

Parallel Imports, Exhaustion of Rights in EU

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*Examination of problems arising
in EC law, national rights control
IP movement among countries.*

It is a basic principle of European Community (EC) law that goods must be allowed to move freely throughout the EC (Articles 30 to 34 Treaty of Rome). On the other hand, most intellectual property rights remain national, and must be respected (Article 293 and Article 6). Tensions accordingly arise and must be resolved.

Difficulties arise particularly in the context of exclusive territorially limited technology and other intellectual property licenses. How far can an intellectual license be protected against competition by "gray" or "parallel" imports from outside his exclusive territory?

The problems arise particularly in the pharmaceutical industry where state-imposed price regimes cause drug prices to differ substantially among the Member States. I shall, in this paper, concentrate on the position in the EU under EC law. Similar principles now extend also to Norway, Iceland and Liechtenstein, which with the EU make up the European Economic Area (EEA). I shall also confine myself to the position within the EU.

Different rules apply to imports from outside the EU. In such cases mainly national, not EC, rules apply. Until recently there has been little uniformity among national rules. The position has also differed among the different rights concerned. In many countries, for example, a doctrine of "international exhaustion" applied to trademarked goods. The Commission's general policy is that there should be no international exhaustion. The Commission has not formally stated this policy but believes the intention is clear from the provisions of Direc-

tives such as the Trade Marks¹ Directive,² Semi-Conductor³ and Rental and Lending Right Directive.⁴

These issues are already having their effect. As a result of the implementation of the Trade Marks Directive into German law, the German Federal Supreme Court in 1986 revised the long-established German doctrine of "international exhaustion" and upheld the right of a German trademark owner to block unauthorised imports of Levin pain-killers into Germany from outside the EU.

FREE MOVEMENT OF GOODS IN THE EU

Articles 30 and 34 of the Treaty of Rome prohibit quantitative restrictions on imports and exports and all measures having equivalent effect between Member States. A direct consequence of this principle of free movement is the clause "Cassis de Dijon"⁵ doctrine of the European Court of Justice that a product lawfully on the market in one Member State must be able to circulate freely within the whole of the EU subject to objectively justifiable exceptions.

Articles 30 and 34 are qualified by Article 36. Their provisions do:

"...in particular prohibit measures which relate to imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of intellectual and industrial property."

¹ Council Directive (79) 100/EEC, OJ L 26/11 and OJ L 26/12.

² Council Directive (89) 100/EEC, OJ L 26/11.

³ Council Directive (88) 300/EEC, OJ L 26/11.

⁴ Directive (82) 92/EEC, OJ L 26/11.

⁵ Case 120/78, *Reffo*, [1978] ECR I-1299.

⁶ Case 120/78, *Reffo*, [1978] ECR I-1299.

"This applies provided that such prohibitions or restrictions do not constitute a means of arbitrary discrimination or disguised restriction on trade between Member States." (Articles 11, 12 and 13 of the EEA Agreement mirror Articles 30, 34 and 36 of the Treaty of Rome.)

CONFLICTS BETWEEN EC RULES ON FREE MOVEMENT AND NATIONAL IP

Currently, most IP in the EU are national. Some are regional (i.e. Benelux). The only community-wide right is the Community Trade Mark, which became available in 1996.

The Treaty of Rome in Article 293 protects the existence of national IP by providing that the Treaty shall "in no way prejudice the rules in Member States governing the system of property ownership."

Article 36 of the Treaty so far as an exception to certain circumstances to the rules on free movement.

When goods protected by IP are marketed in the EU there is an obvious tension between the existence of national IP and the principles of free movement and free competition inherent in the Treaty. Goods must be allowed to move freely throughout the EU, but national IP must be respected. For parallel imports the issue in each case boils down to whether, in the particular circumstances, the respect for national IP or the principles of free movement should prevail.

In considering these issues the ECJ draws a distinction between the "existence" and the "exercise" of IP. Their existence is protected

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by Article 36 but their exercise is subject to limitations arising from the rules of the Treaty. In *Consten* (and as discussed more fully below) the Court has held that the exercise of IPB is only justified under Article 36 if such exercise is for the purpose of safeguarding rights that constitute the "specific subject-matter" of the IPB concerned.¹ What constitutes the "specific subject-matter" is ultimately a matter of Community law, and varies according to the right under consideration.

