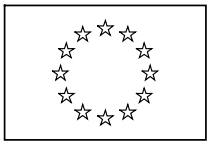

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION

Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted

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Summary

This communication updates the 1982 Commission Communication on the same subject and aims at giving some guidance on the practical application of the jurisprudence of the European Court of Justice to national measures relating to parallel imports, from one Member State to another, of proprietary medicinal products for which marketing authorisations have already been granted in the Member State of destination.

Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty.

When the information necessary for the purposes of protecting public health is already available to the competent authorities of the Member State of destination as a result of the first marketing of a product in this Member State, a parallel imported medicinal product is subject to a licence granted on the basis of a proportionally "simplified" procedure (compared to marketing authorisation procedure) provided:

- **the imported product has been granted a marketing authorisation in the Member State of origin;**

- **the imported product is essentially similar to a product that has already received marketing authorisation in the Member State of destination;**

Parallel importation of a medicinal product is still possible even when the reference authorisation has been withdrawn and the parallel imports licence may not be revoked unless such a measure is justified by reasons relating to the protection of public health.

Regarding industrial and commercial property rights protected by Member State legislation, that legislation may not be used to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right. Moreover, the trade mark proprietor may not use his right in order to prevent repackaging of a product imported in parallel when:

- **the use of the trade-mark right by the owner, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;**

- **the repackaging cannot adversely affect the original condition of the product;**

- **it is stated on the new packaging by whom the product has been repackaged;**

- **the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; and**

- **the proprietor of the trade mark receives prior notice before the repackaged product is put on sale**

1. INTRODUCTION

This communication is mainly addressed to national administrations, economic operators who trade in parallel imports of proprietary medicinal products[1], enterprises and pharmaceuticals operators in general. It updates the 1982 Commission Communication on the same subject[2] and its overall aim is to give some guidance on practical applications of the principle of the free movement of goods to national measures relating to parallel imports, from one Member State to another, of proprietary medicinal products for which marketing authorisations have already been granted in the Member State of destination. Particular reference is made to the rights and obligations of the parties concerned and to the guarantees to which they are entitled according to Community law.

Since the adoption of the 1982 Communication, the European Court of Justice has developed significantly its jurisprudence on the field and has clarified a number of issues regarding the requirements and procedures for licensing parallel imports[3], the use of national patent rights[4] and regarding repackaging, re-labelling and the use of national trade-marks[5]. At the same time, further developments at the level of Community law, have had a considerable technical and economic impact on the trade of proprietary medicinal products while EU enlargement is expected to pose further challenges.

This communication, based mainly on the development of the jurisprudence of the Court, does not address issues dealt with by other Community legislation, especially regarding the marketing for the first time of a medicinal product[6], competition or issues dealt with by the 1998 Commission Communication on the Single Market in Pharmaceuticals[7], unless such issues have been addressed by the Court in its jurisprudence regarding parallel imports. Specific reference is made to more recent judgements that clarify the conditions where repackaging of the medicinal product,

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1 Proprietary medicinal product is any ready-prepared medicinal product placed on the market under a special name and in a special pack; medicinal product is any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product. Directive 2001/83/EC (OJ No L 311, 28/11/2001 p.67-128). The same definitions, in relation to animals, apply for veterinary medicinal products, Directive 2001/82/EC (OJ No L 311, 28/11/2001, p.1-66).

2 OJ C 115 of 6.5.1982, p.5

3 Case 247/81 Commission v Germany (1984) ECR 1111, C-201/94 Smith & Nephew (1996) ECR I-5819, C-94/98 Rhône-Poulenc (1999) ECR I-8789, C-172/00 Ferring (2002) ECR I-6891.

4 Case 434/85 Allen & Hansburys (1988) ECR 1245, C-191/90 Generics (1992) ECR 5335, joined cases C-267 and 268/95 Merck v Primecrown (1996) ECR I-6285.

5 Joined cases C-427, 429 & 436/93 Bristol-Myers Squibb (1996) ECR I-3457, case C-232/94 Rhône-Poulenc (1996) ECR I-3671, C-379/97 Pharmacia & Upjohn (1999) ECR I-6927, C-143/00 Boehringer etc (2002) ECR I-3759, C-443/99 Merck, Sharp and Dohme vs Paranova (2002) ECR I-3703.

6 Directive 2001/83/EC (OJ No L 311, 28/11/2001 p.67-128) as last amended by Directive 2003/63/EC (OJ L 159, 27/06/2003 p.46-94); Directive 2001/82/EC (OJ No L 311, 28/11/2001, p.1-66).

7 COM (1998) 588 final - 25.11.1998

imported in parallel, is objectively necessary so that it can gain access to the Member State of destination. The significance of that jurisprudence of the Court is underlined by the explanation of those conditions and their application in the fifth part of this communication.

