Pharmaceutical Medicine, Biotechnology and European Law

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1 The free movement of goods I: pharmaceuticals, patents and parallel trade

W. R. Cornish

Parallel importation and intellectual property

This essay is not intended for specialists in intellectual property or European Community law. It is addressed to those who, from time to time, have to wrestle with the baffling issue of when it is legal to employ patents for inventions as a means of resisting 'parallel importation', and when as a matter of policy it is desirable to do so. My underlying aim is to set out arguments so that readers can judge for themselves. The arguments vary in relation to the different types of intellectual property – a factor which is often ignored in public debates. The distinctions involved are accordingly my starting point.

Intellectual property rights (IPRs) – patents, copyright, trade marks and so on – exist to prevent those who do not have the rightholder's licence from producing and trading in certain goods or services where otherwise they would be entitled to do so. IPRs indirectly provide their owners with a freedom to trade in a market without direct competition from those with whom they have no connection. Thus composers and record producers have copyrights which they can use to attack pirates who have made illegitimate copies of their music and records; patentees of inventions can prevent their rivals from incorporating the inventive idea into their products, machines and processes.

In essence, IPRs exist on a State-by-State basis and give rights against trading activities within national (or occasionally regional) boundaries. This strict concept of territoriality means that, for instance, patents for a given invention must be obtained for each country. In consequence, a patent may be granted for the invention in one State but not in another;¹

¹ This could occur because applications are not made in every country, or because the applicant fails to satisfy the legal tests for grant in some countries. The system of priority of rights, which operates internationally between different patent systems, ensures that it is extremely unusual for unconnected rivals to obtain the patent for the same invention in different countries.

or the equivalent patents may come to be owned by different persons in separate countries.²

The practice of parallel importation does not relate to unauthorised invasions of an exclusive right by pirates, counterfeiters and other exploiters of the protected subject-matter. It concerns trade in 'legitimate products' – goods which are initially produced and marketed by an IP rightholder, or by some associated company or licensee. Is the relevant intellectual property (be it patent, copyright, trade mark or whatever) available to stop the importation of such goods by an independent operator who quite properly buys them in one country and then tranships them to another?

This form of arbitrage sets in when the goods, though genuine rather than pirated, are differently priced in the two countries. The 'parallel importer' buys them from a proper source in the cheaper country and exports them to the more expensive place without seeking a licence, thus threatening the higher price (and generally, the higher profit) there obtaining. Does the scope of the IPR in this second country, the country of importation, require him to secure that licence, or is the right in that country subject to a rule of 'international exhaustion'? Will the answer to the question vary with the type of intellectual property in question? Will it depend on whether the product has been protected by intellectual property rights in the country where it is first marketed, so that the right-owner has already had one chance to sell free of competition from pirates and other product imitators?

In the years of IPR resurgence – the late eighties and early nineties – the United States sought to persuade negotiators of the TRIPs Agreement³ that there should be a blanket rule of non-exhaustion of all IPRs which would operate at the international level. This was proposed as a founding principle of fair (as distinct from free) trade for the brave new World Trade Organisation. The idea met a wave of hostility and no functioning rule on the subject was imposed on the States which are

² The degree to which one IP owner is likely to have coverage in most countries varies with the type of IPR. In the case of trade marks, the possibility of rival ownership of the same or very similar marks is not uncommon. By contrast, copyright in a work of authorship is likely to exist in all significant States. There will be greater variation in respect of the so-called 'neighbouring rights' to copyright, though the TRIPs Agreement takes some major steps towards ironing out the differences.

