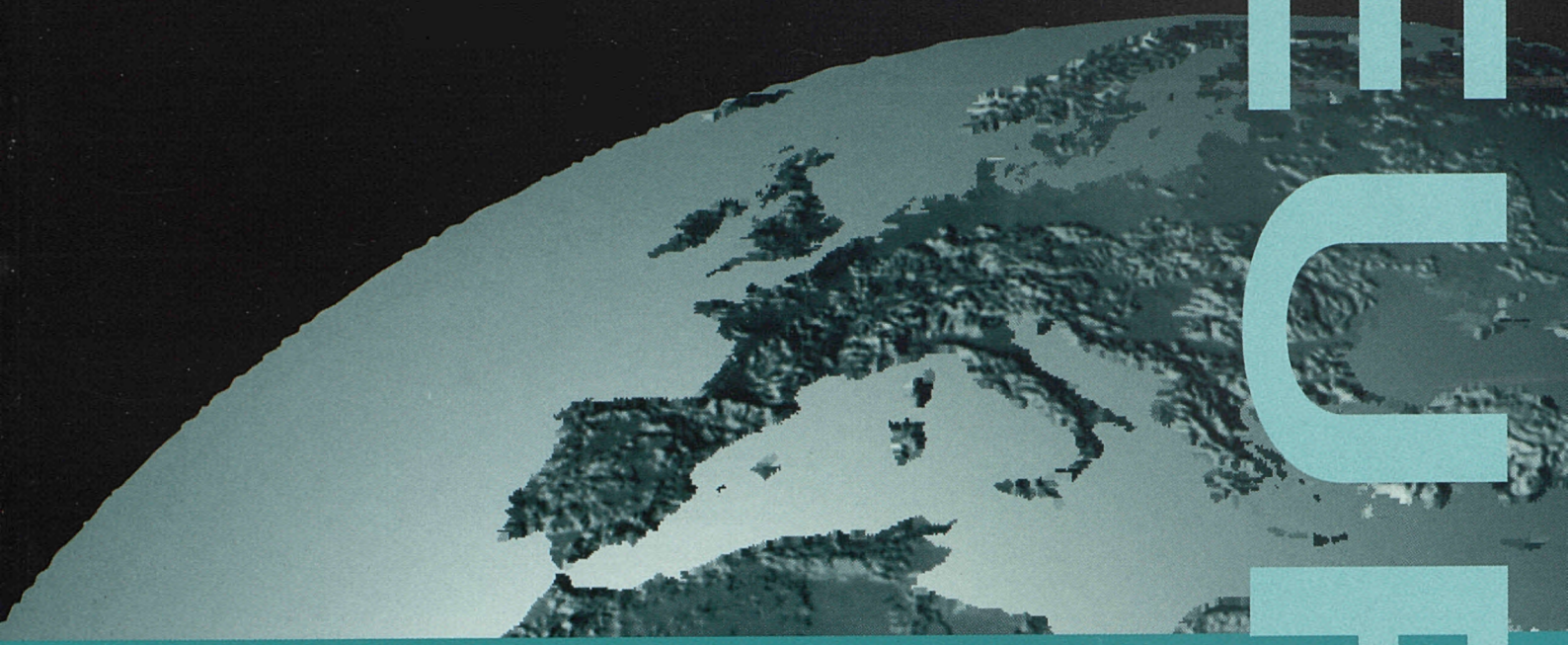
The Single Market Review



EUROPE

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Volume 4:

Industrial property rights

The Single Market Review

IMPACT ON SERVICES

INDUSTRIAL PROPERTY RIGHTS

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EUROPEAN COMMISSION

The Single Market Review

DISMANTLING OF BARRIERS

INDUSTRIAL PROPERTY RIGHTS

The Single Market Review

SUBSERIES III: VOLUME 4

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This report is part of a series of 39 studies commissioned from independent consultants in the context of a major review of the Single Market. The 1996 Single Market Review responds to a 1992 Council of Ministers Resolution calling on the European Commission to present an overall analysis of the effectiveness of measures taken in creating the Single Market. This review, which assesses the progress made in implementing the Single Market Programme, was coordinated by the Directorate-General 'Internal Market and Financial Services' (DG XV) and the Directorate-General 'Economic and Financial Affairs' (DG II) of the European Commission.

This document was prepared for the European Commission

by

CJA Consultants Ltd

It does not, however, express the Commission's official views. Whilst every reasonable effort has been made to provide accurate information in regard to the subject matter covered, the Consultants are not responsible for any remaining errors. All recommendations are made by the Consultants for the purpose of discussion. Neither the Commission nor the Consultants accept liability for the consequences of actions taken on the basis of the information contained herein.

The European Commission would like to express thanks to the external experts and representatives of firms and industry bodies for their contribution to the 1996 Single Market Review, and to this report in particular.

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List of abbreviations

ACEA	Association des constructeurs européens d'automobiles (Brussels)
Art	Article
CPC	Community Patent Convention
CPMP	Committee for Proprietary Medicinal Products
CTM	Community Trade Mark
CTMO	Community Trade Mark Office (see OHIM)
CTMR	Community Trade Mark Regulation
EC	European Community
ECJ	European Court of Justice
EMEA	European Medicines Evaluation Agency
EP	European Parliament
EPA	European Patent Attorney
EPC	European Patent Convention
EPL	Effective patent life
EPO	European Patent Office
EU	European Union
GATT	General Agreement on Tariffs and Trade
IHE	Institute of Higher Education
INN	International non-proprietary name
IP	Industrial Property — collective for Patents, Designs, Trade Marks and Utility Models
IPR	Industrial Property Right
NCE	New chemical entity
OHIM	Office for Harmonization in the Internal Market (Trade Marks and Designs), also called CTMO
OTC	Over the counter
PCT	Patent Convention Treaty
SMEs	Small & medium-sized enterprises
SPC	Supplementary Protection Certificate
TM	Trade mark
TRIPs	Trade Related Intellectual Property Rights
UM	Utility model
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Country codes

AT	Austria
BE	Belgium
DE	Germany
DK	Denmark
ES	Spain
FI	Finland
FR	France
GB	United Kingdom
GR	Greece
IE	Ireland
IT	Italy
Li	Liechtenstein
LU	Luxembourg
MC	Monaco
NL	Netherlands
PT	Portugal
SE	Sweden
CH	Switzerland
JA	Japan
US	USA

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Responsibility for the conclusions of the study is that of the consultants alone.

1. Summary

This summary is in two parts. Part I deals with the subject matter, mainly by type of industrial property, i.e. patents, trade marks, industrial designs and utility models. Part II summarizes key aspects of the report chapter by chapter. There is inevitably overlap between the two, but the dual approach may be helpful given the complexity of the subject.

1.1. Part I

1.1.1. General comments

The economic value of industrial property rights. The economic value of IPR could not be isolated as it is only one of many factors affecting investment. However it is clear that, qualitatively, for the high technology industries protection of intellectual property, in particular patents, is a key factor affecting investment. For many industries trade marks are among their most precious assets. 'Free circulation' is less a consideration than the level and quality of IP protection and its cost. There is in effect competition between differing means of obtaining IP protection, in which firms seek best overall value having regard to quality, speed, cost, and convenience, though the precise criteria will vary. Where research cost is high and production cost is low (as in pharmaceuticals), strong patent protection is needed in every country. Where production cost is relatively high, and the barriers to entry correspondingly high (as in the motor industry), patents may only be needed in those countries in which production takes place.

National rights. In considering the 'risks and rewards' of a one-stop shop for European industrial property protection, in all cases there are fewer risks for the user if a national option exists in parallel with any European option. While the provision of European rights is welcomed, only in recent years has EC action in the field of IP rights begun to be effective. There should be no attempt to weaken existing national rights. However, there was nearly unanimous support for really effective harmonization of national rights, as in a single market significant differences of interpretation by national law and/or national courts leads to problems, lack of clarity and increased costs.

Costs. The study revealed concern, particularly among users about the level of costs in the European Union, compared with the USA and Japan. This concern was not shared by those in private practice, who felt that costs were on the whole justified. Translation costs were singled out. Some felt that most of the translation work done at large cost was not used, and should be avoided. However, those from the smaller Member States were insistent on the need for translation. Suggestions included the use of machine translation; that only an abstract and the main claims should be translated unless opposition proceedings were opened; and an EC directive on translation requirements.

Courts. Because lack of homogeneity of enforcement of IP rights is of the greatest concern as a distortion of the single market, there was support for a possible EC initiative to provide courses, training and meeting opportunities for judges in specialist courts throughout the EC.

GATT TRIPs. These will be an important force in creating homogeneous IP law in WTO states, including EU Member States, though many EU states are behind in implementing the WTO agreement.

1.1.2. Patents

The various routes to obtaining patent protection – national, European Patent Office (EPO), Patent Convention Treaty – are generally considered useful. Different industries seek protection in widely different ways, from blanket multi-country coverage to protection in only a few key countries round the world. The absence of the possibility of opposition procedures in most national offices is regretted as denying the national patent a possible strength. The European Patent Convention (EPC) has harmonized national law as to grant and validity, though infringement and enforcement are not harmonized. Past inhomogeneity in term and patentable subject from some countries will remain until the year 2012. While the added value of the EPC may not be substantial in a tangible sense, because a national right could always be obtained, there are real gains because the standards of the EPO are respected and the possibility of oppositions, slow and expensive though they are, give authority and a good indication of value. There are in addition considerable gains in convenience and savings in costs through administration, and by avoiding translation costs, if the application is abandoned before grant (in comparison with a set of national filings where the translation has to be provided at once).

The system of national patents for limited areas and the European patent (in the form of a bundle of national patents obtained through the EPO) is not prejudicing the single market at the stage of grant. However, the laws of infringement and remedy are unharmonized, and this fragments the effect of patents on the single market. Once patents get into litigation the state of enforcement is very variable. Court procedures are wholly national. There is no common appeal court, and EPO opinions on validity are not relied on by national courts. Not surprisingly there is considerable concern about differing court systems.

The satisfactoriness of national courts differs considerably. Germany, France and Italy are regarded as satisfactory, while the UK, because of the cost, complexity and formalities of proceeding, is no longer so regarded. There was evidence of dissatisfaction in smaller countries on the grounds of slowness, cost, adequacy, certainty, legal and technical expertise of litigation.

The Community Patent Convention (CPC), still awaiting ratification, is unlikely to be used by industry because of one major perceived failing. A patent thus obtained could be rendered useless throughout the EC by virtue of a ruling on validity obtained in a country where courts are not specialist or expert. The study suggests a way forward. The CPC could be replaced by a directive and regulation, analogous to trade marks, which would make it mandatory that national courts, which would try cases for the whole of the EC, ask the EPO for an opinion on validity, and that there should always be a right of appeal to a European Court. Such a European model would be welcomed and used by industry.

The Supplementary Patent Certificate extending the patent life of pharmaceuticals was welcomed, as putting the EC industry at 'less of a disadvantage' compared to the USA and Japan. The extension of this to plant protection products was welcomed. A new directive on

the protection of biotechnological products will be welcomed provided that the draft is not weakened.

1.1.3. Trade marks

National trade mark legislation is supposed to have been harmonized but is still somewhat disparate. The Community Trade Mark Regulation (CTMR) provides the possibility of more efficient trade mark provision and a single mark for the EU, obtained with a single application. The evidence is that the Trade Mark Office, or Office for Harmonization in the Internal Market (OHIM), will be well used by companies in all sectors once confidence has been gained. There were fears about administrative overloading of the OHIM.

While the foregoing comments on court systems in regard to patents apply, the danger from a 'rogue' judgment on the validity of a mark in one Member State is lessened because, unlike patents, an EC trade mark can be converted without loss of priority into a set of national trade marks each with its own distinct validity.

In deciding whether the national route or the OHIM route will be used, the commercial circumstance of the proprietors dominate, and the decision will depend on corporate policy, size, and the trade mark portfolio.

The pharmaceutical industry expressed concern about the linkage of a requirement for a Community trade mark to clearance by the European Medicines Evaluation Agency.

1.1.4. Designs

An EC industrial design system is in draft. This is exactly similar, except for substantive law, to the Community trade mark system, and is in some cases recognized as being a useful alternative to a bundle of national rights. There is support for harmonization of national laws but, as indicated above, there is concern over national court procedures. The motor industry is concerned over design rights for spare parts, and seeks the deletion of the repair clause. The pharmaceutical industry is concerned that the repair clause will create a precedent for automatic compulsory licensing.

1.1.5. Utility models

Utility models do not exist in the national laws of a majority of EC Member States, and the study revealed no demand for an EC-wide right. Those states with utility models find them useful, but other Member States, and the motor and pharmaceutical industries, regard a further unexamined right as undesirable, not least on the grounds that it complicates the search process.

1.2. Part II

Chapter 2. The report aims to clarify the extent to which current and proposed EU legislation in the field of IP rights (notably patents, trade marks, industrial designs, utility models) are likely to achieve their objectives, and to examine the need for further action. It does this in the context of legislation and agreements at national, EU and international levels. It is based on consultation, using detailed questionnaires drawn up by IP experts, with expert IP practitioners in all Member States, in private practice and in industry. The answers were analysed by

leading experts and cross-checked with the respondents in a process which culminated in three seminars with the European Commission. The pharmaceutical industry and the motor industry were taken as case studies.