Finally, the term "import" is used, when referring to intra-community trade, for practical reasons even though it could be argued that the term has lost most of its relevance due to the development of the Internal Market.

2. PARALLEL IMPORTS AND FREE MOVEMENT OF GOODS

Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations provided by article 30 of the EC Treaty

Parallel trade is a lawful form of trade in goods between Member States of the European Union. It is known as "parallel" to the extent that it takes place outside and – in most cases- in parallel with the distribution network that the manufacturers or original suppliers have established for their products at a Member State, while it concerns products which are in every respect similar to the ones marketed by the distribution networks.

Parallel trade is based on the principle of the free movement of goods within the Internal Market (articles 28-30 of the EC Treaty). In the pharmaceutical sector, it benefits from price divergence as Member States set or, by other means, control the price of medicinal products sold within their respective markets[8]. The European Court of Justice has repeatedly confirmed that medicinal products are not exempted from the rules of the Internal Market[9] and has condemned State measures[10] which restrict, without appropriate justification, parallel imports of medicines. The Court has ruled that certain Member State measures restricting parallel imports may be justified on the grounds of protection of industrial and commercial property and the protection of human health and life, according to article 30 of the EC Treaty.

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8 Member States may resort to direct price setting or indirect price setting by means of reimbursement policies, in order to guarantee to all citizens equal access to medicinal products and to safeguard the financial stability of their social security services. The Court has acknowledged that, in the absence of harmonisation, Member States are entitled to set the prices of pharmaceutical products in order to meet such legitimate concerns provided that such an intervention does not discriminate de jure or de facto between national or imported products and the price indicated is remunerative – Case 181/82 Roussel Laboratoria (1983) ECR 3849 and Case 249/88 Commission v. Belgium (1991) ECR I-1275. As regards, in particular, the market of prescription medicines, State intervention may take the form of exclusion of a medicinal product from a reimbursement scheme. Such a restriction may be justified only if: (a) there is no discrimination based on the origin of the product, (b) it is based on objective and verifiable criteria and (c) it provides for procedures to remedy any distortion as it may arise - Case 238/82 Duphar (1984) ECR 523. Additional procedural requirements are laid down in Directive 89/105/EEC (OJ No L 40, 11/2/1989 p.8-11).

9 The Court has noted that to this effect it is "a matter of no significance that there exist as between the exporting and importing Member States, price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product" – Case 15/74 Centrafarm v. Sterling (1974) ECR 1147. This principle was confirmed in joined cases C-267/95 and C-268/95, Merck v Primecrown, (1996) ECR I-6285, paragraph 47; see also case C-436/93 Bristol-Myers Squibb v. Paranova, (1996) ECR I-3457, case 16/74, Centrafarm and De Peijper v. Winthrop (1974) ECR 1183.

10 When a restriction on parallel trade is due to measures taken by undertakings, such as dual pricing or limiting supplies to wholesalers, this is subject to examination under the Community competition rules (articles 81-82 of the EC Treaty).

3. PROTECTION OF HUMAN HEALTH AND LIFE - MARKETING AUTHORISATIONS

A medicinal product may be imported in parallel on the basis of a licence granted according to a 'simplified' procedure under which the applicant needs to provide less information than is required for an application for a marketing authorisation

In general, a medicinal product cannot be put on the market of a Member State without a marketing authorisation, the primary purpose of which is to safeguard public health. Marketing authorisations are granted either at national or Community level[11].

According to the jurisprudence of the Court[12], however, these rules are subject to exceptions resulting from the rules of the EC Treaty relating to the free movement of goods. National authorities may not obstruct parallel imports by requiring parallel importers to satisfy the same requirements as those which are applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product[13], provided that an exception of that kind to the rules normally applicable to marketing authorisations for medicinal products does not undermine the protection of public health.

In particular, when the information necessary for the purposes of protecting public health is already available to the competent authorities of the Member State of destination as a result of the first marketing of a product in this Member State, a parallel imported medicinal product is subject to a licence granted[14] on the basis of a proportionally simplified procedure[15] provided:

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11 Directive 2001/83/EC, article 6.1: No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 2309/93. Article 8 of the Directive details the information which must be submitted to the competent authority in order to have a marketing authorisation issued. The Directive has been amended by Directive 2002/98/EC (OJ L 33, 8/2/2003, p.30-40) and by Directive 2003/63/EC (OJ No L 159, 27/06/2003 p. 46-94). The equivalent provisions in Directive 2001/82/EC are articles 5 and 12.

12 Cases 104/75 De Peijper (1976) ECR 613, C-201/94 Smith & Nephew and Primecrown (1996) ECR I-5819, C-94/98 Rhone Poulenc (1999) ECR I-08789 and C-172/00 Ferring (2002) ECR I-6891

13 This in practice means that the parallel importer does not need to submit documents relating to the medicinal product in general or to a specific batch, that could be obtained only by the manufacturer of the medicinal product or his licensee. Otherwise the manufacturer or his licensee could have impeded parallel imports simply by refusing to produce the necessary documents – Case 104/75 De Peijper (1976) ECR 613.