³ The GATT Uruguay Round, completed at Marrakesh in April 1994, created the World Trade Organisation (WTO) and included among the deals which that organisation now administers the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). TRIPs represents a very considerable advance in the cause of IP internationally, not least because States which do not fulfil their TRIPs obligations may be subjected by other States (doubtless at the instance of their industries) to GATT dispute settlement procedures, backed if necessary by counter-retaliatory measures, i.e. barriers to entry of any type of GATT goods or services into the objecting country.

now ratifying the TRIPs.⁴ The great majority of States consider that they are net losers from conceding IPRs, since, for the present, the really valuable rights will be owned by multinational enterprises; at best they hope to be buying some key to enhanced industrial development, which will bring its return through a gradual shift towards more domestic invention, creativity and production of goods and services. In the meantime, there is no reason to furnish a legal device which would prevent the importation of legitimate goods from cheaper markets abroad: hence, for instance, the recent introduction in New Zealand of a blanket rule in favour of international exhaustion for all intellectual property.⁵

IP policies: the divergences

Most of the world remains uninformed about IPRs. Yet if the problem over parallel imports is to be resolved in a way which makes reasonable sense, it is vital to have some grasp of the different types of protection, their particular subject-matter and the policy objectives at which the State is aiming in granting the right.

Patents are granted over technical and scientific conceptions which constitute inventions. They are therefore directed at ideas which, in a few outstanding cases, can have profound effects on the structure of industries and on the opportunities and benefits available to society as a whole. Such an effect emerges from time to time in the pharmaceutical industry, where patents can be granted both for substances which are shown for the first time to have therapeutic value and for the discovery of new uses for known substances. A new antihistamine or tranquilliser or whatever may effectively replace the drugs in previous use and the firm with the patent may increase in size and importance to a striking degree, at least for the duration of the patent.

The market power which the patent confers in these lucky cases

⁴ The outcome is the curious declaration in Article 6 (Exhaustion) that 'For the purposes of dispute settlement under this Agreement, subject to the provisions Articles 3 and 4 above [which guarantee national treatment and most-favoured-nation treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.'

Article 28 requires that national patent rights operate against the importation of the protected invention for use or sale. The argument has been made that this covers all importation including that of parallel goods, it being prohibited to argue that there is a right of exhaustion applying to them. Such a partisan proposition flies in the face of the negotiating history and the obvious intent that Member States should be left to decide for themselves whether or not to introduce international exhaustion for each type of IPR.

⁵ Much to the fury of sectors of US industry. In consequence, their Government's Trade Representatives threatened New Zealand with the special trade sanctions which still operate in the US alongside the rules of the revised GATT.

allows the patentee to behave as a monopolist in an economic, rather than a merely legal, sense. Because of this potential within the system the period of grant for patents around the world is twenty years from the application for protection (or some broadly equivalent period). In the case of pharmaceuticals and agrochemicals this period can be extended – in Europe, the US and certain other countries – to take account of delays in marketing imposed by the need to satisfy food and drug safety procedures.⁶

The invention for which a patent may be granted is based on technical knowledge which is there to be discovered, and often there is a race within an industry to uncover what is widely hoped to be the next step. In most countries the patent goes to the first to apply for protection, not the first to invent. That person will acquire an exclusive right which can be asserted even against those who reach the same results by independent research. This first-past-the-post element in the patent system is a distinctive characteristic and underscores the essential objectives in adopting such a system. Patents offer the incentive to undertake the investigations which lead first to invention and subsequently to a developed and marketable product. Their opportunities are entirely dependent on market responses.

The basic assumption is that the process of invention and industrial development is so economically and socially desirable that it must be induced by a special market opportunity for a limited period. At the same time, legal protection is given only if the invention is published to the rest of an industry in the patent specification. The system aims thereby to publicise information earlier than it might otherwise become available, and so prevent repetitious research and provide a block upon which others may build.

It is very difficult to show with any exactness how far the patent system produces the effects for which it is designed. Clearly it has greater impact in some industries than others, and by common consent it is most effective in the pharmaceutical and related fields. One indication of its value lies in the fact that, for all the doubting and criticism, the degree of its use around the world continues to grow. One thing, however, is clear: if there are to be incentives that lead to research and development, and to the publishing of successful results, they have to be sufficient. As with any lottery, the greater the potential prize, even against long odds, the more attractive the risk. If therefore a patent not only gives a right against competitors who adopt the invention but also shores up international price differentials for legitimate products, its

⁶ For further details on increasing patent protection, see below, chapter 8.

potential as a reward increases and the whole system grows in attractive power. In relation to patents, therefore, we can say that there is a real case for a rule of non-exhaustion: whether there are countervailing considerations which override it is something to which we shall come in a moment.