Chapter 3. Five alternative models for protecting IPR are briefly analysed, namely, national rights, the European Patent Convention, the draft Community Patent Convention, the Community trade mark solution, and a sole EC IPR system. There are few risks so long as the national option is preserved. Almost free competition between a system at EU level and a system at national level, allowing business to choose the system which in terms of its own criteria gives best results, seems to be the optimal solution. Points of importance include costs, ease of registration and the effectiveness of protection, including the ability to enforce rights throughout EU.

Chapter 4. The European Patent Convention (which is not strictly speaking an EC measure) harmonized national law as to grant and validity, but did not harmonize infringement or enforcement. The Community Trade Mark Regulation is the only EC-wide industrial property measure to have been concluded. National IP laws have developed separately but are slowly drawing together. The Trade Mark Directive and the Supplementary Patent Certificate harmonized national law on the one hand as to grant, validity, and infringement, and on the other as to the life of pharmaceutical patents.

Chapter 5. The greatest homogeneity of IP is found at present in patents through the EPO (although past inhomogeneity in term and patentable subject will last until 2012). Applicants gain from speed and simplicity. Competitors gain in speed of dissemination of information. There is some dissatisfaction with costs, especially of translation. Enforcement at national level is variable and a source of problems, not least because EPO opinions are not relied on by national courts. Trade marks will overtake patents in terms of homogeneity as the new Community trade mark becomes established, offering a single mark for the EU. It will be used by companies in all sectors once confidence has been gained. Slowness of opposition procedures for patents, and in future for trade marks, is a cause of concern. Easier and cheaper access to IP rights will encourage IP protection of innovation, and will therefore be a positive factor. Smaller and medium-sized enterprises, unsurprisingly, derive less benefit than larger companies both from national and from EU-wide schemes.

Chapter 6. Planned action on EC industrial designs is largely welcomed, with reservations by the car industry on spare parts, and by the pharmaceutical industry on the principle of compulsory licensing. While respondents were keen to retain existing national utility models, with possible harmonization through a directive, there was little or no support for an EC-wide right.

Chapter 7 describes international IP law and agreements including the Paris Convention and GATT TRIPs.

Chapter 8 contrasts national law in most Member States. Tables show key common features and variations of national law in the EU. Distortions (due to differing laws on infringement, practices on enforcement, and different degrees of expertise in courts) apply in the patent area and to some extent to trade marks.

Chapter 9. Problem areas in administrative and legal procedures and their effectiveness (international, European, and national in the 15 Member States) include divergence in clarity

(definition of rights) and in structures for upholding rights – sanctions and redress. Trade marks are the only existing EU model with coherent and logical procedural rules for application, grant, opposition infringement and enforcement of IP rights.

Chapter 10. Among the possible national and international arrangements for operators wishing to exploit their industrial property in different Member States, costs loom large for all companies. Representatives of some countries were insistent on the need for full translation, while industry representatives opposed this. Translation costs are highlighted as an area to be tackled: suggestions are made, perhaps by providing only a translation of a high quality abstract and the claims, unless litigation is anticipated, or by allowing delayed translation. A related directive may be the solution because the greater part of the problem appears to arise from national requirements.

In Chapters 11 and 12, the case studies of the motor and the pharmaceutical industries are treated similarly. For the pharmaceutical industry, protection of new chemical entities is of crucial importance. Patents are obtained in every EC Member State and are used offensively to prevent infringement. The SPC is of considerable importance. Action by the EU on a unitary patent option would be of interest, but only if the problem of expert courts at national level could be resolved. For the motor industry the trade mark, in which resides the image of the manufacturer, is extremely important. Patents are obtained only in major manufacturing countries round the world and are used increasingly by manufacturers and their first and second line suppliers in defining ownership and the framework for agreements, rather than offensively to prevent any infringements. Design rights are of importance especially for spare parts, but not for pharmaceutical companies. Utility models are not used by either industry.

Chapter 13. The effectiveness of EC measures in IP depends on the rights provided and whether those rights are respected and upheld. Subsidiary determinants relate to cost, speed, and convenience. Almost all respondents want homogeneity and a common source of case law providing clarity on the effective scope and validity of IP rights. At present there is considerable inhomogeneity. The Community Patent Convention will not be used by practitioners even if finally ratified. This is because of its fundamental problem relating to decisions by national and specialist courts for an EU patent right. This must be solved by mandatory opinions from the EPO and final appeal to the EPO/ECJ in a new EU patent system analogous to the CTM.

Chapter 14. Harmonization of IPR in the Member States of the EU is desired, while unitary rights are of interest only if the problem of uniformity in the courts can be solved. The EPO route to patents is considered to have many advantages. Its shortcomings include translation and renewal costs, and delays in opposition proceedings. The anti-counterfeiting regulation was considered to be disappointing due to problems in implementation by some member states. The CTM starts its life with much goodwill and high hopes, but the stalled Community Patent Convention appears fatally flawed by mistrust of the national courts that could determine the validity of a company patent at European level.

Chapter 15. It is not possible in general to provide quantitative figures for the value of IP. Qualitative ideas of its value are given and discussed in the context of investment and SMEs. IP is but one of a number of important considerations to be taken into account when a company is considering making an investment. Whilst strong IP rights do not guarantee

investment, it is more likely to occur if they are present. Patent filing figures are not reliable comparative measures of inventive activity.

Chapter 16. The 'law of exhaustion' applies within the EU but not (from the EU point of view) outside it. Whether national or EU, rights are exhausted as to the whole of the single market by an owner first putting his product or service on the market anywhere in the single market. This causes problems where the single market is ineffective in certain sectors. Rules for fair competition flow from decisions of the European Court of Justice and the action of the Commission in monitoring competition. Many of these rules are in a series of block exemptions from liability to register particular agreements for examination by the Commission when these consist of clauses approved by the regulation in question, some of which apply to IP.

Chapter 17. GATT agreements on Trade Related Intellectual Property Rights apply to the EU and should be, but have not been, included in national law in all Member States, although some have transposed them. TRIPs dictate that there shall be no difference between treatment of nationals and third countries for IPR, and there is no evidence nor complaint from third country companies of discrimination.

Chapter 18. The key flaw in the new measures, as they exist or are in draft form, is that they do not solve the problem of unsatisfactory enforcement of IPR in the national courts. Failure to reduce costs is criticized.

Chapter 19. Only in recent years has EC action in the field of IP rights begun to be effective. Industries have widely differing requirements of IP, and the continuance of national as well as EU level protection is important. The unratified CPC must be judged ineffective and flawed. Reliance on the European Patent Convention has been sensible and useful, but the lack of a common court system demands action by the EU. Flanking measures, such as the Supplementary Patent Certificate have been useful. The Trade Mark Regulation and Directive is welcomed even though untried. It contains risks, notably administratively, of being overwhelmed by applications. EU design proposals based on the trade mark model, still going through the legislative process, do not meet a wholly enthusiastic welcome, while utility model possibilities at EU level are not welcomed. All steps to harmonize IPR at national level are warmly welcomed, as is the idea of EU supported training for national courts. There is a need to act on 'fair competition' and IPR.

2. Introduction

This study of the impact of European Community action on systems for protection of industrial property rights was designed:

(a) to assess the effectiveness of action taken already at European Community level to create a single market for protection of industrial property;
(b) to gain a reliable guide to further action that is desirable;
(c) to produce results which can be used by the Commission with a high degree of confidence when it comes to deciding future action.

The approach to the study rejected over-reliance on simple 'market research', while using certain market research elements. The consultants agreed with the Commission's choice of motor vehicles and pharmaceuticals as being of particular interest for the sector studies and arranged to gain the co-operation of top level practitioners from major companies in these fields.

The study was based on the use of experts at several levels:

A **Project Co-ordinator** with wide EC industrial and legislative experience (Christopher Jackson) who held overall responsibility and structured the study.

Legal and Industry Co-ordinators – one a Queen's Counsel specializing in intellectual property (Amédée Turner QC), another an experienced industry practitioner in the field of intellectual and industrial property rights (Dr Peter Kolker). The methodology included cross-checking between the two experts in order that the practical and legal aspects of the law at international, European, EC and national level were properly assessed in the study.

The co-ordinators were responsible for parts of the study relating to international, European and EC law relating to the protection of industrial property rights, and for drawing conclusions from other parts of the study.

National Experts – these were senior national intellectual property lawyers and practitioners, covering all the EC Member States (except one), who provided expertise in that aspect of the study dealing with national law, in relation to SMEs, and in relation to a general approach to industrial property protection at all levels (see Table 2.1). They provided the description and analysis of national law, and cross-checking on other aspects.

Table 2.1. National experts

COUNTRY	NAME	COMPANY
AUSTRIA	Walter Holzer	Schütz u. Partner,Vienna
FRANCE	Richard Gilbey	Gilbey de Haas, Paris
FINLAND	Eva Grew	Oy Jalo Ant-Wuorinen, Helsinki
GERMANY	Ludwig Linder	Hasche & Eschenlohr, Hamburg
GREECE	Thanos Masoulas	Thanos Masoulas, Athens
IRELAND	Kieran Comerford	Comerford Technology, Dublin
ITALY	Francesca Moscone	Società Italiana Brevetti, Rome
NETHERLANDS	Charles Gielen	Nauta Dutilh, Amsterdam
PORTUGAL	Nuno Cruz	J. Pereira da Cruz, Lisbon
SPAIN	Dora Bandin	Elzaburu, Madrid
SWEDEN	Christer Onn	Awapatent AB, Stockholm
UNITED KINGDOM	Ian Baillie	Ladas & Parry, London

In Part One of the study the national experts provided assessments of their national law, and answered detailed questionnaires relating to EC and national IP law and its impact. The national experts also covered the impact of Community level protection on the costs of SMEs seeking EC level protection.

Part Two of the study involved industry experts – these were senior practitioners in companies throughout the EC (and outside), responsible for intellectual property management (see Table 2.2). They provided the practical assessment from the point of view of large companies, and gave key input to the case studies. They were drawn from major pharmaceutical and motor vehicle companies, with the addition of one other large multinational (Unilever), which is represented in all EC Member States, as a check.

Table 2.2. Industry experts

MOTOR EXPERTS		PHARMACEUTICAL EXPERTS	
COMPANY	**NAME**	**COMPANY**	**NAME**
ACEA	Marc Greven	AESGP	Hubertus Cranz
BMW	Dieter Löchelt	AWD	Erich Geissler
DAF	P. de Haan	BASF	Andreas Bieberbach
DAIMLER BENZ	Beata Lalk-Menzel	BAYER	Klaus Danner
FIAT	Paolo Sani	BRITISH BIOTECH	Nick Scott-Ram
FORD	Peter Orton	CIBA-GEIGY	Konrad Becker
HONDA	Amanda Bensted	EFPIA	Brian Ager
MAZDA	Kenji Matsuda	FUJISAWA	Atsushi Nagai
RENAULT	E. Srour	HOFFMANN-LA ROCHE	E. Notegen
SCANIA	Erland Holmborn	NOVO ALLE	Anne Secher
VOLVO	G. Bergquist	PFIZER	David Wood
		RHÔNE-POULENC	J. Savina
		SANDOZ	Brian Yorke
		SCHERING	H.-J. Schonherr
OTHER INDUSTRY EXPERTS		SMITHKLINE BEECHAM	Peter Cuelly
UNILEVER	Elizabeth Cratchley	TAKEDA CHEMICAL	Hiroshi Akimoto
		YAMANOUCHI PHARM.	Kunihiro Kurodo

The consultants thank all the experts for their valuable contributions and express particular gratitude to Elizabeth Cratchley (Unilever) and to Peter Orton (Ford) for additional help.

Part Two of the study provided a cross-check on the national level conclusions through the detailed studies of the motor and pharmaceutical sectors, and the responses of experts to detailed questionnaires.

It covered for each sector:

(a) the importance and role of industrial property protection in the sector;
(b) type of industrial property measures used and the relation between them (with examples);
(c) a list of, and commentary on, the factors contributing to the weight attached to industrial property as a strategic asset;
(d) competition, effectiveness of registration procedures, sector-specific considerations such as price/reimbursement policies or standardization of product specifications);
(e) current choice of registration procedure (national, Community or international) and reasons for this choice;
(f) assessment of Community harmonization measures and measures for creation of property rights, in terms of their effectiveness – a detailed analysis of the impact and effectiveness of new arrangements;
(g) consequences regarding costs of registering industrial property rights;
(h) consequences of elimination of obstacles to Community-wide exploitation of these rights, changes in the level of protection, legal certainty, any implications for time required to bring products covered by protection to market and consequences thereof;
(i) expected consequences of any remaining Community measures awaiting adoption;
(j) estimates of the impact of recent changes in the framework for protection of industrial property rights.

A synthesis was drawn up by the co-ordinators and circulated to the industry experts for further comment.

The experts were invited to comment on aspects of the general study, as previously explained, and in this context gave their views on future action by the Union which could be of benefit.

The contribution of industry experts was analysed and cross-checked with the companies on the basis of a written communication inviting representations. Responding companies were invited to assess points which emerged as being of particular importance and were given an open-ended opportunity to put forward other points thought of importance, together with their suggestions for European Community action.