PARALLEL IMPORTS AND THE RULES OF EXHAUSTION OF RIGHTS

In considering parallel imports we are not dealing with counterfeits or other infringing products emanating from unauthorized third parties. We are dealing with "genuine" goods covered with the right holder but which have been marketed outside the country of importation.

The question to be asked in such cases is whether the owner of the national IPB in the country of importation may use them to restrain parallel importation of such goods. First, it must of course be assessed whether the importation complained of would in fact constitute infringement under the relevant national law. The various national laws often differ. If the importation will not infringe national law, that is the end of it. However, if it does so the fact of it infringe national law, the question arises whether under EC law such infringement is actionable. In short, can the relevant IPB be exercised to restrain the infringement?

The general rule is that once a protected product has been put on the market in the EU by a patentee or other right owner, or with his consent, his IPB throughout the EU become "exhausted" and may not be used to restrain further dealings in the product in the EU.

The case law of the ECJ has established that the Article 36 exception only applies where it is in-

dispensable to safeguard the "specific subject-matter" of the right concerned. The specific subject-matter of a patent right was defined in *Consten v. Grainig Drug* as:

"To ensure to the holder, so as to compensate the investment of the invention, the exclusive opportunity an invention with a view to the manufacture and marketing, in a certain or national product, either directly or by the grant of licenses to third parties, as well as the right to oppose any imitations."²

The court concluded that it would be incompatible with the rules of free movement to grant a patentee to use his patent rights to stop a product being marketed that had been put on the market in another Member State by him or with his consent.

As further explained in *Merck v. Stephar*:

"It is for the protection of the patent to decide, in the light of all the circumstances, under what conditions to authorize his product... [and] he has done so, his main aim being the compensation of his efforts in regard to the investment of the product within the Common Market."

Although the definitions of "specific subject-matter" may differ between different types of IPB, broadly similar rules apply.

The position is relatively straightforward where the product is imported as originally marketed. The product will have been made by the owner of the rights, or by an associated company or licensee, and put on the market in the other EC country. Accordingly, the necessary "consent" will be present, resulting in an exhaustion of the owner's rights to restrain importation. Consent has been described as "The key which opens the door of the common market to patented products."³

However, a product imported from one EC Member State, although similar to one already on sale in another, may not be very marketable in such. The patent owner may be inconvenienced if different from the norms in the country of importation. Can the importer repeat the contents to suit the local market? The mark may be different. Can the importer or local whole-

sale or retailer re-mark the products with the mark of the country of importation to make of this the local variant? or trademark owner's local reputation? Whether or not the product has been altered, does it make a difference if, for a patented product, patent protection was not available in the country of first marketing? What if the product is first marketed by a licensee under a compulsory license?

Another issue that remains unsettled is what the ECJ meant in *Consten v. Grainig Drug* when it referred to putting products into circulation "by the grant of licenses to third parties." Did it mean that simply granting a license for a specific territory in itself exhausts all the licensor's EU rights in respect of the licensed products? This would be an extraordinary interpretation, with serious consequences for licensors and licensees, if correct. The European Commission, however, considers this question open, and there are some in the Commission who apparently support the former view. This is discussed more fully later.

NON-PATENT COUNTRIES (ITALY, SPAIN AND PORTUGAL)

Pharmaceuticals per se only became patentable in Italy in 1978, in Spain on October 7, 1982, and in Portugal on January 5, 1992. The Acts Concerning the accession of Spain and Portugal to the EU contained some special provisions concerning the effects of marketing pharmaceuticals in those countries (Articles 42 and 47 concerning Spain, and Articles 203 and 208 concerning Portugal). Essentially, they provided that the normal rules on exhaustion would not apply to sale of pharmaceuticals in Spain or Portugal until three years after pharmaceuticals become patentable there. So until October 7, 1989, for Spain and until January 1, 1990, for Portugal, the patentee could use his patent in other Member States to restrain imports from Spain and Portugal even if the products were genuine and marketed there by him or with his express consent. No

¹ *Consten v. Grainig Drug* (1976) 2 CMLR 993.