First, we must complete the distinctions which are needed from other forms of intellectual property. Copyright gives exclusive rights against the unauthorised copying and performing of literary and artistic works (in a broad sense), and also against misappropriations of subject-matter such as films, sound recordings and performances, which are costly to produce and much cheaper to imitate. Since protection is given only against a taking of the protected material, and therefore only to the particular expression embodied in the work or other material, and not to all embodiments of a general idea, it is plain that the prevention of unfair free-riding by others is a primary motivation behind the law's intervention (which, by way of balance, can be for much longer periods than under the patent system). But some measure of encouragement for what is culturally beneficial is also present here, and therefore raises some case in favour of a non-exhaustion rule, as with patents, though it is probably less pressing.

When we reach the law of trade marks and associated rules protecting the indicators which one competitor uses to distinguish his goods from those of others, the very purpose of the law's intervention is different. Exclusive rights are granted for marks and names in order, in some general sense, to protect their ability to indicate origin. So much is common ground. There are those today who argue that every aspect of the investment in marketing which can be associated with a mark should fall within the ambit of the property right in it; but that remains a highly controversial position, which has recently suffered some reverses at the hand of the ECJ.⁷

One aspect of this drive has been the claim that registered trade mark rights should not be subject to any concept of external exhaustion of rights. If such a rule is enacted without distinction, it must mean that even where a trade mark proprietor in two countries markets the same goods under the same mark in each country, those first sold in the cheaper market cannot be taken by a purchaser for resale in the dearer market. Since trade marks are applied to virtually all finished goods, such a rule places in the hands of international producers the private equivalent of a State ban on particular imports, in which the State will be implicated through use of its judicial and associated systems to

⁷ See below, chapter 2.

enforce the rights. The immediate losers under such a ban are consumers inside the more expensive market, and they, their politicians and their low-price retailers are often vociferous objectors, where parallel importation is not allowed. Accordingly there is a powerful case in favour of international exhaustion when it comes to trade marks. Its detailed examination is taken up in Isaac's chapter in this volume. The one point to be stressed here is that the trade mark situation is very different from that relating to patents.

A non-exhaustion of right rule for patents?

Parallel importation sets in only where there are price differentials between markets, and the reasons why these may occur are varied. Leaving aside for the moment the special conditions affecting pharmaceuticals, we may identify some recurrent circumstances affecting patented products in general:

- 1. Probably the commonest cause of differing price levels between countries is the shifting of exchange rates. Goods may start their sales life at equivalent prices and veer apart over time. There are always inhibitions on too readily altering prices within a given country. To this extent the differential is fortuitous and a non-exhaustion rule may be thought not to contribute greatly to the incentives underlying the patent grant. Nonetheless, if most patent systems have a non-exhaustion rule, patentees with protection across those systems can rely on protection of their prices in whichever markets for the moment have gained in value. To that extent, non-exhaustion may after all be considered a truly significant contributor to the incentive effect.
- 2. Marketing needs and practices may have various effects on comparative price levels. In a higher-priced country, the distribution system may be less competitive. That is not something which it is desirable to support. On the other hand, it may require greater advertising expenditure in order to get the inventive product known and sought after. Societies differ in many ways in their appreciation of products, particularly when they are novelties. Of course the over-selling of junk is not a desirable activity, but a market system has some inherent capacity to bypass the meretricious. In worthier cases, advertising expenditure will be justified and parallel importation from cheaper countries will take on the colour of undesirable free-riding. The profits of the practice go to the parallel importer who contributes nothing to the introduction or popularising of the product.
- 3. Economic and social conditions differ radically between the richest

and poorest nations, making it scarcely feasible for a novel product to be offered at equivalent prices in them all. There may well be good commercial and social reasons for getting the product to less developed countries at a price that at least some substantial sector of the populace can pay – obviously so in the case of new pharmaceuticals and medical aids, improvements in food production, ideas which can form the basis of local industry, materials and machines for use in education, and so on. Yet if these low-priced products can be exported to higher-priced markets so as to undermine the commercial prospects there, the products will either be marketed at industrial country prices (i.e., for the very few) or they will not be allowed on the developing market at all. This is surely a powerful argument against international exhaustion in relation to inventive products which have patents only for a strictly limited term, yet which are the subject of the strongest incentive policy in the whole IPR field.