Part Three of the study consisted of three one-day seminars hosted by the European Commission in Brussels, respectively for pharmaceuticals and motor vehicles; and for national experts. This proved to be a crucially important part of the methodology. The numbers and scope of those attending the seminars were limited, and the results must be taken as a qualitative, not quantitative, representation. Nevertheless, the degree of agreement among those attending the seminars indicated that the opinions expressed seemed representative of their particular sections. All three parts of the study thus reinforced each other and ensured that all conclusions were thoroughly checked.

In conclusion, the approach involved the use of experts at every level and in such a way as to provide significant cross-checking of results on at least three occasions. The Commission itself participated in the seminars.

The final report and summary includes conclusions 'which can be confidently applied on a Community-wide basis', both about the impact and effectiveness of EC legislation in the field of industrial property, and about the nature and scope of further action which might usefully be investigated by the Commission.

3. A benchmark: possible risks and rewards of an extended system of European protection of IPR, providing a one-stop shop

3.1. IPR owners, their competitors and the consumer public

Although, for the purposes of analysis, the interests of IPR owners are considered separately from those of their competitors, in real life nearly all companies are IP owners in some instances and competitors of such owners in others. Most companies want a balance of rights between owners and competitors of owners. The risks and rewards for each are considered; equally important, however, are the rewards and risks for the health of the economy of the single market and of the consumer in it.

It is necessary to consider the various possibilities for IPR protection in the single market from two other angles. The first is the effectiveness, efficiency, convenience, fairness and cost from the points of view of those directly affected, namely IPR holders and their competitors. The second is to consider whether, even if there are options in the system enabling industry and commerce to treat the single market as a frontier-free market, the system as a whole is in fact used by a substantial part of industry and commerce as a means of fragmentation of the market. This issue arises because even if there are market-wide IPR provisions for those who want them, there must remain national based IPR systems, at least to protect existing national IP rights. As a matter of law, existing property rights must under the Treaty of Rome be respected. In addition, many SMEs and individuals cannot be assumed to be able to afford or to want market-wide IPR. Furthermore, in the case of trade marks it would not be possible to confine rights to marks capable of EU-wide use, because many marks can only be local because language, if nothing else, means and always will mean that many marks could not be used EU-wide.

The continuing existence of these national-based IPR leaves industry and commerce with an option to use them rather than market-wide rights to maintain market fragmentation if they wish. Thus it is vital to consider whether EU-wide provisions will be sufficiently attractive to be widely used. The questionnaires addressed this point.

Before considering optimal solutions, it is necessary to consider the various possible forms of IPR protection theoretically possible in the single market. They are as follows.

3.2. Alternative models

3.2.1. Alternative One: one or a bundle of national IP rights

This is essentially the current situation. There can be one or a bundle of national IP rights up to the maximum number of Member States covering the whole of the single market. This requires sufficient harmonization of national laws by EU directives to ensure that rights are reasonably equivalent throughout the single market, because national differences create frontier conditions within the single market. For instance, different scopes of protection, or different effectiveness of court systems to prevent infringement represent grave fragmentation of the single market and prevent industry and commerce from treating the single market as one.

Therefore, even though IPR owners may decide that the effectiveness, efficiency, convenience, fairness and cost of each national system is adequate, it may nonetheless be necessary to impose harmonization because differences of substantive law, or of enforcement of remedies, fragment the single market. This is not a question which can be left solely to commerce and industry, because it may raise factors not necessarily related to their own interests.

A system of reliance solely on national rights (where they are granted) exists at present with regard to industrial designs and utility models, though the first is in the legislative process as a draft directive for harmonization of national law and the provision through a draft regulation of an optional parallel single-market-wide right, with single-market-wide enforcement and remedies. The second is under consideration possibly for the same treatment.

3.2.2. Alternative Two: the European Patent Convention

The second alternative is that of the European Patent Convention. (This can be considered for practical purposes to be a single market system, even though it includes Switzerland which is not in the EU.) This system provides a largely harmonized substantive law of patents relating to patentability, scope of protection and validity of patents, though recently certain lacunae in the fast developing technologies of biotechnology and computer software have become apparent and have led to different treatment by the national courts and patent offices of those subjects. Biotechnology is undergoing legislative procedure (a second attempt) for harmonization, and the second, computer software, should be similarly dealt with.

However, the laws of infringement and the court procedures for enforcement and remedy under this system remain wholly national. Undoubtedly, these factors lead to serious fragmentation of the single market because, although the fact of infringement is in practice probably dealt with fairly uniformly as to general principles in each Member State, the enforcement of patents and remedies (where there are serious differences of substantive law, extent of remedies and court procedures) is not subject to any unifying influences. Naturally, there is also the need to sue in each MS separately, with possible varying results in the single market.

This patent system provides an option between application, opposition and grant via the European Patent Office in Munich leading to as many national patents as the applicant wishes; and application, opposition (in some Member States) and grant in each country, where the procedures will vary quite substantially, even though the substantive law is harmonized by the European Patent Convention. Thereafter, each patent is treated nationally. There is, however, recourse to a single validity trial in the European Patent Office for patents originating from the EPO application procedures in the early stage of the life of a patent (called 'opposition'). In addition, courts can ask for validity opinions from the European Patent Office under Art. 25 EPC, though this apparently is never done, and is not binding.

This hybrid system as it stands undoubtedly fragments the single market. The differences with regard to infringement of patents and remedies as well as the differences with regard to court procedure are so great as basically to affect the nature of the patent in different countries and, because patent infringement cases are so complicated, these factors prevent companies from operating as if in a single market.

3.2.3. Alternative Three: the draft Community Patent Convention

A solution worked on for many years to avoid fragmentation of the single market by patent rights is the draft Community Patent Convention which provides for the option of a single Community-wide patent with (a) a uniform substantive law of validity, (b) a new single substantive law of infringement, (c) a common court system for enforcement and remedies.

The court system involves specialist national patent courts at first instance and on first appeal with jurisdiction for the whole of the EC, and a single common appeal court for final appeal.

The Convention has been seriously held up by constitutional issues, namely the failure of sufficient Member States to ratify it, and if the EU is to pass such a law it will presumably have to act by means of directive and regulation as it has done with trade marks; in this case it would be similar to the next case below.

3.2.4. Alternative Four: the new trade mark system

The new trade mark system operated by the Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM), running in parallel as an option to national systems, is an important variant on Alternative Three. The OHIM, which opened its office for applications on 1 January 1996 in Alicante, provides the same complete substantive law of trade marks as that being adopted by all Member States for their national trade mark systems in accordance with the EC directive. The Community Trade Mark Office (OHIM) in Alicante will examine applications for trade marks concerning the whole of the single market and oppositions thereto and subsequent validity issues. A court system is set up consisting of nationally designated Trade Mark Courts at first instance and first appeal which will try infringement and validity of Community Trade Marks granted by the Alicante Office with jurisdiction for the whole of the EC, with final appeal to the European Court of Justice (ECJ).

This system has the advantage of a common court system for infringement and validity with homogeneity of the law maintained through the final appeal to the ECJ. The system is untried and totally novel, but provides the prospect of establishing a single system of law without imposing unduly on national legal systems. It is similar to the basic court system which has grown up under the Treaty of Rome for EC law generally, in which there is final appeal from national courts to the ECJ on Community law matters. It is radically different, however, in that these nationally designated courts are dealing with subject matter (Community Trade Marks) relating to the whole of the Community regardless of frontiers and remedies over the whole of the EC. In the normal case, national courts only consider matters in their national jurisdiction; so this is an immense change.

In parallel, there exist national trade marks obtained by national registration with infringement and validity decided in national courts but with all substantive law harmonized throughout the EC by the EC Trade Mark Directive.

3.2.5. Alternative Five: a sole European Community IPR system

A further possibility, in theory, would be to institute a sole European Community IPR system where the only right was EC-wide. This, however, has never been considered, because it is not within the Treaty to replace national rights nor is it permitted to prejudice existing property rights. In addition, to do so might prejudice the interests of SMEs whose activities are often

only local and do not cover the single market. Furthermore, a sole trade mark law for the EC would be impossible, because many trade marks are incapable of being used in a single form throughout the Community.

3.3. Future options – patents, trade marks, industrial designs, utility models

3.3.1. Patents

The present system has been largely outlined in Section 3.2 above. Something must clearly be done to harmonize the law of patentability in biotechnology and computer software, as national variations of these arising from lacunae in the European Patent Convention fragment the single market in these two fields.

It is urgent to find a solution to the fragmentation of the single market arising from the different national substantive laws of infringement (not harmonized by the EPC) and the different national infringement court enforcement procedures and remedies. A court system such as that proposed in the at present inoperative Community Patent Convention (CPC) and as established by the Trade Mark Regulation could achieve this but for the difficulty of 'non-expert' courts. The requirement is for a court system which produces the same results in the same way with the same finality of decision at the same speed and cost throughout the single market. The proposed CPC, through its long delay in ratification, cannot achieve this as efficiently as would a regulation similar to the Trade Mark Regulation.

The biggest question here is whether this type of hybrid court system would work as it should (owing to real differences in levels of experience and expertise in different national patent courts) and whether such a system would obtain the confidence of industry and commerce. The views of industry, and suggested solutions, are given later in this report.

It would, of course, be necessary to maintain national patents for large local companies as well as SMEs which do not wish to obtain IP rights for the whole of the single market. Differences of court procedures for enforcement of national remedies have a serious effect on the single market when only national rights are concerned. However, harmonization of the substantive law of infringement (as done with trade marks), with uniform application of such substantive law in the courts, would be desirable. The importance of creating an alternative, sufficiently attractive EC-wide system is clear. However, a hybrid court system where designated national courts act for the whole of the EC will only be acceptable if a means is found to ensure confidence from industry in decisions on validity so made.

3.3.2. Trade marks

Trade marks have largely been covered in Section 3.2.4 above. It should be added here that there must always remain a parallel national system to the Community trade mark system, because many national trade marks are incapable of becoming single-market-wide marks because of language, and consequent confusion as to meaning owing to language rendering marks descriptive or misdescriptive in certain areas of the single market (both being grounds for invalidity), and finally because many marks only have, and their owners only wish them to have, limited-area reputation in only one or a number of Member States, or even more locally.

Different national court systems administering infringement, enforcement, and remedies should be no threat to the single market as national cases will presumably be normally

confined mostly to national trade marks which have no significance to the single market as a whole, and issues concerning wide areas of the single market will be pursued through the Community Trade Mark Court system set up by the regulation. Confidence in the efficacy of the court system for Community Trade Marks is essential to the success of the newly instituted system. This is considered later in this report.

3.3.3. Industrial designs

These rights are at present only national, though the optional parallel Community rights now being legislated, very similar to the Community trade marks system, have a qualified welcome. The draft directive also provides for substantial harmonization of the substantive law of such rights in national law. At present, national laws differ significantly in these respects. The lack of homogeneity of court systems and remedies should not cause any considerable fragmentation of the single market where national rights are concerned, especially if the proposed Community system is used by larger companies. However, support for this, especially the proposed court system, is qualified.

3.3.4. Utility models

Support for harmonization of national laws relating to utility models (very different in many respects from country to country) is patchy, and there seems to be no real support for a parallel EC-wide system.

4. Development of IP law as it affects industry in the European Union

4.1. Introduction

Because of long investment time scales, industry needs legal certainty, not least in IP. The period between invention and production may be years; indeed, in the pharmaceutical industry it is generally estimated at at least 10 years. Thus, for an industrial investment to be attractive, business has to have confidence in continuity in the macro-economic and political climate as well as this business prospect. Strong enforceable rights are essential in order to provide the environment for risk investment in research and development, from which new products and indeed new industries may result. The patent right provides exclusivity for inventions, the design right for industrially applied shapes and ornaments irrespective of artistic merit, and the trade mark by providing a connection between goods and their manufacturer or supplier, thereby conveying the connection of their manufacturer to the goods.

In the European Union IP rights in the various Member States have naturally been very dissimilar, but they are slowly being brought into line. There are still many differences, however, in scope, interpretation and enforcement, which create difficulties of inhomogeneity in the European Union.

4.2. Patents

The first major attempt at providing homogenization was the European Patent Convention (EPC) which came into effect on 1 June 1978. The EPC provides a route to prosecution and grant of a patent which leads to a national patent in all the countries designated in the initial application. The EPC patent has a term of 20 years from application and provides for patentability of any invention which is novel, inventive and capable of industrial application. EU Member States have now all enacted patent legislation which is based on the EPC. However, the transitional provisions in such statutes will mean that there will be inhomogeneity until 2012 in respect of term and patentable subject matter in the EU for patents applied for in some Member States before 1992. Any inhomogeneity leads to obvious uncertainty of protection and of exclusivity in a market which is intended to be homogeneous or unitary.

4.3. Industrial designs

Different national rights have been established in respect of industrial designs. However, one Member State, namely Greece, has no such Registered (or Industrial) Design statute. A draft directive and the draft regulation[1] show the intention to create an EU-wide harmonized law and unitary rights for designs; these will provide a single term and definition of protectable subject matter.