² *Merck v. Stephar* (1984) 2 CMLR 603.

such special arrangements were approved by Italy.

As far as all these three countries is concerned, marketing in one of them by a producer or with his consent entails all patent rights in the EU. It makes no difference that patents were never available.

This was established in Italy in *Merck v. Sphar*, and has recently been upheld for Spain and Portugal by the ECJ in *Abrax v. Parnac*¹⁰ involving imports from Spain following apparent expiry of the three-year manufacturing described above. For a while the position was in doubt.

Following the hearing the Advocate General (who summarised the arguments and seeks to guide the Court) rendered an Opinion that the judgment in *Merck v. Sphar* went too far. He suggested a unanimously restricted proper exercise of national patent rights, and was acceptably detrimental to the legitimate interests of patentees and to the function that patents perform in the EU. A right that does not exist cannot be exhausted, and therefore cannot be exhausted. The ECJ did not agree and *Merck v. Sphar* remains good law.

REPACKAGING OF BRANDED PRODUCTS

The essential subject-matter of a trademark according to the ECJ is:

"the guarantee that the owner of the trade mark has the exclusive right to certain made goods, for the purpose of putting products produced by the trade mark's proprietor on the free market" (*Compassi v. Grimaldi*)¹¹

Once the trademark owner has exercised that exclusive right in any Member State by putting trademarked goods on the market himself or through another, his rights in respect of the goods so marketed are exhausted and he cannot use his trademarks to restrict their further marketing in the EC.

This still allows the importer of an other state in such goods to repackage them, to make them more readily saleable in the relevant market¹²

The extent to which repackaging is permissible was set out originally by the ECJ in one of various cases involving *Constratum* back in 1978. In *Hoffman-La Roche & Co v. Dowling*¹³ the drug concerned was manufactured by Hoffman in Germany and in the UK by its subsidiary. *Constratum* brought some of the UK product, repackaged it in the Netherlands, and imported it into Germany.

The court held that the essential function of a trademark is to guarantee the identity of the origin of the trademarked product i.e. the manufacturer) to the consumer, enabling him to distinguish that product from other products of a different origin without any possibility of confusion. The guarantee of origin meant that the consumer could be certain that the product had not been intermixed with at an earlier stage by a third party so as to affect the original condition of the product.

The proprietor of a trademark therefore possesses had the right to prevent a product to which a mark has been lawfully applied in one Member State from being marketed in another Member State after being repackaged and the mark retained, where this occurred without his authority.

However, in such case it had to be examined whether the exercise of this right might not be a disguised restriction on trade between Member States, depriving the trademark owner of the benefit of Article 36. The example was given of following a strategy of putting the identical product on the market in different packages in different Member States, and then using the trademark rights to restrict repackaging to conform with the local packaging, even if this did not affect the identity of origin or the original condition of the goods.

The court noted that repackaging will in many cases inevitably affect the condition of the product. In others there will be a risk of intermixture with the product or that its original condition may be affected. In others there may be no

such risk, for example if the product is marketed in a double package.

Where the conclusion is a particular case is that the use of the trademark right by the proprietor, having regard to the marketing system he has adopted, will contribute to an artificial partitioning of the market, the exercise of his rights may constitute a disguised restriction within the meaning of Article 36 and deprive him of its protection.

The court held, however, that freedom of trade must be balanced with the trademark owner's interests. After all, the trader is effectively being given a licence to do something normally reserved for the owner.

With this aim in mind the court held that repackaging will therefore only be permissible where:

1. As discussed above, the trademark owner's use of the mark, having regard to his chosen marketing system, will contribute to the artificial partitioning of markets between Member States.

2. It is shown that the repackaging cannot adversely affect the original condition of the product.

3. The trader gives the trademark owner prior notice of his intention.

4. The trader states on the new packaging that he has repackaged the product.

If there were no need to repackage, in the sense that the market would not otherwise be artificially partitioned, any repackaging, whether or not notice were given or the condition of the product were affected, would be an actionable infringement.

Since these rules were established, the trademark laws of the EU have been reformatted and harmonised in accordance with the EC Trade Mark Directive. Article 7 deals specifically with exhaustion of rights in the EU.