4. Variations in quality may exist between the products put on different markets, which may explain price differences. Many factors may dictate these differences: climate, geographical conditions, consumer preferences, cost of materials, national standards, marketing and safety controls, and so on. To take an obvious, if rather unusual, case: a television set must comply with a country's technical standards for broadcasting if it is to be usable there. Whatever the cause, in such situations parallel imports bear a potential for misleading purchasers and other users, which may not be adequately met by clear advertising or labelling.

Exhaustion in the internal EC/EEA market

For a quarter of a century, it has been settled in principle that within the European Community (and latterly within the slightly wider range of the European Economic Area), patent rights are to be considered exhausted to the extent that they may not be used to prevent the importing of patented goods from one EEA State to another. This exhaustion comes about whenever the first marketing of the goods is by or with the consent of the owner of a patent for them in any of the countries, whether or not the invention is protected by a patent in that particular country.⁸ The same rule applies in relation to authors' rights, neighbouring rights to copyright, trade marks, names and similar symbols, and other intellectual property.⁹

⁸ For the case law, see below, pp. 18–19.

⁹ For the subject in detail see, e.g., W. R. Cornish, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights (4th edn, London: Sweet & Maxwell, 1999) ch. 18;

The rule arises from the Treaty of Rome itself, rather than from any specific rule of patent law. It is an interpretation of the Treaty's principle of free movement of goods between Member States (Article 28 (ex 30) EC),¹⁰ as it falls to be read in the light of the limited exception to that principle, allowing for the protection of 'industrial and commercial property' (Article 30 (ex 36) EC).¹¹ The ECJ concluded that while these provisions left Member States free to enforce the exclusive rights in patents against commercial activities of unconnected third parties (a power which was characterised as embracing the 'essence' of the right), the rights could not also relate to goods legitimately placed elsewhere on the internal market (this being a mere 'exercise' of the right).¹²

The incantations of 'essence' and 'exercise' made a poor substitute for plain reasoning,¹³ but the outcome was clear enough. The central EC policy of a unified market demanded that national patent and other IP laws should (if necessary) adopt a Community-wide doctrine of exhaustion once there had been consensual sale of the goods somewhere within the EC (or now the EEA).

'Consent' for these purposes arises wherever there is any connection – legal, economic, financial or technical – between enterprises.¹⁴ Thus if the marketing in France is by one subsidiary of a group, or by a manufacturing licensee, and the patentee in Britain is the parent company, or another subsidiary, or the licensor, none of the latter can object to parallel importation of the French product into England. Only if the patent has been assigned so as to belong to different owners in separate countries will there be no exhaustion.¹⁵ Even then, if this is a mere pretext within a continuing arrangement for splitting up the single

C. Bellamy and G. Child, *Common Market Law of Competition* (4th edn, London: Sweet & Maxwell, 1993) ch. 8.2; P. Oliver, *Free Movement of Goods in the European Community: Under Articles 30 to 36 to the Rome Treaty* (3rd edn, London: Sweet & Maxwell, 1996) ch. 8.2.