4.4. Utility models

No utility model law exists in the Benelux, Ireland, Sweden and the UK; and even where it does exist there are wide divergences of term and subject matter. Utility models cover inventions having very small inventive step. Consideration is being given to harmonization of law, and possibly a unitary, EU-wide right for utility models.[2] While this would *prima facie*

appear to be of advantage to industry in that the term and the subject matter of the right granted would be homogeneous throughout the EU, strong contrary views emerged in this study. They are discussed in 14.3.2.

4.5. Trade marks

The situation regarding trade marks is much more homogeneous. A trade mark can last indefinitely if it is used in a proper fashion and renewal fees are paid. All EU Member States broadly have had similar trade mark statutes for many years. The national trade mark law has been harmonized.[3] A major problem, which is that faced by the EU in a much greater context, is that of language. It is helpful, but not a legal necessity, from the aspect of free circulation of goods to have a single trade mark for a given product of a manufacturer for the whole of the EU. However, the differences of pronunciation and translation will mean that there will forever be serious impediments to attaining that objective.

The Community Trade Mark Regulation (CTMR)[4] came into effect on 1 January 1996, and the related office (OHIM) for consideration of the Community Trade Mark (CTM) applications opened on 1 April 1996. The CTMR provides for the registration of a single mark for the EU. However, it is subject to invalidation by the adverse decision of a court in any Member State. In the event that a CTM is invalid, the proprietor can obtain national marks without loss of priority where no objection exists. This is of major importance. It is too soon to judge the performance and attraction of the CTM and OHIM.

4.6. Enforcement

At present, enforcement is for national courts to determine. Enforcement of IP rights is very variable in the national courts of the EU Member States, which is itself not conducive to a unitary market. This is not as serious as might be expected, for, having regard to the long tradition of national litigation, industry can still often predict how the litigation will progress and result; in other words, there is some degree of certainty for industry, even though there is serious fragmentation of the single market because of the different national court attitudes. Litigation in a given country such as that of the infringer, for a unitary EU right even though there is appeal at EU level, would present an unacceptable risk to industry; hence, without considerable improvement to the present local situations such a unitary right is not likely to be used. Thus, a major problem to be addressed is the enforcement in the EU of IP rights, bearing in mind the importance of expense and the dangers of unacceptable delay and long litigation.

4.7. Costs of IP

In almost all industries, cost cutting is of great competitive importance, and there is no doubt that for most industries the cost of IP is a significant factor in determining whether companies seek IP protection and in how many countries. The EPC, although itself by no means inexpensive, has helped by enabling a single prosecution route to patent grant, so delaying the expensive costs of translation until it can be more accurately estimated whether the patent is likely to be of commercial interest. Translations are not a factor in obtaining design registration, or in trade marks where generally only the description of the goods is translated, but for utility models translations of the specification and claims are still required.

Thus, whilst there has been, and there is ongoing, improvement in the level of and the homogeneity of IP rights in the European Union to the advantage of industry, much needs to be done towards increasing uniformity of the IP rights available. Many companies, and not only SMEs, may only require rights in a single or very few Member States for a variety of reasons, for instance costs of production, limited market for the associated products, or high entry barriers in other countries. Thus, rights granted in individual countries must always remain as an alternative option for all companies to use without prejudice.

5. Current EC legislation: assessment and analysis

5.1. Patents

5.1.1. Homogeneity

The greatest homogeneity of IPR is found in the patent area (though trade marks will probably overtake patents in this respect as the new Community Trade Mark and the wholly harmonized national substantive trade mark law come into full use). The EPC has been the foundation for similar patent statutes in all EU Member States, some concurrent with the start of the EPO in June 1978, and others as they have joined the EU or availed themselves of transition provisions in the EPC (Article 167). Now, all EU Member States have patent statutes in line with the EPC. However, there is inhomogeneity in term and patentable subject matter which will last until 2012. Several respondents considered this to be a real difficulty. This inhomogeneity arises in countries where the term of a patent was different from the 20 years provided in the EPC. Certain subject matter was not patentable before a given date (e.g. chemical compounds: Austria, October 1986; Spain, Greece, October 1992; Portugal, January 1992). Therefore, at present there are essentially corresponding patents in Europe having different terms and claiming different subject matter. 'In the pharmaceutical industry we are very concerned by this problem due to lack of protection (of chemical products) in countries like Greece, Spain, Austria...'

The EPO itself has enjoyed, rightly, a high reputation in the examination of patent applications and the granting of patents. It is popular as a filing route, either directly or through the Patent Convention Treaty (PCT), for industry in general and is used where patent property in four or more countries in Europe is desired. It has created generally sound and logical case law, which is to a large extent followed by European countries in the national courts; though there are some major and worrying exceptions, and some other concerns with the EPO, all of which are discussed later.

On the general question as to whether the European Patent or national patent is preferable, the general view is that it depends on the number of countries one is concerned with, with some inclination to suggest that SMEs prefer national patents, but this is only on the ground of the width and scope of their activities.

5.1.2. Value

The added value of the EPC is, however, not substantial in a tangible sense, compared to the inherent value of the IP right, because it can be reasonably assumed that patents would have been obtained by the national route in the absence of the EPC. Thus, the financial advantage to companies of the EPC has been twofold. Firstly, an administrative saving as a single patent attorney, often in-house, has been able to file and prosecute patent applications, rather than use patent attorneys in all the countries where filing is sought. Secondly, a saving may be made by avoiding translation costs if the application is abandoned before EP grant (in the national route, a translation has to be submitted on filing).

The EPC has also benefited companies, patentees and third parties, by providing homogeneity in patent law up to the stage of grant.

5.1.3. Information

An important advantage gained by competitors through the EPO is the speed of dissemination of information. The patent bargain includes publication of the subject matter of the patent grant; the patent applications in the EPO are published 18 months or so after filing (or priority date, whichever is the earlier), generally weekly on a Wednesday. Those specifications are available on CD-ROM (EPO ESPACE system) and hence are text-searchable; also the EPO supplies a CD-ROM giving quarterly data (for example applicant, titles, classification, dates) to allow access to the weekly CD-ROMs. This greatly increases current awareness of technical developments and company activity, and provides an example followed by many national offices.

The existing EPC system clearly caters for the need of any putative patentee who is interested in treating the single market, or large areas of it, as one for the purposes of obtaining his right. Furthermore, the answer is the same for large and small companies, and it therefore appears that small companies are not disadvantaged so far as widespread single market activities are concerned.

5.1.4. Speed of proceedings

Generally speaking, practically, regardless of size of company, the speed of the proceedings for grant of patents by either national offices or the EPO is considered satisfactory. In a few cases answers suggest that the speed is not as satisfactory for SMEs, and practitioners in a few countries consider that the EPO is a little more or less satisfactory than proceedings in their own country. The same goes for cost, and again there is little suggestion that conditions are less satisfactory from the point of view of SMEs than from that of large companies.

5.1.5. Translation cost

There is, however, somewhat greater dissatisfaction with costs in the EPO than in national patent offices and it is suggested – mainly by industry – that translation costs are a burden. Although there is some support for the solution of translations only for the claims or for the technical abstract, many oppose this on the grounds that it would give less certainty of scope of protection to third parties. It is, however, clear that European patent costs are, in terms of international comparisons, high, and this must be a competitive disadvantage.

5.1.6. Opposition

On the effect of the opposition proceedings from the patentee's point of view, most respondents say that these (available in the EPO and in a number of national patent offices) are helpful to the patentee. The reason for this is that early opposition gives the patentee a good measure of the valid scope of his monopoly and presumably also because it makes him aware of industry concern over his patent. In practically all cases, competitors of patentees are regarded as finding the right to oppose helpful. There is, however, general complaint that EPO oppositions are too slow, some respondents specifically complaining about the possibility of adding further grounds of opposition throughout the proceedings. In general, the cost of the proceedings in the EPO is complained about. Again, however, there is not much indication that small companies find cost more unsatisfactory than do large company patentees. The problem of attending oral hearings from more distant Member States is referred to, and

teleconferencing is suggested for this purpose. Cost and slow procedures concern competitors of patentees in opposition proceedings (i.e. opponents) about as much as they do patentees.

5.1.7. Clarity

Patentees generally find that their granted patents define their rights reasonably clearly and that it is possible to negotiate licences with potential users satisfactorily on the basis of their patents without resorting to litigation. Generally speaking, patentees do not think that less complex patent granting procedures could attain satisfactory results. Competitors of patentees are satisfied with the clarity and certainty of the monopoly defined in patent grants, and again there is no difference between large companies and SMEs.

The conclusion on all aspects of patents, apart from litigation, is therefore that national patents are generally regarded as satisfactory by both patentees and their competitors (presumably when protection is only wanted in one or two countries, because for more than this number the EPO is resorted to by patentees). The EPO-granted patent (resulting in a bundle of national patents), and opposition proceedings therein, are regarded as satisfactory by both sides when the territory of three or more Member States comprises the potential area of concern. However, the solution to this in so far as translation (often referred to as a reason for high cost) is concerned, is not agreed, because there is a view that translations are necessary for clarity. Furthermore, it must be remembered that translation would be required to an even greater extent if only national applications covering the single market were available. The complaint therefore presumably is that the expected cost advantage of EPO applications over separate applications in each Member State is not as great as applicants for patents would have hoped. The cost complaint in EPO opposition proceedings (cost of oral proceedings and of adding further grounds as an opposition proceeds) is a matter which could more easily be alleviated.

The flavour of responses is given in the following quotations: 'Because we file our inventions in most of the EPO countries, the EPO procedure is cheaper [than] the sum of national patent applications.' 'Good examination and opposition grant procedures [give] better knowledge of strength and weakness.' 'EU is driving the standards of patents up and encouraging a high level of effectiveness throughout the EU.' 'EPC: Very important in unifying patenting in the EU. It had a rather large impact, is rather effective and very valuable.' 'We generally use the European route for patents.' 'Better examination of EPO has some value after grant.'

5.1.8. National patents

In general, however, national patents for limited areas of the single market, and European patents (i.e. a bundle of national patents granted through the EPO) for wider areas, are not prejudicing the single market as at present operated. This does not, however, apply once patents get into litigation.

In the matter of enforcement, the situation in Europe is very variable. For instance, the possibility of gaining an interlocutory injunction in a patent action is in the UK very good, in Germany good, in France poor, in Spain almost impossible. The statutes of limitations are similarly variable, thus dictating by when action must be taken – UK 6 years, Germany 3 years (unless infringer and act unknown then 30 years), France 3 years. In some countries there are specialist IP courts (e.g. UK, Germany), but in most others the courts are not specialist and hence not used to dealing with technical, commercial and to them maybe obscure points of

detail. The importance to industry of speed in resolution of IP matters is not felt to be appreciated, even by the EPO where an opposition can take many years. Without better enforcement procedures, IP will not be respected as it should, to the detriment of business generally.

The real test of the effect of patents on the single market comes when patent litigation arises. Here also is the real test as to whether patentees and their competitors want a system which reflects the characteristics of a single market. Although the grant of a patent, opposition to it, and the substantive rules of patentability have been harmonized since the European Patent Convention was put into effect, there has not been the slightest harmonization of the substantive law of infringement or of court procedures, which are wholly national. Remedies must be sought in each Member State under the laws of that state. Furthermore, there is no common appeal court to ensure that even the harmonized part of the law (patentability) is applied uniformly in the single market.

A most notable answer of the respondents is that EPO opinions on validity are not relied on in the national courts. Thus, even the limited degree of harmonization of court decisions over validity open to the national courts is not used by them. It is not at all clear that patentees accept a decision made in one Member State court when contemplating litigation in another Member State. They presumably are prepared to litigate again. On the other hand, competitors (defendants) do appear to accept a decision in one Member State when the matter arises in others. This suggests that patentees use the fragmentation of the court system to their advantage, while competitors of patentees do not. Needless to say, national patents and European patents (as they are essentially the same) are regarded as equivalent in litigation by all respondents when considering satisfaction or otherwise with litigation.

The satisfactoriness or otherwise of national courts differs considerably. Germany, France and Italy are regarded as satisfactory. The UK, because of the great cost, complication and the 'formalities' of proceedings, is regarded as unsatisfactory. In the Anglo-Saxon system oral evidence, cross-examination and the adversarial system are no longer appreciated as they once were. Many smaller countries are dissatisfied, even highly dissatisfied, with litigation in their own countries also on the ground of slowness and cost and adequacy, certainty and effectiveness of their remedies. The same attitudes exist among the competitors of patentees (the defendants) in each Member State among the patentees. The difference of attitude between large companies and SMEs is not particularly notable.

Invalidity proceedings brought by a competitor against a patentee (i.e. in cases where the latter has not alleged infringement) are available in most Member States and are considered helpful. Attitudes to court procedures follow the attitudes expressed above over infringement proceedings.

The present fragmentation of the single market by the patent system is thought to be of disadvantage to large companies. There is no overt suggestion that fragmentation could be advantageous to owners of patent rights.

On the vital question as to whether to reduce fragmentation by harmonizing the court system by giving national patent courts EU-wide jurisdiction, as in the draft Community Patent Convention, with a common court of final appeal, among the national experts one respondent states firmly that this should only be done if the national court procedures are harmonized.