14 Time related issues, such as the time limits within which national authorities must respond to a parallel import license applicant and the duration of such licence, remain to be further clarified. Regarding the former, it must be noted that article 18 of Dir.2001/83 provides for a 90 days period within which a Member State may decide on the recognition of a marketing authorisation issued by another Member State; it may therefore be argued that 45 days is a reasonable time limit for applying a simplified procedure to decide on a parallel imports licence application. As for the duration of the licence see note 21.

15 "If the public health authorities of the Member State of importation already have in their possession, as a result of importation on a previous occasion, all the pharmaceutical particulars relating to the medicinal product in question and considered to be absolutely necessary for the purpose of checking that the product is effective and not harmful, it is clearly unnecessary, in order to protect the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect

- the imported product has been granted a marketing authorisation in the Member State of exportation;

- the imported product is sufficiently similar to a product that has already received marketing authorisation in the Member State of destination even if there are differences relating to the excipients[16].

The Court has clarified the issue of similarity, ruling that the two products do not have to be identical in all respects but they should have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects[17].

That a medicinal product sufficiently similar to the parallel import has already received marketing authorisation in the Member State of destination does not necessarily imply that this "reference" authorisation is still valid at the time of importation. In particular, the Court has ruled that parallel importation of a medicinal product is still possible even when the reference authorisation has been withdrawn and that the parallel imports licence may not be revoked unless such a measure is justified by reasons relating to the protection of public health, in accordance with the provisions of Article 30 EC[18]. It may reasonably be assumed that the same principles apply when the reference marketing authorisation of a medicinal product is still valid in the Member State of exportation but is left to expire[19] in the Member State of importation so that a new version is marketed.

The issue arises of when a marketing authorisation of reference is withdrawn in the Member State of importation for reasons other than the protection of public health and the imported product continues to be lawfully marketed in the Member State of exportation under the marketing authorisation issued in that State. This is the case where, for example, a new version of a medicinal product is marketed in a Member State while the old version continues to be imported from another Member State.

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the same or whose differences have no therapeutic effect, to produce these particulars again", Case C-201/94 Smith & Nephew and Primecrown (1996) ECR I-5819

16 The fact that the manufacturer of the imported product and of the product already marketed in the Member State of destination is either the same or they belong to the same group or, in case of independent companies, they have concluded agreements with the same licensor was also taken into account by the Court in cases 104/75 De Peijper (1976) ECR 613 and C-201/94 Smith & Nephew and Primecrown (1996) ECR I-5819 when addressing the issue of similarity.

17 Case C-201/94 Smith & Nephew and Primecrown (1996) ECR I-5819 - As for the condition regarding the formulation of a product the Court went on to rule that national authorities are required to authorise, in accordance with the rules relating to parallel imports, a medicinal product imported as a parallel product where they are convinced that that product, in spite of differences relating to the excipients, does not pose a problem for public health – Case C-94/98 Rhone Poulenc (1999) ECR I-08789

18 Cases C-172/00 Ferring (2002) ECR I-6891 and C-15/01 Paranova (2003) ECR

19 Article 24 of Directive 2001/83/EC provides that: "Authorization shall be valid for five years and shall be renewable for five-year periods, on application by the holder at least three months before the expiry date and after consideration by the competent authority of a dossier containing in particular details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinal product" - OJ L 311, 28/11/2001 p. 67-128. The equivalent provision in Directive 2001/82/EC is article 28.

The Court has ruled[20] that the withdrawal of such a marketing authorisation does not mean in itself that the quality, efficacy and safety of the old version are called into question. It has been acknowledged that the competent authorities of the Member State of importation must adopt the measures necessary for the purpose of verifying the quality, efficacy and safety of the old version of the medicinal product and that this objective must nevertheless be attained by measures having a less restrictive effect on the import of medicinal products than the automatic cessation of the validity of the parallel import licence. A possible way of attaining such an objective is through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer or other companies in the same group, relating to the old version in the Member States in which that version is still marketed on the basis of a marketing authorisation still in force[21].

Moreover the Court has held that restrictions on the importation of the old version may be justified if it can be demonstrated that there is in fact a risk to public health arising from the coexistence of the two versions in the same market. The question, however, of the existence and the reality of the risk is a matter which is primarily for the competent authorities of the Member State of destination to determine, and the mere assertion by the holder of the marketing authorisation for the new and old versions that there is such a risk is not sufficient to justify a prohibition of the importation of the old version.