- ¹⁰ The prohibition in Article 28 EC, as between Member States, is of quantitative restrictions on imports or measures having equivalent effect. An example of the latter is an injunction enforcing an IPR.
- ¹¹ After allowing exceptions to Article 28 EC, Article 30 (ex 36) EC adds a proviso: 'such prohibitions or restrictions shall not, however, amount to a means of arbitrary discrimination nor to a disguised restriction on trade between Member States'. A law which gives preference to local over other EC nationals will involve arbitrary discrimination. What characterises a *disguised* restriction on trade is much less easy to identify.
- ¹² Centrafarm v. Sterling Drug [1974] ECR 1147; and the cases mentioned in the subsequent footnotes.
- ¹³ Later attempts to define the 'specific subject-matter' of the IPR went little further, since they were largely tautologous.
- ¹⁴ Centrafarm v. Sterling Drug, [1974] ECR 1147.
- ¹⁵ So held in relation to trade marks in *IHT* v. *Ideal Standard* [1994] ECR I-2789.

market, the arrangement may well be an infraction of the EC Rules of Competition (Article 81 (ex 85) EC).¹⁶

Most of the patent cases which have settled this basic principle have concerned pharmaceuticals, because in the variously regulated national markets for health products there tend to be considerable variations in prices. The products can generally be procured by determined parallel exporters and they are cheap to transport. Two types of issue have raised complications in pharmaceutical cases.

The reasons for price differentials

In the first determinative decision of the ECJ, *Centrafarm* v. *Sterling Drug*,¹⁷ the urinary infection drug in question had been bought in the UK by the parallel importer for half the Dutch price, and then exported to the Netherlands. The patentee, seeking to protect itself under Article 30 EC, emphasised a variety of explanations for that price differential, and also claimed that the public might receive defective products if distribution could not be controlled on a national basis. The Court would not accept that any of these grounds were sufficient to displace the free movement policy. In the particular case, the price differential followed very largely from currency fluctuations between the two countries. But, over and above that, the Court was strongly in favour of a clear, undifferentiated rule which fostered a basic objective of the single market, however much it might distort patenting policy.

The absence of patent protection in the country of export

Patent protection may not have been secured in all countries of the EEA. It may not have been applied for everywhere, or the application may have been rejected (or a granted patent annulled) for failing the tests of patent validity (patentable subject-matter, adequate disclosure, etc.). In previous decades, the issue has been exacerbated in the field of pharmaceuticals because of real or supposed legal inhibitions on the securing of patents, and in particular patents for substances with a therapeutic effect. Where the drug in question was not patented in one country, its price was often lower, since (subject to medical safety regulations) competitors could put it on the market there without any patent licence. Even under EU law there could not thereafter be any parallel importing of that competitor's goods into EU States where there was patent coverage. But if the patentee (or a licensee) went on to the

¹⁶ See, e.g., the root decision, Consten and Grundig v. EC Commission [1966] ECR 299.

¹⁷ [1974] ECR 1147.

free country's market, that was held by the ECJ to result in sales with the patentee's consent. The goods were therefore subject to the Community-wide exhaustion of the patent.¹⁸

Joliet (later an ECJ judge) led those who argued that this was inconsistent and unfair.¹⁹ Parallel imports subject to a patent could be resisted if they originated from any involuntary source. Indeed the Court applied this solution to the case where there were patents in both countries, but in the cheaper country a competitor was able to procure a compulsory licence from the State and so to enter the market without paying a full royalty, such as might have been negotiated voluntarily.²⁰ Yet where there was no IPR to protect the first marketing at all, the mere fact that a proprietor of rights elsewhere in the EC was connected with the goods when initially marketed made all the difference: the connection supplied 'consent' and no objection could be taken if they were afterwards exported to a Member State where there was a relevant patent. Yet the absence of a chance to make the first sale at a price derived from intellectual property protection could well explain the price differential at the root of the issue.

When Spain and Portugal joined the Union, the severe limitations on pharmaceutical patenting in their previous laws, combined with vigorous governmental price controls, meant that there had to be an interregnum against parallel exporting from those countries in this field as part of the terms of accession. When this intercession expired, the differentials remained serious enough for the issue to be brought back to the ECJ.²¹ Advocate-General Fennelly proposed a revision of the earlier approach, but the Court would not accept his advice. It considered that the demands of the free movement desideratum remained determinative.