One, while welcoming a common court of appeal is open-minded about reliance or national courts having EU-wide jurisdiction. One favours the latter so long as 'forum shopping' is controlled. Three find the present fragmented court system satisfactory. However, the industry answers are quite clear that reliance on national courts as they now exist is unacceptable. This was strongly reinforced in the seminars.

It is clear, therefore, that there is discontent with national courts in most countries except Germany, France, and Italy (and presumably respondents from these countries would find the courts in other Member States, on which they would have to rely for single market wide actions, unsatisfactory). Face to face discussion among the respondents at the seminars established that there would be confidence in reliance on national courts to try Community patents, as long as an opinion of the EPO was mandatory in the national courts.

5.1.9. The Supplementary Protection Certificate

The Supplementary Protection Certificate (SPC), which provides patent term restoration for pharmaceutical products, was introduced by regulation on 2 January 1993.[1] It will be an encouragement to the innovative industry, which is a major employer in the EU and provides a large positive balance of external trade. The SPC is of considerable value to the innovative pharmaceutical company. If it is realized that the SPC restores patent life at the end of the normal term when sales of a patent medicine are at its highest, then to be able to ward off competition from a direct copy is financially very valuable to that company. Because sales of a single patented medicine might in the EU be, for example, ECU 1 million, but the sales in ECU terms from the innovator can fall by 50% within five years of patent expiry, the SPC is clearly of considerable assistance to the innovator, in an environment where innovation is becoming more difficult and less successful in producing NCEs (see Figure 12.1). Such incentive to innovation is also in the interests of the generic medicines industry, because without a supply of new medicines, they would have nothing to copy. The SPC will delay their access to a new medicine by a few years, but in the long run may well have no net effect on them. The SPC also now puts industry in the EU less at a disadvantage to those in Japan and the USA. As one respondent said: 'Given the long time-scale for developing pharmaceutical drugs, there is usually about eight years of effective life to recoup the R&D investment. The need for SPCs is therefore critical to this process.'

5.2. Trade marks

5.2.1. Homogeneity

In the area of trade marks, the national statutes are supposed to have been wholly harmonized, but have been somewhat disparate. The Community Trade Mark Regulation will provide the possibility of more efficient trade mark prosecution and a single mark for the EU. The regulation only came into effect in January 1996, and hence it is too early for definitive trends and effects to have been established. However, a single mark is highly desirable for trade within the Member States in what is essentially a common market. From the replies to the questionnaires, it is clearly apparent that the Community Trade Mark Office (OHIM) will be well used by companies in all sectors, once confidence has been gained as to its efficiency and

[1] Council Regulation (EEC) No 1768/92, OJ L 182, 2.7.1992, p. 1.

recognition in the Member States. There are indications that its use may grow so fast that problems of overload may occur. The growth in use of the EPO is an interesting precedent.

5.2.2. Options

The new trade mark regime instituted on 1 April 1996 provides two options. On the one hand, of registration of trade marks in national trade mark offices, with national court action relating to their infringement and with no appeal beyond the national courts. On the other hand, registration with the Community Trade Mark Office which covers the whole EU, with court action in the nationally designated trade mark court appropriate to the proper forum for the trial, and with eventual appeal to the European Court of Justice.

This new choice of routes to trade mark registration and for subsequent court proceedings in the exercise of the proprietor's rights has led at this very early stage to a variety of attitudes as to best use for the Community option. Some professional advisers say that when registering a new mark a large company should register simultaneously nationally and with the OHIM and that SMEs should register with the OHIM only. Others recommend that SMEs should only register in the appropriate national offices. Some say that both large and small companies should only register new marks with the OHIM and others that all companies should register with the OHIM and the appropriate national offices. Others, finally, say that SMEs should register only in the national offices, while large companies should register in both. It is clear that views have not yet crystallized.

Where policy towards already existing trade marks registered in national offices is concerned, most advisers say that large and small companies should now also register their existing marks with the OHIM. There is equal variety as above on the question as to whether to maintain national registrations once OHIM registrations have been successfully obtained. Some recommend maintaining the national marks for five years; others say that both large and small companies should allow national registrations to lapse. Obtaining OHIM registrations is recommended when a proprietor would, in the absence of the OHIM, intend to obtain in general three to four national registrations. Higher minima of 7 or 8 or even 12 national registrations are recommended by some practitioners for SMEs as justifying OHIM registration.

5.2.3. Convenience and cost

Procedures for obtaining national registrations are generally regarded as convenient and reasonable in cost, though there are complaints over a few national trade mark offices. The convenience and cost of OHIM grants are naturally regarded more neutrally at this early stage, though there is little indication of premonition of unfavourable conclusions in these respects once experience is gained. Initial signs are that the OHIM will attract many more Community trade mark applications than expected, causing fears that prosecution and registration will be delayed.

5.2.4. Clarity

There is fair confidence on the part of proprietors that nationally granted trade marks and OHIM registrations are and will be sufficiently clear to obtain the respect of competitors without litigation. In no case is a distinction in this regard made between the two types of

registration. On the part of competitors of proprietors also, grants are considered to be clear and to enable policy decisions to be taken without resort to litigation in most cases.

5.2.5. Opposition

There is very general support for the availability of opposition proceedings on the part of applicants as strengthening their registrations, and by the proprietors' competitors for the procedure as being of benefit to them too. However, on the part of both proprietors and competitors the slowness of opposition proceedings is heavily criticized nationally, and is not expected to be better through OHIM. Here is an area for improvement. The cost of opposition proceedings is criticized to a lesser extent both from experience in national offices and on the grounds of expectations as to the OHIM. This is the case equally for large and small companies.

Views with regard to litigation are roughly equally divided as to whether the convenience, speed and cost are acceptable in national actions. Satisfaction on these points is a little more pessimistic with regard to the proposed CTM court system. There is little differentiation between large and small companies. There is a general view that more costly procedures would not improve the system.

5.2.6. Remedies

The effectiveness and certainty of court remedies are generally acceptable on the part of both proprietors and defendants. Invalidity proceedings are regarded somewhat less favourably by competitors to proprietors of registered marks.

The general picture is, therefore, of both proprietors and their competitors having confidence and satisfaction over the existing national registration to which they are accustomed, and to their projecting onto the new CTM registration and opposition procedures and onto the new court system much of this confidence. It is interesting to note the extent to which the new system is accepted with equanimity compared with the doubtful views as to the similar proposed reliance on national courts for the patent system proposed in the draft Community Patent Convention. In the latter case, the seminars disclosed that there would only be confidence in such a court system if validity was decided by a mandatory opinion of the EPO.

Finally, there is a clear view that in deciding between national registrations and CTM registration the commercial circumstances of the proprietors dominate, whether the company is large or small, the decision in each case depending on corporate market policy with regard to the single market, expansion plans, management requirements and the size and complexity of the trade mark portfolio.

'For the future we intend to use principally the CTM.' 'Will help globalization of the IP Group.' 'Easier to license if a single trade mark.' 'The chance for the CTM is to be faster, cheaper and more efficient than other systems.' 'For us, the SPC and CTM are the most important [measures] to our company.'

There is a generally open and not unfavourable attitude to the new court system of the Community trade mark, an unqualified welcome for the Single Final Appeal Court and an open minded attitude to the designation of national courts of first instance and first appeal. But

doubts are expressed as to the equal effectiveness to be expected from all such nationally designated courts.

Generally, it is considered that the option to treat the single market from a trade mark point of view as unfragmented will be more attractive to large companies. There is, however, recognition that in some circumstances the option to continue a fragmented approach to the single market from the point of view of trade marks may be attractive. There is certainly no suggestion that this would be generally sought after in the trade mark field. The seminar showed that where an applicant for CTM only intended to use it in a limited area, the rest of the EC would be blocked. However, this could only happen if no other company was interested in the trade mark in question; furthermore, it is legitimate to register for a CTM in order to give the opportunity of future development of one's market to cover the whole area.

6. Planned and future EC legislation

The Community trade mark system is of course now in being, though as yet unproven.

6.1. Industrial designs

The only measure in draft is the EC industrial design system which is exactly similar (except for substantive law) to the Community trade mark system. It will run in parallel with newly harmonized national systems provided for in the Amended Proposal for a European Parliament and Council directive on the legal protection of designs[2] and the Proposal for a European Parliament and Council Regulation on the Community Design.[3]

Responses to the questionnaires are predicated on the assumption that a Community industrial design system is established as provided for in the draft directive and draft regulation.

In practically all cases the respondents would apply for a Community industrial design rather than national registration both for large and small companies, and the minimum number of Member States for which the applicant wanted protection to justify this was four or five, and in some cases three – without regard to size of company. Except in a few cases, there is general satisfaction with the speed and cost of present national grant procedures. Registration procedures should be kept simple, even though some wish that there were clear claims to scope of novelty, provided this did not increase cost. In one or two cases, there are complaints about the inefficiency of the national offices.

Generally, however, resulting grants are not considered by industrial design owners likely to be sufficiently effective for them to be accepted by competitors merely because they have been successfully obtained. They therefore do not provide a sure basis for negotiating licences. Thus, less complex procedures for grant would not be acceptable. There are no clear views as to how this situation could be improved.

The speed, convenience and cost of litigation are not generally regarded by industrial design owners as likely to be satisfactory, nor are the remedies regarded as adequate, certain and effective, and the inexperience of national courts is criticized.

The same attitude to the lack of usefulness of the grant in guiding competitors whether to take licences exists as to whether to accept the validity of the grant or to litigate. Apart from suggestions that the scope of the monopoly should be better defined, no suggestions are made for improvement; generally speaking, more time and expenditure in obtaining grants are not recommended.

However, a larger proportion of competitors (i.e. defendants) in infringement actions than of owners of rights find litigation likely to be satisfactory as to speed and certainty, but not cost. The action to contest validity, where it exists, is found to be helpful, though the speed and cost are criticized.

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[2] COM(96) 66 final.

[3] COM(93) 342 final.

A Community industrial design system, as an option, is favoured by most as being cheaper for EU-wide protection, though one respondent states that as there would be no real effective examination of the grant this route would be too risky for an applicant. SMEs would use national routes when they only wanted limited geographic protection.

There is equal support and opposition to an EC court system along CTM lines, because of doubts as to national courts and fear over language and distance. There are fears over different court procedures. There is more support for a common court of appeal. Harmonization of national laws is supported. Nonetheless, most regret the fragmentation of jurisdiction as a hindrance to effective protection.

6.2. Utility models

It is possible, but not yet agreed or proposed, that the same model of parallel Community and national systems, with harmonization of substantive law, could be applied to utility models.

Responses were predicated on the assumption that a Community utility model system similar to the CTM system is to be put in place.

In most cases, respondents said they would register new utility models with a Community-wide system, if it existed, for large or small companies, but, in most cases, would not translate existing national registrations into Community models even if this were open to them: one respondent gave as the reason the short life of utility models. In the majority of cases, they would not abandon national regulations. The minimum number of Member States for which protection is needed to justify a Community application is generally four to five, but there is some support for three and, in the case of small companies, for six. Generally speaking, however, on all the above issues there is little difference stated as between large companies and SMEs.

It must be stressed that these responses assumed the existence of an EC-wide right. In the seminars, it became clear that no such right was desired.

Apart from Italy, applications in existing national systems are considered reasonable as to speed and, indeed, as to cost. The resulting protection is considered reasonably clear by most respondents. Answers as to litigation are much less uniform; more than half are dissatisfied with the likely speed, convenience and cost. Satisfaction in large Member States is clearer on these counts. The certainty of remedies is regarded as likely to be satisfactory.

From the point of view of competitors of the utility model owner, there are as many respondents who consider the clarity of the scope of protection and the ease of deciding to take or ask to take a licence less than satisfactory, as those that find these acceptable. Litigation from the point of view of defendants is considered slow and costly, or reasonable, in equal proportions, though certainty of litigation is regarded as satisfactory.

Generally speaking, national rights are considered satisfactory; these would clearly be more strongly supported if national laws were harmonized; and for an unsearched right the expense of Community-wide protection and the risk of having all one's eggs in one basket militate against a Community system. To justify a Community system some minimum level of examination is considered desirable. Similarly, competitors of utility model owners can probably find more scope for evasion of the monopoly if national rights are relied on, because

of the possibility of finding loopholes in the protection. However, the competitor then has to accept variations in the scopes of protection which may be disadvantageous.

There is little support for a Community court system using national designated courts, partly because of lack of experience of the courts, and partly because there seems to be a feeling that such as an edifice is rather Utopian, or that such a system would 'over egg' the pudding for rights as slight as utility models. On the other hand, there is support for a common final court of appeal.

Most respondents consider that fragmentation of the jurisdiction is, so far as utility models are concerned, a hindrance to large companies, though not of such moment to SMEs; but it is pointed out that a full patent may be obtained where the subject matter merits it.

6.3. Patents

There is discussion of, but no overt moves by any official body in the EC regarding a similar system for patents to that for a TM, to take the place of the unratified Community Patent Convention. Discussion of certain possibilities takes place later in this text.

6.3.1. Supplementary Protection Certificate (SPC) for plant protection products

This new right, analogous to the SPC for medicinal products, is expected to be finalized by regulation by the end of 1996. It will provide an effective patent life of 15 years from first marketing approval by the introduction of an SPC having a maximum five-year term. Such a regulation is widely welcomed by the industry and the new regulation is expected to assist in the interpretation of the medicinal products SPC.