When a medicinal product has been authorised at Community level[22] the marketing authorisation is valid throughout the Community. Centrally authorised medicines distributed in parallel which are identical[23] to those distributed by the manufacturer are covered by one and the same marketing authorisation. The parallel distributor may therefore under Community pharmaceutical law directly place on the market the medicine and distribute it in parallel. He may also do so if the marketing authorisation

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20 Cases C-172/00 Ferring (2002) ECR I-6891 and C-15/01 Paranova (2003) ECR

21 The Court referred to the principle of co-operation of the authorities of Member States in joint cases 87 and 88/85 Legia and Gyselinx (1986) ECR 1707. On the basis of this principle it may be argued that national authorities, when granting a parallel imports licence, may not, as a general rule, restrict its duration until the expiry date of the original marketing authorisation. In any event, if the health authorities of the Member State concerned consider, in specific cases and for clearly identified reasons, that the lack of pharmacovigilance obligations on the holder of the withdrawn marketing authorisation could compromise the safeguarding of public health, they must be able to adopt the appropriate measures, namely, where necessary, to restrict the duration of the import licence to the validity of the marketing authorisation (C-223/01, AstraZeneca A/S, judgement of 16/10/2003, not yet reported). The case concerned the granting of an authorisation for a generic product and not an import licence. It remains to be decided by the Court whether this principle also applies to parallel imports.

22 Authorisation at Community level is granted according to the centralised procedure provided by Council Regulation (EEC) 2309/93 OJ 1993 L 214, 1-21. Regulation 2309/93 has been the subject of Commission Communication on the Community Marketing Authorisation Procedures for Medicinal Products of 1998 (98C 229/03). The Communication also provides guidance on the mutual recognition procedure of Directives 2001/83/EC and 2001/82/EC.

23 The Court held in Case T-123/00, Thomae/Commission (2002) ECR II-5193, that considerations deriving from the unitary nature of the Community MA and the fundamental principle of the free movement of goods suggest that a medicinal product which is the subject of an application for a Community market authorisation must, as a general rule, have a single package layout such as colour, logo, format and general layout. It went on however to declare that under exceptional circumstances the package layout may vary. The case concerned the holder of the marketing authorisation and not a parallel distributor.

holder, for one reason or another, has not yet placed the relevant product on a given national market.

4. PROTECTION AND EXHAUSTION OF INDUSTRIAL AND COMMERCIAL PROPERTY RIGHTS

The owner of an industrial and commercial property right protected by Member State legislation may not rely on that legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right

Medicinal products are generally covered by industrial and commercial property rights, namely patents and trademarks, which are essentially national in nature[24]. They can be invoked before the national authorities and the national courts in order to prevent the sale on the national market of imported medicinal products infringing these rights.

The existence of industrial and commercial property rights is not affected by the EC Treaty; their exercise may however be affected when it is repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market. The Court has ruled[25] that the derogation to the free movement of goods justified on the grounds of protection of industrial and commercial property is only admissible when it is justified for the purpose of safeguarding rights, which constitute the specific subject matter of the property[26].

This rule is known as the principle of exhaustion of industrial and commercial property rights[27]. According to this principle, the owner of an industrial and commercial property right protected by Member State legislation may not rely on that legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right. The right is considered to have been exhausted once the product has been put on the market somewhere in the Community.

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24 See however Council Regulation (EC) No 40/94 of 29 December 1993 on the Community trademark, OJ L 11, 14.1.1994, p.1, and proposal for a Council Regulation on the Community patent, OJ No C 337E, 28.11.2000, p. 278.

25 See among others case 78/70 Deutsche Grammophon v. Metro (1971) ECR 487 and case 102/77 Hoffmann-La Roche (1978) ECR 1139.

26 "The specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements", Case 15/74 Centrafarm v Sterling Drug (1974) ECR 1147 as confirmed by joint cases C267/95 and C-268/95 Merck v. Primecrown (1996) ECR I-6285.

27 This general principle, based on the distinction between the existence and the exercise of patent rights, has been enshrined in EC legislation on industrial property. See article 7 of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks (OJ L 40, 11.12.1989, p. 1) which reiterates the case-law of the Court, in particular case 15/74 Centrafarm v Sterling (1974) ECR 1147, case C-10/89 CNL-SUCAL v HAG GF (1990) ECR I-3711 and case C-9/93 IHT Internationale Heiztechnik v Ideal Standard (1994) ECR I-2789.

An industrial property right will be exhausted even in the case of a product which the owner of the industrial property right first markets in one Member State where protection exists, then markets it in another Member State where there is no such protection: the owner of the right cannot prevent the parallel importation of the product from the latter Member State to the former[28].

An important, even if temporary, exception to this rule has emerged, during discussions on the G10 Medicines initiative[29], with the accession of the new Member States in 2004 and, in particular, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia[30]. The Treaty of Accession provides[31] for a specific mechanism whereby parallel imports from the above mentioned new Member States are prevented until the patent or supplementary protection of the medicinal product concerned expires in these Member States[32].