Article 7 provides:

"1. The trade mark shall not enable the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

"2. Paragraph 1 shall not apply where there is legitimate reason for the proprietor to oppose the use of the trademark of the goods, in-

¹⁰ *Compassi v. Grimaldi* and *Cheloni v. Scalet* and *Merck v. Parnac*, and *Roche v. Parke-Davis* (unreported).

¹¹ *Compassi v. Grimaldi* (repackaging being EUJ 124).

¹² *Hoffman-La Roche & Co v. Dowling* (1978) 3 CMLR 207.

precisely where the content of the goods is changed or improved after they have been passed to the market.¹¹

In July 1990, the EC in a number of cases considered together¹² held that the rules set out above still apply. The case law under Article 36 of the EC Treaty remains relevant when applying Article 7(2) of the Trade Marks Directive.

RE-MARKING IMPORTED BRANDED PRODUCTS WITH THE LOCAL TRADE MARK

Sometimes a manufacturer will own and use different trademarks for the same product in different territories. In such cases, whether or not the parallel importer wishes to repackage, he may want, if the mark used on the imported products is different, to mark the products with the same mark as is used in the country of importation by the manufacturer. The reasons are obvious — the manufacturer will have promoted his products heavily under that mark, and the parallel importer will prefer to trade off that effort rather than incur the expenditure of further advertising himself. Further, local prescribing rules might make re-marking advantageous even. In the UK the rules of the Pharmaceutical Society of Great Britain require a pharmacist, presented with a prescription of a branded as opposed to generic drug, to dispense only the branded product (i.e. generic substitution is not allowed). Obviously, this is a potential incentive for the parallel importer to rebrand.

The law is illustrated by the EC in *Centrafarm v. American Home Products*¹³ in that such re-marking is not permitted, and is trademark infringement, unless again the exercise of the trademark owner's right amounts to a "disguised restriction on trade between Member States." This would be so, for example, he set out to use different marks for the purpose of partitioning the market. Accordingly, the result should be each case looks at the par-

ticular facts and determine the reasons for the decision to use different marks. If the reasons are objective then it is lawful to use different marks for the same product in different Member States. But if the different marks are used as part of a marketing system intended to partition the markets artificially, the position will be different.

PRODUCTS MADE BY LICENSEES

As discussed earlier the EC in *Centrafarm v. Sterling Drug* defined the specific subject-matter of a patent right to include the right of "first putting into circulation of industrial products, either directly or by the grant of licenses to third parties..."

This broad reference to "putting into circulation" by the "grant of licenses" failed to come unambiguously and conclusively.

In particular, the European Commission has argued in the past (and apparently still persists with its view) that the simple grant of a patent license anywhere in the EC amounts to an exhaustion of all corresponding patent rights everywhere in the EU in respect of the products made under that license. The point was left open by the EC in *Pharmos v. Heptel*.¹⁴

If this interpretation were upheld, the implications for technology license agreements, and the licensing of IP generally, in the EU would be considerable. A patentee/licensor who granted a license for any territory in the EU would find himself then unable to control competition by that licensee anywhere else in the EU except by way of accepted contractual restrictions. His valuable national patents or other intellectual property rights would be worthless in respect of any activities by that licensee so long as the licensee remained in force.

A certain degree of contractual protection by way of contractual restrictions is automatically exempted by the European Technology Transfer Regulation.¹⁵ For example, it exempts licensees limited to particular territories in the EC, and

obligations on a licensee to keep completely out of territories reserved by the patentee/licensor for himself, or licensed to other licensees, so long as there are parallel patents in those reserved territories.

The patentee/licensor may keep his own territories for himself, even against unlicensed or "passive" competition from licensees, so long as the patents are in force. But licensees are in a weaker position.

Licensees in different territories can only enjoy complete or absolute territorial protection from other licensees for a maximum period of five years from the date a licensed product is first marketed anywhere in the EC by any licensee. After that five-year period they can only enjoy "relative" territorial protection in that only "active" but not "passive" (i.e. unlicensed) sales into their territories may be prohibited contractually.

If a licensee and his licensee want better contractual protection than this may only be obtained by notifying the agreement to the European Commission and seeking an exemption.