6.3.2. Protection of biotechnological products

The new proposals for patent protection of biotechnology inventions would harmonize the patentability criteria of biotechnology, a very important development as the EPC does not cover the issue for modern purposes. The present proposal, if adopted in its original form proposed by the Commission, would accord completely with the principles of patentability already well established. As such it would be an important addition to IPR law. It is interesting to note that because the EC is nearly coterminous with the EC in territory, it is possible to 'amend' the EPC in some respects by directive. However, the seminars made clear the fears of the pharmaceutical industry that the proposal would be 'watered down'.

6.3.3. Protection for software

Software protection by patent was also not adequately defined in the EPC for current purposes and supplementary legislation by EC directive has been discussed.

7. International IP law

This chapter is not a résumé of the finer details of IP law in the many countries of the world, but a short description of the subject matter that is covered by the various IP rights and the international conventions and practices under which they operate. At present no unitary EU IP rights exist, except in the trade marks area, and this is discussed below.

7.1. Patents

A patent is essentially an agreement struck between the inventor (or more generally the company by whom the inventor is employed) and the country in which the patent is granted. In exchange for the inventor disclosing the invention to the public (in the form of a patent specification), the state grants an exclusive right (defined by 'claims' in the specification) to the inventor to prevent others from working the invention for limited period (the 'term'). This notion is the basis of patent grant in all countries, although it may be somewhat old fashioned in that, with rapid means of communication, disclosure of the invention in one country makes the invention available almost everywhere.

A report on the nature and effect of the British Patent System[1] commented: 'If resources are to be put at risk to develop a new process or product, which has yet to be tested, then he (the inventor) will hesitate, lest the expense of the development may prove irrecoverable while his competitors can wait and, without equivalent expense, pick up and use the successful results. It is the knowledge that a patent monopoly will enable him to hold off competition for a period which encourages him to take the risk and use those resources to develop new industrial inventions.'

The European Patent Office in its 1993 Annual report[2] states that 'The European Patent Office intends, with the Member States of the European Patent Organization, to create the conditions needed for a more intensive use of patent protection in Europe in order to enhance the innovative strength and competitiveness of European Industry'.

A patent is granted for an invention which is new and not obvious over what is already known (sometimes called the 'prior art') and is capable of industrial application.[3] In theory, a patent should be available for any type of invention, but, in practice, the patent statutes in many countries do not grant patents for abstract ideas such as, for example, discoveries, mathematical methods, artistic works.[4] Some countries, however, discriminate between industries, for example, by refusing to grant patents on chemical compounds.

A party is said to infringe the claim or claims of a patent if its activity falls within the scope of the claim or claims. If it does so fall, then there is said to be 'infringement', and the third party must stop the activity, reformulate the activity outside that scope, obtain permission from the patentee through, for example, a patent licence, or attempt to show that the patent is invalid – that is to show, maybe before a court in that country, that the patent should not have been granted or the relevant claim is unenforceable, because the invention is not new or is obvious over the prior art or there is some other deficiency in the patent.

If the patent is found to be valid and infringed by the third-party activity, the patentee ought to be able to obtain an injunction to restrain further infringement (and maybe an interlocutory injunction), damages and, sometimes, the costs of the action.

From the point of view of industry, which invents and develops new products and processes, three features must be present in the patent right:

(a) Firstly, the patent term must be long enough for the patentee to be able to obtain a return for his investment.
(b) Secondly, the patent must cover the invention; namely if the invention is a product, the patent should cover the product and not a process by which it is made.
(c) Thirdly, the patent right must be given strength by the local statute and be respected by the judicial process, and be free from provisions that dilute the strength of the patent right, such as, for example, availability of compulsory licences on trivial grounds.

Without all three being present, the patent system would be of little help to industry. The patent has to protect the essence of the invention, last long enough for the patentee to have an opportunity (not a guarantee) to obtain a reward for the associated effort, investment and risk, provide teeth so that action can be taken against an infringer; the last includes not only effective measures to restrain infringement but absence of other provisions which artificially dilute the patent right such as the availability of compulsory licences under the patent on facile grounds.

The patent system may therefore have a profound effect on the establishment and success of industry according to the absence of one or more of the above features.

The patent law in each country developed somewhat independently, although the law in some countries acted as a precedent for others. The laws of Member States have been precedents in other countries of the world. This resulted in wide range of the above three essential components of term, patentable invention and enforcement of the patent rights. There are, however, some international agreements relating to IP and patents.

7.1.1. Paris Convention

The World Intellectual Property Organization (WIPO) based in Geneva is responsible for administration of the Paris Convention, sometimes referred to as the 'International Convention'. This Convention was signed in 1883 in Paris by some 11 countries to provide some international harmonization on patents; revisions of the Convention, which lay down certain provisions to which each member must conform, take place periodically through diplomatic conferences, the most recent in Stockholm in 1967, and 129 countries are now members.

The Paris Convention has a number of ongoing effects. It provided model IP draft laws for the above members which provided that everyone, whether a national of that country or a foreigner, shall be treated similarly in respect of IP protection in that country, and the right of priority which, in the case of patents, has the effect that if a corresponding patent application in country A is made within 12 months of the filing in country B, then use or a publication, which takes place in that 12-month period, cannot defeat that filing in country A.

The framework for patent law provided by WIPO is open to considerable local modification and interpretation. This, and the resultant basic deficiencies in patent law, had a direct influence on IP being considered in the recent GATT Round[5] and resulted in an agreement on IP.

7.1.2. TRIPs

The GATT Agreement on Trade Related Intellectual Property Rights (TRIPs)[6] provides for minimum provisions that shall be found in the IP laws of all members (119 members of the WTO)[7] of the World Trade Organization. The WTO commenced on 1 January 1995. The Press summary[8] relating to TRIPs issued at the conclusion of the Uruguay Round stated:

'The Agreement recognizes that widely varying standards in the protection and enforcement of intellectual property rights and the lack of multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods have been a growing source of tension in international economic relations. Rules and disciplines were needed to cope with these tensions. To that end, the agreement addresses the applicability of basic GATT principles and those relevant international intellectual property agreements: the provision of adequate intellectual property rights; the provisions of effective enforcement measures for those rights; multilateral dispute settlement; and transitional arrangements.'

The minimum standard of patent law given in TRIPs states that patents shall be available, and the rights enjoyable, without discrimination as to the place of invention, the field of technology, and whether the products are imported or locally produced. TRIPs also provides for at least a 20-year term (provided that the [generally annual] renewal fees are paid), patentability of all inventions, subject to very limited exclusions, restricted availability of compulsory licences, and for all IP, provisions for enforcement and penalties for infringement of the IP right. TRIPs will therefore be a considerable, and very important, force in creating homogeneous patent, and other IP law, in all countries which are members of the WTO, although the transitional provisions will not make that homogeneity immediate. Some developed countries have brought their IP laws to the TRIPs standard by the 1 January 1996 deadline (Australia, New Zealand, and of the EU, Italy and Spain, but so far not the other Member States, which are in the process of doing so).

There are, in the patent area, some other important international agreements.

7.1.3. Patent Co-operation Treaty (PCT)

The PCT is an international treaty administered by WIPO to which all members of WIPO can belong, although only 82 (as at 12 December 1995)[9] do so. It provides a route through which a single patent filing at a patent office can be effective in all the countries of the PCT chosen by the applicant on filing. The PCT therefore eliminates much duplication of work by patent attorneys and patent offices by reducing the amount of paperwork and the need for a multiplicity of essentially similar prior art searches. The PCT route is becoming an increasingly popular route for filing patent applications; 37,906 international applications were filed in 1995, equivalent to 916,273 national applications, and 68,206 regional applications, equivalent to 890,943 national applications, the total being equivalent to 1,807,216 national applications, an increase of 14.1% over 1994.[9] In brief, a patent application is filed under PCT, a prior art search is carried out, and then the application together with the search report is sent to the patent office of each of the countries designated in the original application for them to examine the application and eventually grant any patent.

7.1.4. European Patent Convention (EPC)[10]

The EPC came into effect on 1 June 1978 and is a route for the granting of patents effective in any country in Western Europe requested by the applicant by using a single patent application filed at the European Patent Office in Munich. After the grant, the patent is subject to national law; major provisions such as term, patentability and suitable subject matter for a patent are homogeneous and defined in the Convention. National laws up to grant have been made compatible with the EPC, and the case law in the individual countries is becoming aligned with a few exceptions, as will be noted elsewhere in this study, but laws relating to infringement and remedies against infringers have not been harmonized.

7.1.5. Draft Community Patent Convention (CPC)[11]

The CPC is an extension of the EPC and provides a single patent for the whole EU. It is significantly different from the EPC in that it provides post-grant provisions, including a definition of what constitutes infringement. Although the CPC was originally intended to come into effect also on 1 June 1978, it has not attracted sufficient ratification and will not come into force for some time. The CPC is the subject of much comment in this study.

The above discussion, whilst mainly relating to patents, has much in common with all types of IP discussed in this study.

7.2. Trade marks

A trade mark is intended to be used on goods or services to show the relationship in the course of trade between the goods or services and the owner of the trade mark. A trade mark should at least therefore be capable of distinctiveness; it should therefore not be the same or similar to the trade mark of another owner used on the same or similar goods. The trade mark may be registered or used without registration. It may be in the form of words, names, designs, numerals, or shapes of the goods or their packaging or even, in the EU, sounds and smells provided that they can be graphically represented. Registration is effected by application at the local IP Office for the trade mark in respect of certain goods or class of goods, often but not always followed by examination and prosecution. Once registered, the owner of the registration has statutory rights against the user of the same or a similar trade mark on the same or similar goods. The owner of an unregistered trade mark has only non-statutory law, or in some countries the law of unfair competition, to challenge the unauthorized use of a trade mark. Thus registration gives security to the proprietor.

Trade mark law in the EU Member States has developed largely independently, but satisfies the above general comments. Registration of trade marks in the EU is made by application at the trade mark registry of the Member State where registration is required (Benelux has a single law to cover the three countries), possibly using the Madrid Agreement if applying in that state, or similarly the Madrid Protocol. The Madrid Agreement of 1891 provides for an international registration of a trade mark, but not all countries in the EU are members of that Agreement. The European Commission in its First Council Directive[12] provided for considerable harmonization of the national laws in Europe, and the Community Trade Mark Regulation[13] established a unitary mark for the whole of the EU, with a central Trade Mark Office – the Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM) – in Alicante, Spain. The OHIM opened in January 1996. The CTM provides for central opposition, but after registration the CTM is susceptible to national court decisions

which apply common CTM law in respect of infringement and validity. Invalidity found in one Member State invalidates the CTM as a whole, although conversion to national applications can be made without loss of priority. Remedies for infringement extend to the whole of the EU.

GATT TRIPs also provides minimum standards for trade mark law, such as what can be the subject of a trade mark; the nature of the goods cannot be an obstacle to registration of the trade mark. Article 20 requires that the use of a trade mark in the course of trade shall not be encumbered by special requirements.

7.3. Designs

A registered design right is very similar to that of a granted patent but relates to the shape, configuration, pattern or ornament on an article produced by an industrial process. Thus a work of sculpture itself cannot be the subject of a registered design right, but an industrially made copy could, provided that the design is new and not a common variant of one in the trade concerned. The design must not be totally dictated by the function that the article has to perform or satisfy; it must have some artistic merit, albeit very small.

The design right is applied for by formal application and is made to the local IP (Patent) Office. The application is generally very straightforward, involving a drawing or photograph of the article, with a claim which denotes the new feature for which the exclusive right is sought. As shown below, the maximum term is very variable. The rights available against an infringer are the same as those for a patent. There are very few international agreements, except that under the Paris Convention the priority is six months (12 months for patents).

TRIPs is concerned with registered designs; it provides that all WTO members shall have a registered design statute for the protection of new or original designs; it lays down a minimum term of 10 years. There may be limited exceptions to the protection of registered designs, provided that such exceptions do not conflict with the normal exploitation of the protected design and do not prejudice the interest of the owner having regard to legitimate third-party interests.

Designs can also find some measure of protection under a variation of copyright provisions in some countries. Such a right is automatic on application of the design to an article. The right cannot be created as a figment of the imagination. Such a right, however, suffers from the difficulties found with copyright in that the owner of the right must prove opposite the alleged infringer that copyright exists and that actual copying has taken place. With a registered design, the latter criterion, which is often difficult to prove as two people can independently arrive at the same design, is irrelevant. However, the owner of a valid registered design right, as with a patent, can stop any unauthorized act falling within the scope of the claim.

In Europe, there is no homogeneity in the design right. Not all countries have such a right (for example, Greece). The European Commission has recently introduced a second draft directive[14] to harmonize design right laws and a draft regulation to provide a unitary right.[15]

7.4. Utility models

Utility model protection is a similar right to a patent except that it has a shorter term, and the protected 'invention' has a lower level of inventiveness. Such rights exist in many countries,

but not in Luxembourg, Sweden, the UK or the USA. In Germany, there could be simultaneous filing of a patent and utility model application so that there could be an enforceable right protecting the invention pending resolution of the patent prosecution. There are no international agreements relating to utility models.