The ECJ has been left to devise a policy for exhaustion of patent rights within the EEA because the issue is too controversial for political bodies with legislative powers. So far as the issue is a general one for patents as a whole, the results of the Court's decisions are likely to remain in their present uncomfortable state until it proves possible to introduce a Community patent. This project is currently stranded amid

- ¹⁸ Merck v. Stephar [1981] ECR 2063 (ECJ).
- ¹⁹ R. Joliet 'Patented Articles and the Free Movement of Goods within the EEC' [1975] 28 Current Legal Problems 15; P. Demaret, Patents, Territorial Restrictions and EEC Law: A Legal and Economic Analysis (Verlag Chemie, 1978); W. A. Rothnie, Parallel Imports (London: Sweet & Maxwell, 1993), ch. 6.
- ²⁰ Pharmon v. Hoechst [1985] ECR 2281. The case was only rather arbitrarily different from Musikvertrieb Membran v. GEMA [1981] ECR 147, which concerned a statutory licence of music copyright; in that case, the Court insisted upon Community-wide exhaustion.
- ²¹ Merck v. Primecrown [1997] 1 CMLR 83.

arguments about translation costs, which pit national emotions against the demands of efficiency. A Union-wide patent would settle whether or not there is to be protection of a claimed invention for the whole unified market; a concept of exhaustion of rights for that area would then follow the traditional concept of most patent systems. So far as concerns pharmaceutical patents in particular, it is not easy to discover just how damaging the free flow of the internal market is to patentees' profitability.²² There is nonetheless a case for a special rule disallowing parallel imports between one country and another, even where there is consent to the initial marketing, if in the country of first marketing there is a causal relationship between the low price there and governmental policies towards selling prices of the drugs concerned. Since progress towards establishing a true common market in pharmaceuticals is so beset with difficulties, the argument for such protection is the stronger. But there can be little realistic chance of it succeeding.

Patented products entering the EEA from outside

A different policy attitude appears to predominate in the EEA, when the question is whether patent rights may be used to prevent the entry into that area from countries outside it. The national laws of most Member States traditionally allowed the patent right to be asserted against the importation of patented goods even though they were initially marketed by the patentee or an associate elsewhere. There were differences in the principles to be applied, but these went to the issue of notice: must sufficient indication be given that no licence for international movement of the products was being granted? Or was there no exhaustion of right unless permission to import had been sufficiently given? In Britain, for instance, while the patent was conceived as continuing to apply to products deriving from the patentee, even after their sale to an independent owner, they were treated as bearing an implied licence allowing use and exportation unless that licence was expressly denied by conditions which were adequately notified to all purchasers down the chain of distribution.23

²² Cf. J. S. Chard and C. J. Mellor, 'Intellectual Property Rights and Parallel Imports' (1989) 12(1) World Economy 69; L. Hancher, 'The European Pharmaceutical Market: Problems of Partial Harmonisation' (1990) 15 European Law Review 9; REMIT Consultants, Report to EC Commission, 'Impediments to Parallel Trade in Pharmaceuticals within the EC' (1992, OPOCE, IV/90/06/01); Rothnie, Parallel Imports, esp. chs. 8, 11; R. Rozek and R. Rapp, Parallel Trade in Pharmaceuticals: The Impact of Welfare and Innovation (1992).

²³ Interestingly, the Japanese Supreme Court has recently introduced an equivalent principle into Japanese patent law: BBS Kraftfahrzeugtechnik v. Rashimekkusu (1995 H-

At present this result follows simply from the various national patent laws of the States concerned. There is as yet no overarching law, operating at the European level, which imposes a common solution upon all of the countries concerned. It is true that the States of the EU are signatories of the Community Patent Convention (CPC), originally of 1975 and revised in 1989. However, that Convention has not been brought into effect and will only become operative if the European Commission brings off its new campaign in favour of its introduction – still a problematic manoeuvre. It provides principally for the creation of a unitary patent for the entire EU territory. But will the patent specification for this instrument have to be translated into an official language of each Member State? To do so would be impracticably costly, yet not to do so would be deeply offensive to some national sensibilities.