5. PROTECTION OF TRADE MARKS AND REPACKAGING

The proprietor of the trade mark may not use his trade mark right in order to prevent repackaging when: (1) the use of the trade-mark right by the owner will contribute to the artificial partitioning of the markets between Member States, (2) the repackaging cannot adversely affect the original condition of the product, (3) it is stated on the new packaging by whom the product has been repackaged and manufactured, (4) the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner and (5) the proprietor of the trade mark receives prior notice before the repackaged product is put on sale

In certain circumstances[33], repackaging the product and reaffixing the trade mark or replacing it with a different trade mark used for the same product in the Member State of destination is necessary to allow the product imported in parallel to be marketed in a Member State. The issue has been addressed by the Court and a number of conditions

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28 Cases 187/80 "Merck v. Stephar" (1981) ECR 2603, C-10/89 HAG (1990) ECR 3711, C-191/90 Generics and Harris Pharmaceutical (1992) ECR 5335, joined cases C-267/95 and C-268/95 Merck v. Primecrown (1996) ECR I-6285.

29 See recent Commission Communication on "A stronger European-based pharmaceutical industry for the benefit of the patient – A call for action", COM (2003) 383.

30 Patent or supplementary protection could be obtained in the other two new Member States, Malta and Cyprus, and they are therefore not included in the list.

31 "With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent", Accession Treaty, Part three, Title II, Annex IV, Section 2 "Company Law", AA2003/ACT/Annex IV/en p.2499, signed in Athens on 16 April, 2003.

32 These new Member States introduced patent protection rights in the period between 1991and 1994.

33 For example, requirements relating to the language of the labelling and the instructions or national rules relating to the size of packaging.

have emerged regarding the necessity and the extent of changes to the original packaging.

According to Article 7, paragraph 2 of Directive 89/104[34], the principle of exhaustion of the rights conferred by a trade mark does not apply where the proprietor of a trade mark has legitimate reasons to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market. The Court has accepted that Article 7 of the directive comprehensively regulates the question of the exhaustion of trade mark rights for products traded in the Community noting however that, like any secondary legislation, the directive must be interpreted in the light of the EC Treaty rules on the free movement of goods and in particular Article 30[35]. This is explained on the grounds that a directive cannot justify obstacles to intra-Community trade save within the bounds set by the Treaty rules[36].

It has been already mentioned that the derogation to the free movement of goods principle based on the grounds of protection of industrial and commercial property[37] is only admissible when it is justified for the purpose of safeguarding rights, which constitute the specific subject matter of the property. The Court has ruled that the specific subject-matter of a trade mark is in particular to guarantee to the owner that he has the exclusive right to use that trade mark for the purpose of putting a product on the market for the first time and therefore to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products bearing it illegally[38]. Accordingly, the essential function of the trade mark is to guarantee to the consumer the identity of the product's origin by enabling him to distinguish it without any risk of confusion from products of different origin; it is also to assure the consumer that the product has not been subject to interference by a third person, without the authorization of the trade mark owner, in such a way as to affect the original condition of the product[39].

It follows that the proprietor of the trade mark may not use his trade mark right in order to prevent repackaging when:

- the use of the trade-mark right by the owner, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;

- the repackaging cannot adversely affect the original condition of the product;

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34 OJ L 40, 11.12.1989, p. 1

35 Joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others (1996) ECR I-3457

36 According to the jurisprudence of the Court, case C-51/93 Meyhui v Schott Zwiesel Glaswerke (1994) ECR I-3879, the prohibition on quantitative restrictions and measures having equivalent effect –art.28 EC- applies not only to national measures but also to those emanating from Community institutions.

37 Art. 30 EC Treaty

38 See among others cases 16/74 Centrafarm v Winthrop (1974) ECR 1183, 102/77 Hoffmann-La Roche (1978) ECR 1139 and 1/81 Pfizer v Eurim-Pharm (1981) ECR 2913 confirmed by joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others (1996) ECR I-3457.

39 note 38

- it is stated on the new packaging by whom the product has been repackaged and manufactured;

- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; and

- the proprietor of the trade mark receives prior notice before the repackaged product is put on sale[40].

On the other hand, the Court has ruled that the condition of necessity will not be satisfied if the parallel importer wishes to repackage the product and reaffix or replace the trade mark solely in order to secure a commercial advantage. In that case the proprietor of the trade mark may lawfully use his right to prevent the actions mentioned above.

Whether repackaging is objectively necessary according to the conditions explained below is, in any case, to be assessed on the basis of the circumstances prevailing at the time of marketing of the medicinal product in the Member State of destination.

5.1. Artificial partitioning of the Internal Market

This is the case where the trade mark proprietor has placed an identical pharmaceutical product on the market in several Member States in various forms of packaging and/or under a different trade mark[41] and the size of the packet marketed in the Member State of exportation may not be marketed in the Member State of destination for various reasons[42]. Furthermore, the Court also ruled that even when one of the many sizes of the product marketed in the Member State of destination is also marketed in the Member State of exportation, this is not enough to justify the conclusion that repackaging is unnecessary. Partitioning of the markets would still exist if the importer were able to sell the product in only part of his market.