The main advantages of such protection are quick and simple application and prosecution procedures, and associated lower costs. These should therefore be attractive to SMEs and other companies where narrower rights are desirable. Whether those objectives are actually achieved with a utility model is open to doubt as discussed below in the context of the Commission Green Paper.[16] However, a particular problem is in the area of overlap of a patent and utility model protection, unless the two rights are made mutually exclusive.

8. National laws compared

8.1. Key common features in the national IP laws in the EU

8.1.1. Patents

The advent of the EPC has resulted in much improved homogeneity in the patent statutes up to patent grant. Thus all statutes now provide for:

(a) patentability of all novel, inventive, industrially applicable inventions with a few limited exceptions, all conforming to the EPC;
(b) patentability of chemical compounds and pharmaceuticals;
(c) 20-year term from application;
(d) improved homogeneity of standards of novelty and inventive step.

8.1.2. Industrial designs

It is evident from Table 8.3 below that there are no common features of design law in the EU Member States, except that there are such laws in all but Greece.

8.1.3. Utility models

It is evident from Table 8.4 below that there are no common features of utility model law in the EU Member States, except that there are such laws in all but the Benelux, Ireland, Sweden and the UK.

8.1.4. Trade marks

The situation regarding trade marks is more homogeneous. A trade mark can last indefinitely if it is used in a proper fashion and renewal fees are paid. All EU Member States have, and have had, trade mark statutes for many years, which have developed over the years in their own separate manner. A major problem is that of language.

The First Council Directive 89/104EEC of 21 December 1988 harmonized the trade mark laws in EU Member States, and more recently the Community Trade Mark Regulation has established a single trade mark for the EU; however, it is subject to invalidation by the adverse decision of a court in any Member State. In that event the CTM is wholly invalid, but the proprietor can obtain national marks without loss of priority. It is too soon to judge the performance and attraction of the CTM and the OHIM.

8.2. Key national variations in IP law in the EU

As discussed above, the IP laws in the EU Member States developed over a different timespan, and indeed may well have had different objectives. There is therefore a wide variation in their scope. The following tables provide an indication of the variations in some key areas.

8.2.1. Patents

Term and patentable subject matter are major points of difference in the EU Member States, as shown in Tables 8.1 and 8.2.

Table 8.1. Patent term in current EU Member States and certain other countries

Country	Patent term
AT	18y from publication if filed before 1.12.84 18y from publication after examination with maximum 20y from application if filed after 1.12.84 20y from application from 1.5.79 if filed through EPC
BE	20y from application whether national or through EPC
DE	18y+1d from application if filed before 1.1.78 20y+1d from application if filed on or after 1.1.78 20y from application if filed through EPC
DK	20y from application whether national or through EPC
FI	20y from application whether national or through EPC
ES	20y from grant if granted before 26.6.86 20y from application after 26.6.86 whether national or through EPC
FR	20y from application whether national or through EPC
GB	16y from application (extendible) if filed before 31.5.78 additional 4y if patent existing at 1.6.78 and more than 5y term remaining but licences of right endorsement 20y from application whether national or through EPC if filed on or after 1.6.78
GR	15y+1d from application if filed before 1.1.88 20y from application whether national or through EPC if filed on or after 1.1.88
IE	16y from application (may be extended) if filed before 1.8.92 20y from application whether national or through EPC after 1.8.92
IT	15y from application if filed before 22.8.79 20y from application whether national or through EPC if filed on or after 22.8.79
LU	20y from application whether national or through EPC
MC	20y from application whether national or through EPC
NL	20y from first month following month of application or 15y from grant, whichever the longer, if granted between 1.1.64 and 1.1.78 As above if filed between 1.1.78 and 1.2.79 and grant before 1.2.79 20y from application whether national or through EPC thereafter
PT	15y from grant if filed up to 31.5.95 20y from application whether national (agreed but not yet enacted) or through EPC if filed after 31.5.95
SE	17y from application if filed before 1.6.78 additional 3y if patent existing at 1.6.78 and more than 5y term remaining 20y from application whether national or through EPC after 1.6.78
	FOR COMPARISON
CH	18y from application if filed before 1.1.78 all patents existing at 1.1.78: term increased by 3 years 20y from application whether national or through EPC if filed after 1.1.78
JA	15y from publication after examination or 20y from application, whichever the shorter
US	17y from grant or 20y from application if filed after 8.6.95

Table 8.1 illustrates the considerable variation in patent term which existed prior to June 1978, and whilst the term is now 20 years from application, the transitional provisions associated with the changes in the statutes means that inhomogeneity will exist for at least a decade.

Furthermore, oppositions before or shortly after grant cannot be lodged in Belgium, Ireland, France, Greece, Italy, Luxembourg, the Netherlands, Portugal.

Table 8.2. Patentability in current EU Member States and certain other countries

Country	Exclusions from patentable subject matter
AT	Chemicals, foods, pharmaceuticals before 8.10.87
BE	none
DE	Chemical compounds before 1968
DK	Chemical compounds limited to use before 1.12.78 Pharmaceuticals before 1.12.83
FI	Foods, pharmaceuticals before 1.1.95
ES	Chemicals, pharmaceuticals before 7.10.92
FR	none
GB	none
GR	Chemicals, pharmaceuticals before 7.10.92
IE	none
IT	Pharmaceuticals before 20.3.78
LU	none
NL	none
PT	Chemical, foods, pharmaceuticals before 1.1.92
SE	Chemical compounds limited to use before 1.12.78 Pharmaceuticals before 1.12.83
	FOR COMPARISON
CH	none
JA	Pharmaceuticals, foods, beverages before 1.1.76
US	none

The above table shows again the considerable variation that existed in the patent statutes of EU Member States. They are now homogeneous in that they all conform to the patentability found in the EPC (denoted by 'none' in this table), but existing patents will retain past inhomogeneity in the EU until the year 2012.

8.2.2. Industrial designs

The protectable subject matter for industrial designs also varies considerably in the EU Member States, as shown in Table 8.3.

Table 8.3. Registered designs in current EU Member States and certain other countries

Country	Term	Novel subject matter
AT	5y+5y+5y	Pattern industrial model
Benelux	5y+5y+5y	Novel outer appearance unless necessary for a technical effect
DE	30y+1d	2 or 3 dimensional industrial product satisfying aesthetic feeling or visual taste
DK	5y+5y+5y	Decorative or utilitarian appearance of an article
FI	15y	Creative, novel, distinctive designs, pattern, ornament, including shapes which satisfy exclusively technical requirements of the product
ES	20y	Structure shape ornamentation on industrial model
FR	50y	Distinctive configuration on an industrial object
GB	25y	Shape, pattern, ornament on industrial article
GR	none	
IE	15y	Shape, pattern, ornament on industrial article
IT	15y	Special appearance of industrial article
MC	15y	Distinctive configuration on an industrial product
PT	Indefinite	Ornamentation on an industrial product
SE	15y	Decorative or utilitarian appearance of an article
	FOR COMPARISON	
CH	15y	External shape for model for industrial production
JA	15y	Form, pattern or colouring applicable to industrial articles giving a sense of beauty by sight
US	14y	Ornamental design for article of manufacture

NB: All terms are from the date of application except JA and US which are from the date of issue/grant.

8.2.3. Utility models

The protection provided by utility model statutes varies even more than patents and industrial designs; indeed three countries provide no protection, although that appears not to cause difficulty.

Table 8.4. Utility models in current EU Member States and certain other countries

Country	Term	Novel subject matter
AT	10y	'Small inventions'
BE	none	
DE	6y prior to 1.1.87 filed 1.1.87 to 1.7.90 10y filed after 1.7.90	Essentially same scope as patents but methods or processes
DK	10y only from 1.7.92	Lower inventive step than patents; apparatus, tools, chemicals, medicines can be the subject of a later patent application
ES	20y from grant before 26.6.86 10y from filing after 26.6.86	Novel inventions, inventive step, giving object form or structure resulting in substantial practical advantage
FI	8y	Novel inventive design or structure
FR	6y	Same scope as patents
GB	None	
GR	7y only from 1.1.88	Three dimensional object with definite shape
IE	None, but 10y	Short term patent lower inventive step than full patent
IT	10y	Models conferring efficiency, usefulness to machine parts, tools
LU	None	
MC	6y	Same scope as patents
NL	None	
PT	Indefinite	Tools, utensils, containers having usefulness to which novel form adds utility
SE	None	
	FOR COMPARISON	
CH	None	
JA	6y	Novel device relating to shape, construction of article
US	14y	

8.2.4. Other matters

Enforcement of IP rights and the remedies available against a proven infringer of a valid IP right vary widely in the EU. These are discussed elsewhere in this study and will not be considered here.

Thus, whilst there has been, and there is ongoing, improvement in the level and homogeneity of IP rights in the European Union to the advantage of industry, much needs to be done to increase the uniformity of the IP rights available. The needs of industry, particularly in the area of cost and enforcement, require serious and urgent attention. Whilst homogeneity of IP is highly desirable, this is not synonymous with a single or unitary right, for example, patent right, for the whole of the EU. Many companies, in particular but not only smaller companies, may require rights only in a single or very few Member States for a variety of reasons, for instance, costs or limited market for the associated products or requirement for quick grant. Thus, rights granted in individual countries must always remain as an alternative or option for all companies to use without prejudice.

9. Comparison of administrative/legal procedures and their effectiveness

The first part of this chapter considers the national procedures in the EU Member States, whilst the second part deals with unitary European matters.

9.1. National considerations

The IP statutes and procedures in the EU Member States have developed along different routes, and both statutes and enforcement procedures vary widely throughout the EU. Nevertheless, the statutes are gradually being harmonized, although a significant period will elapse before all are the same. No such harmonization has occurred in the area of enforcement, except for trade marks.

The procedures up to the grant of national IP rights have been discussed elsewhere in this study. Application for the IP right is made, generally through a local attorney, to the national receiving office for that IP right, and following prosecution, the right is granted. The prosecution varies considerably, involving in some cases (for example, in the patent area) novelty examination, substantive examination, response by the applicant and grant followed by opposition (e.g. Germany, UK), but involving in others merely a search for prior art and grant with a request for comments but no substantive prosecution, followed by grant and no opposition (e.g. France, Netherlands). Most national patent offices do not have an opposition procedure. Absence of opposition, although less costly, is much regretted by respondents to the surveys, because an opposition, or possibility thereof, gives the patent more authority and perceived strength. Designs follow similar procedures, but utility models where they exist generally have no examination and are granted automatically on payment of the fees. For trade marks there is generally a search for prior registrations, but the applicant must be wary of prior unregistered rights, which may take precedent under unfair competition (most countries), sometimes similar to passing off (UK).

9.1.1. Infringement, validity, opposition

In some countries (e.g. Ireland, UK) the matters of infringement and validity are taken together, but in most other EU Member States, the two are considered separately. Opposition to patent grant in the EPO generally results in a stay of any national infringement action under the patent so that infringement is not considered until disposal of the opposition.

9.1.2. Absence of specialist courts

Another difficulty raised is the absence of specialist patent courts in most EU Member States, Germany and the UK being exceptions, although in some countries, courts in certain major towns have IP expertise.

9.1.3. Cost and time

The cost and time taken to decide an IP matter is considered by most respondents to be too high and too long; in the UK, this is mentioned in particular, although the soundness of decisions is also considered high. There is always a suspicion that courts favour local parties,

but nevertheless the standard of IP decisions in some countries (Greece, Italy, Spain, Portugal) is generally perceived to be low.

9.1.4. Proof of infringement

Proof of infringement is often difficult. The reversal of the burden of proof may assist a patentee to determine infringement re process patents. Discovery of documents or other evidence is generally limited in the courts of EU Member States, but in some countries (e.g. Belgium, France) a 'saisie description' is available to an IP right owner to gain access to the premises of an alleged infringer; the 'Anton Pillar Order' may have a similar effect in the UK.

9.1.5. Litigation

IP litigation is generally of a civil nature, although it can be criminal (particularly in trade mark matters) if certain matters are raised, e.g. deceit, counterfeiting, theft, but the penalties generally held against a proven infringer include an injunction, delivery-up, destruction of offending articles, damages (in the form of monetary payment, account of profits), sometimes costs of the action and publication of the decision.

In certain instances, an interlocutory injunction may be granted. This is a separate right which can be sought if it can be shown that damage in the market to the IP right owner cannot be met by monetary reward – this will often be the case in a trade mark when use for a period by the defendant will ruin irrevocably the reputation of the proprietor, or in a patent action where the infringer may ruin the price structure in a market irrevocably. However, the right is somewhat risky because the proprietor will have to recompense the defendant fully if the action is lost. However, it is a right that should be available to the IP right owner.