This leaves open the question whether the licensee's patent rights remain intact and enforceable against any unauthorized and therefore infringing activities. The Regulation appears on the face of it to assist the licensee. In Article 2 of the Regulation various types of clauses are listed that are said to be "generally not restrictive of competition" and therefore may safely be included in a technology transfer agreement without prejudicing the automatic exemptions provided by the Regulation. These are often termed "white" clauses. One of these clauses (Article 2(b)(3)(b)) is a "reservation by the licensor of the right to exercise the rights conferred by a patent to oppose the exploitation of the technology by the licensee outside the licensed territory."

If the European Commission is right and simply granting a license for one territory exhausts all the licensor's rights not only in the patents for that territory but also the corresponding patents throughout the EC, this reservation of rights is worthless.

¹¹ Case No. 247/85, *CBM*, [1986] ECR II-1029 (referring to the patentee's obligation to improve and to file a new patent application).
¹² Case No. 23/89, *Pharmos v. Heptel* (1990) 13 CMLR 375 (1990) 13 CMLR 375 (1990) 13 CMLR 375.

¹³ *Centrafarm v. American Home Products* (1991) 13 CMLR 395.

¹⁴ *Pharmos v. Heptel* (1990) 13 CMLR 375.
¹⁵ Regulation No. 2400/93, *CBM* 375.

In my view the argument that granting a license for one territory exhausts corresponding EU patent rights generally is illogical and inconsistent with the emphasis in various decisions by the ECJ on the need for consent. Where a license allows a licensee to make and sell products under a particular patent in a particular territory, that should be the full extent of the consent. In deciding what rights have been exhausted, and to what extent, the court should look at the terms of the agreement and determine the scope of the "consent." Rights that are not the subject of the "consent" should not be exhausted. The patentee's rights will be exhausted in respect of any products properly made and marketed in the licensed territory. But the ability of the patentee to enforce his rights outside the scope of the license, which are unauthorized activities.

The recommended approach when drafting a license agreement must be to specify the limits of any license clearly in the agreement and unambiguously reserve patent rights in other territories. When drafting contractual restrictions on "passive" sales to comply with the five-year term envisaged by the Regulation, care should be taken that the provisions are not worded so as to amount to a consent to such activities after the expiry of the five-year term. The licensee should

make it plain that while the contractual restriction on "passive" sales shall endure for the five-year period only, on expiry of this term, he reserves all his patent rights, and does not consent to any such passive activities by the licensee.

COMPULSORY LICENSES

A product put on the market by a licensee pursuant to a voluntary license is clearly marketed with the consent of the licensor. In *Parsons v. British* the ECJ held that the same does not apply to a compulsory license.

The ECJ also held in *ACTO II*¹¹ that where trademarks of common origin are put into different ownership under compulsion (e.g., expropriation by the State) there is no "consent" and the new owner may rely on those trademarks to restrict sales of other, identically marked goods. In such a case the licensee has not "consented" to the licensee, not to products being made or sold under that license. His parallel patent rights are not thereby exhausted but remain fully enforceable to stop parallel imports of products made under the compulsory license.

VOLUNTARY ASSIGNMENTS

As we have seen, expropriation

of compulsory assignments, like a compulsory license, is not a consent. Is a voluntary assignment of a trademark, like a voluntary license, a consent? In *Med Simons*¹² the ECJ held that parallel assignment results in a "clean break" if it is so. As in the case of an expropriation the different owners may enforce their rights against one another's products.

The break must be "clean" and complete. In the case concerned there was a no remaining "economic link" at all between the assignor and assignee. The court said the parties would be different if the assignment were the implementation of an illegal market sharing agreement, or if the parties were linked economically so that there was effectively still some central or single quality control, a give the examples of patent, subsidiary, distributor, etc.

It is not clear from *Acto* just how, i.e. what degree of "economic link" is necessary before the break. Generally, parties who intend maintaining some links and/or not laboring after the assignment may not be covered, and should consider carefully the other advantages and disadvantages of licensing as against an assignment.

¹¹ [1992] ECR II-3303 (1992) 3 CMLR 571.

¹² [91] International Intellectual Capital 2 (1991) 3 CMLR 587.