It must be noted that, in all circumstances, repackaging is permitted only if it is necessary. If, for example, the imported product may have effective access to the market a Member State simply by having new labels affixed to the original packaging or new user instructions and information added, then the proprietor of the trade mark may indeed oppose repackaging to the extent that it is not objectively necessary.

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40 These conditions were clarified by the Court in a series of judgements since the case 102/77 Hoffmann-La Roche (1978) ECR 1139. See in particular, case 1/81 Pfizer v Eurim-Pharm (1981) ECR 2913, joined cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others (1996) ECR I-3457, case C-379/97 Upjohn (1999) ECR I-6927, case C-443/99 Merck, Sharp & Dohme (2002) ECR I-3703 and case C-143/00 Boehringer (2002) ECR I-03759

41 The issue of replacing the trade mark with the one used for the same product in the Member State of destination was addressed by the Court in case C-379/97 Upjohn (1999) ECR I-6927.

42 The artificial partitioning of the market may not necessarily be directly attributed to and intended by the proprietor of the trade mark but to such factors as the ones mentioned by the Court: a rule authorizing packaging only of a certain size or a national practice to the same effect, sickness insurance rules making the reimbursement of medical expenses depend on the size of the packaging, or well-established medical prescription practices based, inter alia, on standard sizes recommended by professional groups and sickness insurance institutions.

The Court has clarified the term "effective access", ruling[43] that there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to relabelled medicinal products that there must be held to be a hindrance to effective market access. Therefore, in those circumstances, the proprietor of the trade mark may not oppose repackaging.

5.2. Adverse effects on the original condition of the product

The concept of adverse effects on the original condition of the product refers to the condition of the product inside the packaging. It is accepted that the condition of the product is not adversely affected

- when repackaging affects only the external layer, leaving the inner packaging intact, or

- where the repackaging is carried out under the supervision of a public authority in order to ensure that the product remains intact.

It follows from the jurisprudence of the Court that the mere removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging cannot affect the original condition of the product inside the packaging. The same applies to operations consisting in the fixing of self-stick labels to flasks, phials, ampoules or inhalers, the addition to the packaging of new user instructions or information in the language of the Member State of importation, or the insertion of an extra article, such as a spray, from a source other than the trade mark owner.

On the other hand, the Court has acknowledged that the original condition of the product inside the packaging might be indirectly affected where, for example:

- the external or inner packaging of the repackaged product, or a new set of user instructions or information, omits certain important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product, or

- an extra article inserted into the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer.

5.3. Indication on who repackaged and manufactured the product

Since it is in the trade mark owner's interest that the consumer should not be led to believe that the owner is responsible for the repackaging, an indication must be clearly shown on the external packaging of who repackaged the product. That indication must be printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness. Moreover, where the parallel importer has

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[43] Case C-443/99 Merck, Sharp & Dohme (2002) ECR I-3703

added to the packaging an extra article from a source other than the trade mark owner, he must ensure that the origin of the extra article is clearly indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.

It is, nevertheless, not necessary to require that the further express statement be made on the packaging that the repackaging was carried out without the authorization of the trade mark owner, since such a statement could give the misleading impression that the repackaged product is not entirely legitimate.

5.4. Presentation of the repackaged product

The Court has acknowledged that even if the person who carried out the repackaging is indicated on the packaging of the product, there remains the possibility that the reputation of the trade mark, and thus of its owner, may nevertheless suffer from an inappropriate presentation of the repackaged product. In such a case, the trade mark owner has a legitimate interest, related to the specific subject-matter of the trade mark right, in being able to oppose the marketing of the product. In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trade mark, account must be taken of the nature of the product and the market for which it is intended[44].

5.5. Prior notice to the proprietor of the trade mark

The proprietor of the trade mark must be given advance notice of the repackaged product being put on sale. The proprietor may also require the importer to supply him with a specimen of the repackaged product before it goes on sale, to enable him to check that the repackaging is not carried out in such a way as directly or indirectly to affect the original condition of the product and that the presentation after repackaging is not likely to damage the reputation of the trade mark[45]. If the parallel importer[46] does not satisfy that requirement, the trade mark proprietor may oppose the marketing of the repackaged pharmaceutical product.

Both parties, nevertheless, must make sincere efforts to respect each other's legitimate interests. Accordingly, the proprietor is expected to be given a reasonable time to examine the product before reacting to the notice while consideration must also be given to the parallel importer's interest in proceeding to market the product as soon as possible after obtaining the necessary licence from the competent authority. In the

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44 The public is particularly demanding as to the quality and integrity of pharmaceutical products, and defective, poor quality or untidy packaging could damage the trade mark's reputation. However, the requirements to be met by the presentation of a repackaged pharmaceutical product vary according to whether the product is sold to hospitals or, through pharmacies, to consumers. In the former case, the products are administered to patients by professionals, for whom the presentation of the product is of little importance. In the latter case, the presentation of the product is of greater importance for the consumer.