Even in its present State of suspended animation, the CPC has had a considerable effect as a model for voluntary harmonisation of the national laws concerned. The CPC, Article 28 deals with the issue of parallel importation to the extent that it states:

The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territories of the Contracting States after that product has been put on the market in one of these States by the proprietor of the patent or with his express consent unless there are grounds which, under Community law, would justify the extension to such acts of the rights conferred by the patent.²⁴

When this takes effect, national patent laws are required to adopt the same principle of Community-wide exhaustion:²⁵ hence the introduction of the legal formula into those national laws in advance of the CPC requirement. In any case, so far as the internal market of the EEA is concerned, the Article only formulates in particular language the principle derived by the ECJ from Articles 28–30 of the EC Treaty.²⁶ Whether this necessarily implies that there is no exhaustion of rights when the patented products are first marketed outside the EEA is a matter still awaiting judicial consideration.²⁷ Certainly most States

7(O) Case 3 No. 1988, Judgment of 1 July 1997). For the impact of the principle in EU trade mark law, see below, chapter 2.

- ²⁶ See above, p. 18. The formula is distinctive in two elements: first, it makes exhaustion turn upon *express* consent – an attempt to prevent courts from presuming consent merely from failure to obtain patent protection in a given State; and second, it leaves room for future exceptions to exhaustion to be defined.
- ²⁷ The largely equivalent formula which is introduced into the now operative Regulation for a Community Trade Mark, and the associated First Harmonisation Directive on national trade mark law, has been argued to have just this effect by the European Commission and several Member States: see the *Silhouette* case, discussed below in

 $^{^{24}}$ The text has not yet been amended to make the principle embodied in it operative throughout the EEA.

²⁵ CPC, Article 76.

would assume that this is the correct implication to make, because, in one or other version, that is the traditional understanding of their own national patent law.

Until that point is reached, the British approach is as follows: when goods to which a British patent applies are imported from (say) the United States or the Far East, their entry into Britain requires the consent of the British patentee. If that authorisation has not been given, expressly or impliedly, the act of importation will infringe the patent, as will subsequent sales and uses. The authorisation will be assumed to be given, when the marketing of the goods abroad has been by the British patentee; it can be countermanded only by notification that importation into Britain is not after all permitted.²⁸ The notice must be such as will alert a reasonable man that such a condition is operative, even if he does not know precisely its terms. Moreover, that notification must have been sufficiently given to each person who acquires the goods down the chain of distribution,²⁹ a matter which may be difficult to prove.

The present British approach is regarded by some as the best outcome because it honours the expectation of buyers generally that they take ownership without conditions; yet at the same time it allows conditions to be imposed at the right-owner's behest if they are made plain enough in advance. But those who want to block parallel imports and who, at the same time, understand the British position amongst the differing solutions around the world, will make it their business to give the necessary notice. So it can be doubted whether this form of solution does much more than add expense and uncertainty to the manner in which the parallel movement of patented products can be prevented. It is certainly not a solution which advocates of international exhaustion ought to accept, and so not an outcome which they would want to see if, for example, the TRIPs Agreement were to be revised so as to lay down an international law rule on the subject.

In the end, the issue should be resolved one way or the other as a matter of law. Global industry is likely to benefit most by having a clear rule under which to operate. The hard fact is that countries and industrial groupings remain intensely divided on the question whether the economic balance is broadly for or against adopting a rule of exhaustion. That is not surprising, given in particular that a rule one way or the other is a choice for a long period across widely differing

chapter 2. In my idiosyncratic view, the judgment of the ECJ in that case does not go so far as to establish such a proposition, though in future the Court may well be obliged to accept it.

²⁸ Betts v. Wilmott (1871) LR 6 Ch App 239.

²⁹ Roussel Uclaf v. Hockley [1996] RPC 441.

industrial and commercial conditions. In the meantime, the world has accepted the need for patent systems and their use is growing. They are above all incentive systems, and necessarily their inducement will be enhanced if patentees can engage in international price discrimination. It is for the proponents of a rule of international exhaustion to establish that the case for it ought to overrule this basic objective of all patenting.