criterion.

Consequently a diagnostic method is only excluded from patentability if all procedural steps of a technical nature relating to this diagnostic method are basically meant to be performed on the human or animal body, implying an interaction with the latter, rather than in vitro. It is thus justified to require that all procedural steps of a technical nature of such a method should satisfy the criterion "practiced on the human or animal body". The presence of a human or animal body is thus necessary to fulfill the requirements of Art. 52(4) EPC.

Prospects

To summarize: the Opinion emphasizes that under Art. 52(4) EPC diagnostic methods are to be interpreted strictly and narrowly.

In order for a method to be excluded from patentability, the procedural steps of a technical nature have to be practiced on a body.

If only a single step or several (but not all) such steps in the course of a diagnostic method is/are practiced on a body, patentability of the method is not excluded per se.

A medical or veterinary practitioner cannot be considered to be hampered by the existence of such a patented method, as it is possible to purchase the device in question in order to be entitled to carry out the method.

In an additional remark the Enlarged Board of Appeal emphasized that its Opinion equally applies to the "Act Revising the Convention on the Grant of European Patents", which will come into force in December 2007, since the corresponding passages of the EPC were only shifted from Art. 52 to Art. 53 in the course of an editorial amendment.



We are pleased to announce that Mr.

RALF PECKMANN
DEUTSCHER UND EUROPÄISCHER PATENTANWALT
GERMAN AND EUROPEAN PATENT ATTORNEY

has become associated with our firm.

His area of expertise lies in the fields of mechanical engineering and general physics.

Please, note that this newsletter provides information about recent developments in national and international IP matters. We have carefully elaborated the contents. However, do not assume any liability for its correctness and completeness. Should you have specific questions on these subjects, please feel free to contact us by email or under the address given below.



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