45 Such a requirement also affords the trade mark owner a better possibility of protecting himself against counterfeiting.

46 It is not sufficient that the proprietor be notified by other sources, such as the authority which issues a parallel import licence to the importer - case C-143/00 Boehringer (2002) ECR I-03759

Boehringer case[47] the Court suggested that a period of 15 working days seems likely to constitute such a reasonable time where the parallel importer has chosen to give notice to the trade mark proprietor by supplying it simultaneously with a sample of the repackaged pharmaceutical product. The Court added that, that period being purely indicative, it remains open to the parallel importer to allow a shorter time and to the proprietor to ask for a longer time to react than that allowed by the parallel importer.

It must be noted that, regarding parallel imports of medicinal products covered by the exception provided in the Accession Treaty 2003, the rule is that the parallel importer must give one month's prior notification[48].

5.6. Authorisation at Community level

When a medicinal product has been authorised at Community level[49] the marketing authorisation issued in accordance with Regulation 2309/93 relates to the specific packaging prescribed for the medicinal product in the application for authorisation. The authorisation determines the pack sizes and the immediate packaging to be used for the medicinal product, as well as the information to be included on the immediate or outer packaging[50]. The Court has held that the detailed and specific requirements regarding the packaging, which are intended to prevent consumers from being misled and, thereby, to protect public health preclude the joining together and re-labelling of packages of that medicinal product[51]. The Court added, however, that the creation of new packaging may be possible if that repackaging is objectively necessary[52] so that the imported product gains effective access to the market of a Member State.

Although no further authorisation is required, the Community (in practice the European Agency for the Evaluation of Medicinal Products –EMEA) and national authorities of the Member States in which the medicinal product will be distributed in parallel shall be informed that such parallel distribution will take place in order to enable the EMEA to check compliance with the terms of the Community marketing authorisation and the national authorities to monitor the market (batch identification, pharmacovigilance, etc.) and to carry out post-marketing surveillance (Commission Communication on the

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47 Case C-143/00 Boehringer (2002) ECR I-03759

48 "Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection". (Accession Treaty, Part three, Title II, Annex IV, Section 2 "Company Law" AA2003/ACT/Annex IV/en p.2499, signed in Athens on 16 April, 2003

49 Authorisation at Community level is granted according to the centralised procedure provided by Council Regulation (EEC) 2309/93 OJ 1993 L 214 , 1-21

50 Pursuant to Articles 9(3) and 10(1) and the second sub-paragraph of Article 11 of Regulation No 2309/93, the authorisation will include, in annex, the draft text of the labelling and package leaflet, presented in accordance with Directive 92/27/EEC (now Directive 2001/83/EC, articles 54-69). Accordingly, the particulars and information to be printed on the product packaging are specific to those packagings, since they are based on the pack size and immediate packaging used, as specified in the application pursuant to Article 6(1) of that regulation.

51 Case C-433/00 Aventis Pharma Deutschland (2002) ECR I-7761

52 The circumstances prevailing at the time of marketing in the Member State of importation are again assessed according to the criteria set in the jurisprudence of the Court, see note 38.

Community marketing authorisation procedures for medicinal products, OJ C 229, 22/7/1998, p.4-17)[53].

6. CONCLUSIONS

Since the adoption of the 1982 Commission Communication, the Court has addressed a great number of issues regarding parallel imports of medicinal products and has confirmed that a parallel imported medicinal product is subject to a licence granted on the basis of a simplified procedure when the information necessary for the purpose of protecting public health is already available to the authorities of the Member State of destination. This is the case when the product in question has already received a marketing authorisation in the Member State of exportation and is sufficiently similar to a product that has already received authorisation in the Member State of destination. Accordingly, the Court has ruled that when the marketing authorisation in the Member State of destination has been withdrawn for reasons other than the protection of public health, this does not affect the validity of the parallel imports licence.

A further development that has significantly contributed to legal certainty and thus to the smooth functioning of the internal market, is the series of rulings delivered by the Court regarding repackaging of a product imported in parallel. The Court has clarified that the protection of a trade-mark right is not without limits, noting in particular that it may not contribute to the artificial partitioning of the internal market. Therefore, the parallel importer may repackage a proprietary medicinal product and reaffix the trade-mark or indeed replace it with the trade-mark used in the market of destination, provided that repackaging does not adversely affect the original condition of the product or the reputation of the trade-mark and its owner. Further conditions confirmed by the Court are that the new packaging states by whom the product has been repackaged and also that the trade-mark proprietor receives notice before the repackaged product is put on sale.

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53 The Commission is proposing to make this system compulsory in the on-going review of the pharmaceutical legislation (articles 76(3) of Directive 2001/83/EC and 57(1)(n) of the proposed regulation replacing Regulation (EEC) No 2309/93). The Commission proposed, in November 2001, a legislative package for the review of the pharmaceutical legislation comprising a regulation intended to replace Regulation (EEC) No 2309/93 and two directives amending Directives 2001/83/EC and 2001/82/EC (COM (2001) 404 final). The package is currently in its second reading in the European Parliament (2001/0252 (COD), 2001/0253 (COD) and 2001/0254 (COD)).

Nevertheless, not every issue regarding parallel imports has been addressed by the Court. As the internal market develops, new questions keep emerging and old answers need further clarification. While all parties pursue their legitimate interests in the framework of the internal market, respect of what has already been achieved and close cooperation among Community institutions, national authorities and economic operators continues to provide the solid basis for the resolution of all outstanding issues.

ANNEX

Questions and Answers

Who is this communication addressed to?

It is addressed to national administrators as well as to companies or individuals dealing with the marketing of medicinal products.

How can it help me?

Policy makers and national administrators handling parallel imports applications can find solutions to complex problems by referring to the relevant jurisprudence of the Court while market operators can clarify their respective rights and obligations deriving from the principle of the free movement of goods.

Are parallel imports legal?

Parallel imports are legal and have been a direct consequence of price divergence and the development of the Internal Market which guarantees the free movement of goods; certain conditions must, as in all cases, be respected, namely those derived from the need to protect public health.

Doesn't the word "parallel" indicate something not quite proper, though?

This is clearly not the case. It simply indicates that the marketing of a medicinal product takes place outside the distribution network of the manufacturer or his licensee. In any case it is the same or a sufficiently similar product.

Isn't this "similarity" rather ambiguous, then?

On the contrary, it has been clarified by the Court for the benefit of patients as well as national public health authorities. In particular, the product imported in parallel (i.e. after a first marketing authorisation has been granted by the Member State of destination) does not have to be identical in all respects to the product already marketed by the manufacturer but it should have at least been manufactured according to the same formulation, using the same active ingredient, and should have the same therapeutic effects.

Can't the Member State of destination nevertheless stop or restrict parallel imports?

Indeed they can, provided they can establish that any restrictive measure aims at the protection of human health and life or the protection of industrial and commercial property (i.e. patents and trademarks). National authorities must also show that such measures are necessary and proportionate.

How can human health and life be effectively protected?

Member States have at their disposal several tools and procedures in order to safeguard public health and, in the case of medicinal products, a marketing authorisation is granted only after the

product has been thoroughly checked. The marketing of a medicinal product having been authorised, it would be unnecessary, disproportionate, time consuming and costly to apply exactly the same procedure all over again. Therefore, national authorities are entitled to confirm that a product imported in parallel is the same or sufficiently similar to the one already authorised for circulation in their market. The parallel importer is accordingly required to submit all relevant information, fulfilling the conditions described above, in the framework of a much simpler procedure. For the same reasons, when the first authorisation is withdrawn on grounds other than the protection of public health, that does not automatically result to the withdrawal of the parallel imports licence.

Can't a manufacturer stop or restrict parallel imports?

The manufacturer or in general the owner of an industrial or commercial right may indeed ask national authorities or courts of the Member State of destination to protect the specific subject-matter of these rights. In other words, a patent holder may seek protection of his exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties. Consequently, as soon as he markets his product for the first time his exclusive marketing right is exhausted within the Internal Market, i.e. the parallel importer may indeed buy the product at one place and market it at another.

Can the parallel importer go further than that and interfere with the product itself?

Parallel importers cannot alter the essential characteristics of the product itself; that would possibly result to a different product which consequently would not fall under the definition of products imported in parallel. There are circumstances, however (e.g. difference in language), whereby certain alterations in the form of packaging are considered necessary for the marketing of the medicinal product in the Member State of destination, in other words, in order to avoid the artificial partitioning of the Internal Market. For this purpose, the parallel importer may change the packaging and may re-affix the trade mark on the new packaging or even replace it with the trade mark used for the same product in the Member State of destination provided that this does not adversely affect the original condition of the product, it is stated on the new packaging by whom the product has been repackaged and manufactured, the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner and the proprietor of the trade mark receives prior notice before the repackaged product is put on sale. The Court has provided guidelines for each of these conditions.

So, have all problems been finally resolved?

Not quite. Even though the Court has addressed a great number of issues and despite the Community legislation that deals with general issues regarding the marketing of medicinal products, there can by no means be any "definitive" guide to parallel imports. New questions keep emerging and old answers need more clarification. Respect of what has already been achieved and continuous cooperation among Community institutions, national authorities and economic operators has been and still is a solid basis for the resolution of all remaining problems.