Table 9.1. General details of the courts in EU Member States

	Court	Specialist	Duration[1]	Cost	Separate validity/ infringement
AT	Vienna	No	2-4 years	quite high	Yes
BE	Brussels, Ghent, Antwerp, Liège, Mons	No	1 year	low	The same court decides validity first
DE	Regional court	Yes, in some	2 years	medium	Yes
DK		No	18-24 months	high	Yes
ES	Most large cities	No, but best in Barcelona, Madrid	3 years	medium	Yes
FI	Helsinki	No		high	Yes
FR	Most large cities	No	3 years	medium	Yes
GB	London	Yes	2 years	high	No
GR	Any civil court	No	very slow	medium	Yes
IE	Dublin	No	2 years	medium	No
IT	Tribunale	Yes if in Milan, Turin	1-2 years	medium	Yes
LU	Luxembourg	No	1 year	low	Yes
NL	The Hague	Yes	2 years	medium	Yes
PT	Lisbon	No	3 years	low	Yes
SE	Stockholm Gothenburg	No	3 years	high	Yes

[1] In the court of first instance.

9.2. European measures

9.2.1. Patents

The administrative procedures for the grant of a patent in the European Patent Office are clear, certain and effective, though – bearing in mind that up to grant stage an applicant is in effect only making one application (though this will give the basis for grants in a plurality of countries up to the full number of Member States) – the procedure is relatively expensive. However, the level of examination of the application and search for prior art is very high.

Opposition proceedings for revocation of grant take place during a period of nine months after grant. With the possibility of other opponents joining the proceedings up to the time they are concluded, they are also clear, certain and effective, but they can result in very high costs and can be very slow. For this reason, though the proceedings are highly valued, there are suggestions from respondents for reducing their slowness and cost by introducing restrictions on the ability of others to join as opponents at a late stage, and for reducing the time for commencement of proceedings to six months from grant.

The legal aspects of these procedures throughout these stages, i.e. the litigation aspects, have the characteristics described above (see Section 9.1).

The patent, once approved, is granted in the form of a number of identical national patents. All uniformity then disappears both administratively and as to legal procedures. If a competitor wishes to challenge the validity of any or all of the national patents, he must do so through national procedures which differ in each Member State. Although the European Patent Convention allows for national tribunals to apply to the EPO for an opinion on validity at any time during the life of a national patent, the institutions of none of the Member States make more of this facility. Thus, each applies the law of invalidity in its own way, though the law itself (being that of the EPC) is harmonized in each Member State. There is no common court of appeal beyond the Member States on validity, or, of course, infringement.

The laws of infringement and remedies have not been harmonized by the EPC, and so not only are the administrative and legal procedures for infringement action different in all Member States according to national practices, but so are also the substantive laws of infringement and remedies different. There is thus complete and unsatisfactory fragmentation of the effect of patents on the single market.

9.2.2. Trade marks

The Community trade mark system set up by the Trade Mark Regulation is the only purely Community IP system in being. It commenced operating on 1 April 1996. It provides administrative and legal procedures for application, opposition and grant of Community trade marks. These proceedings are wholly uniform, and can be expected to be clear, certain and efficient. There are doubts as to cost and slowness, but these can only be confirmed by experience.

Administrative and legal procedures for infringement and claims for revocation for invalidity are wholly dependent on national rules and practices in the specialist designated national courts, which will give judgments covering the whole of the EC, with final appeal in the ECJ. Concern has been expressed by some respondents over the complication of operating under

different national procedures in these designated national 'EC' courts. The disparities concern not only court procedure *per se*, but also the treatment of evidence and the attitude to remedies and costs, etc. In the seminars, however, these fears were found to be less real than in the written responses.

A unique feature of trade mark law is that a mark valid in one part of the EC may be invalid in another part because of local circumstances in the relevant market as to prior registration of other marks, or confusion because of the nature in the relevant language leading to confusing similarity, descriptiveness or misleading indications. It is for this reason that in the case of trade marks the regulation provides that where local conditions render a CTM invalid in a limited area and hence invalid for the whole of the EC, the proprietor is entitled to convert the CTM into a national mark wherever the facts leading to invalidity do not exist.

9.2.3. Industrial designs

The system proposed in the draft regulation and directive is exactly the same as for trade marks, except for the paragraph above. No further comment is necessary.

9.2.4. Utility models

The position for utility models is under consideration in the Green Paper.

10. Analysis of possible national and international arrangements for operators wishing to exploit their IP in different Member States

In order that the discussion in this study may be more readily understood, it is useful to give a brief summary and analysis of the routes available to obtain IP and of the arrangements for exploitation in the different Member States of the EC. These routes are to some extent complex and interrelated. First, there is an analysis of the routes.

10.1. Patents

A patent may be granted to protect almost all novel and non-obvious invention susceptible to industrialization. The patent application begins with a patent specification drafted by the patent attorney after consultation with the inventors. The specification contains a description of the invention and how it may be carried out, which usually includes a discussion of what is already known (prior art). The specification ends with a number of single sentences (claims) which define the exclusive right sought in the patent.

The procedure to patent grant is shown in Figure 10.1. The patent specification is almost always filed initially in one country of the Paris Convention as a priority application to establish a filing date. A substantive application is filed generally within one year of the priority application to derive benefit from the Paris Convention provisions that any publication by anyone of the invention described in the priority application after that filing cannot prejudice novelty of the invention in the subsequent substantive application. The substantive application could be filed after that one year as a self-standing patent application provided that there has been no earlier publication of the invention.

The patent applicant has a choice of routes in filing the substantive application. To take a specific example to illustrate the choices, let us assume that the priority patent application is filed in the UK in English, and the applicant requires a patent application in France, Germany, the Netherlands and the UK. The choices are as follows.

10.1.1. National route

The applications are filed in the patent offices of each country through a local patent attorney in the local language. This is the traditional route, but it is expensive in that it requires the national filing fees, attorney charges and translation costs to be found immediately, when the fate of the invention in terms of a potential product is unknown. Also, it is likely that there will be a spread of filing dates and hence expiry dates and probably slightly different claims and hence exclusive rights. However, this route may be less expensive than other routes below if patents in three or fewer countries are required and prosecution to patent grant is generally fastest.

10.1.2. European Patent Convention (EPC)

The EPC provides a route to national patents through a single prosecution in English, French or German at the EPO in Munich. The substantive patent application is filed at any patent office in the EC as an EP application in which the states where patent protection is required

are stated on application. The EPC route is an efficient route to patents in Europe and enables one patent attorney, generally the one who drafted the priority application, to obtain the patents in all designated states by a single prosecution in his own language. On grant, the European patent becomes a national patent in all the states required in the application, all of which will expire on the same date, although one might choose to maintain all, some or none by payment or non-payment of the national renewal fees. It is generally reckoned that the cost of prosecution at the EPO is roughly the cost of four individual national applications (in 1995, an average of 7.86 countries were designated in each EPC application).[1] The EPC has an advantage in that translations may be delayed until after grant, by which time the applicant has a better idea as to whether the invention is likely to be of commercial interest.

10.1.3. Patent Co-operation Treaty (PCT)

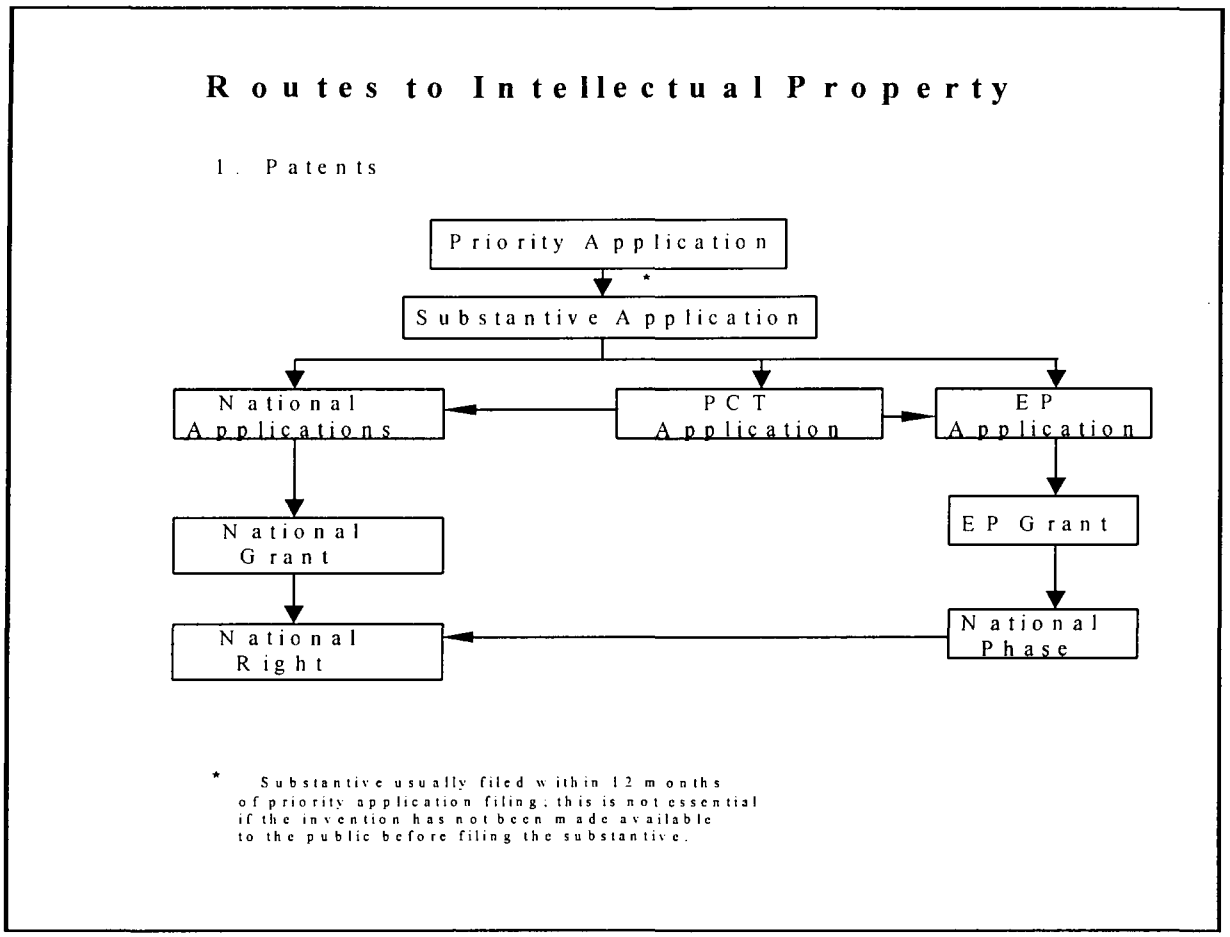
The PCT is another route to filing patent applications. There is no patent prosecution but the PCT enables a single filing at any subscribing patent office to be a filing effective in all countries belonging to the PCT. Thus in the PCT application, one could designate the above national filings or the EPC route (or indeed both). The advantages of the PCT are that it permits a very wide filing up to the last day of the priority year, so maximizing the possibility of a 20-year term from the end of that year, and that the translations are not required for at least 20 months from the priority filing.

Thus, there are four routes to the national filing in the above countries. This appears complicated, but it gives the patent applicant an excellent choice, and this is to the advantage of the patent applicant. Such a choice has cost implications. A major cost in obtaining a patent is the costs of translation; this can be as much as 70% of the cost of patenting. If a patent application is filed by the national route in a foreign language country, a translation must be filed with the application (or very shortly thereafter); in the PCT the translation is filed about a year later, but in the EPO the translation is filed in the national phase after grant (i.e. about three years after filing). Thus, depending on the route chosen other than the national one, the date for filing the translation can be delayed, giving the applicant a greater chance to abandon the application if it turns out to have no commercial value. This matter is further discussed in Chapter 14, together with possible solutions. Detailed costs of patenting are given at the end of this chapter, but a summary is presented in Table 10.1 for a patent application of 25 pages filed at the EPO designating all EC Member States.

Table 10.1. Typical costs of patents in the EC

Activity	Attorney fees (ECU)	Official fees (ECU)	Total (ECU)
Drafting	2,000		2,000
Filing, search, designations, examination	4,470	7,520	11,990
Prosecution	950		950
Grant, printing fees, claim translations	900	780	1,680
Specification translations (10)	16,350		16,350
Attorney fees (15)	5,500		5,500
Total	**28,170**	**8,300**	**36,470**
Av. cost per country (16)			2,280

Figure 10.1. Procedures to patent grant



10.2. Trade marks

A trade mark is intended to show the connection in the course of trade between the goods on which it is placed and the proprietor of the mark. It is therefore important in conveying to the customer all the qualities of that product and of the proprietor. A trade mark is therefore a very important piece of IP in the marketplace. Deciding upon a trade mark is a very difficult matter, particularly in the EC, where there are different languages and accents to consider; a trade mark must at least be capable of being distinguished, and avoidance of confusion is an absolute necessity. Thus, close co-operation between the trade mark agent and the marketing function of a company in all Member States is crucial.

The trade mark is registered in respect of the goods or classes of goods on which it is used or intended to be used. It is simpler to register in respect of a class of goods rather than to name individually all the goods – a problem is that the definition of the classes may not be consistent. A major difference from patents is that there are only small translation charges (essentially translation of the goods), so avoiding a major factor in the choice of routes. Almost always the first application for registration of a trade mark will be in the 'home country' of the applicant. In trade marks, the priority period is six months. Priority may be important in the situation of two conflicting applications for the same or similar marks for the same or similar goods. The procedure to registration of a trade mark is shown in Figure 10.2.

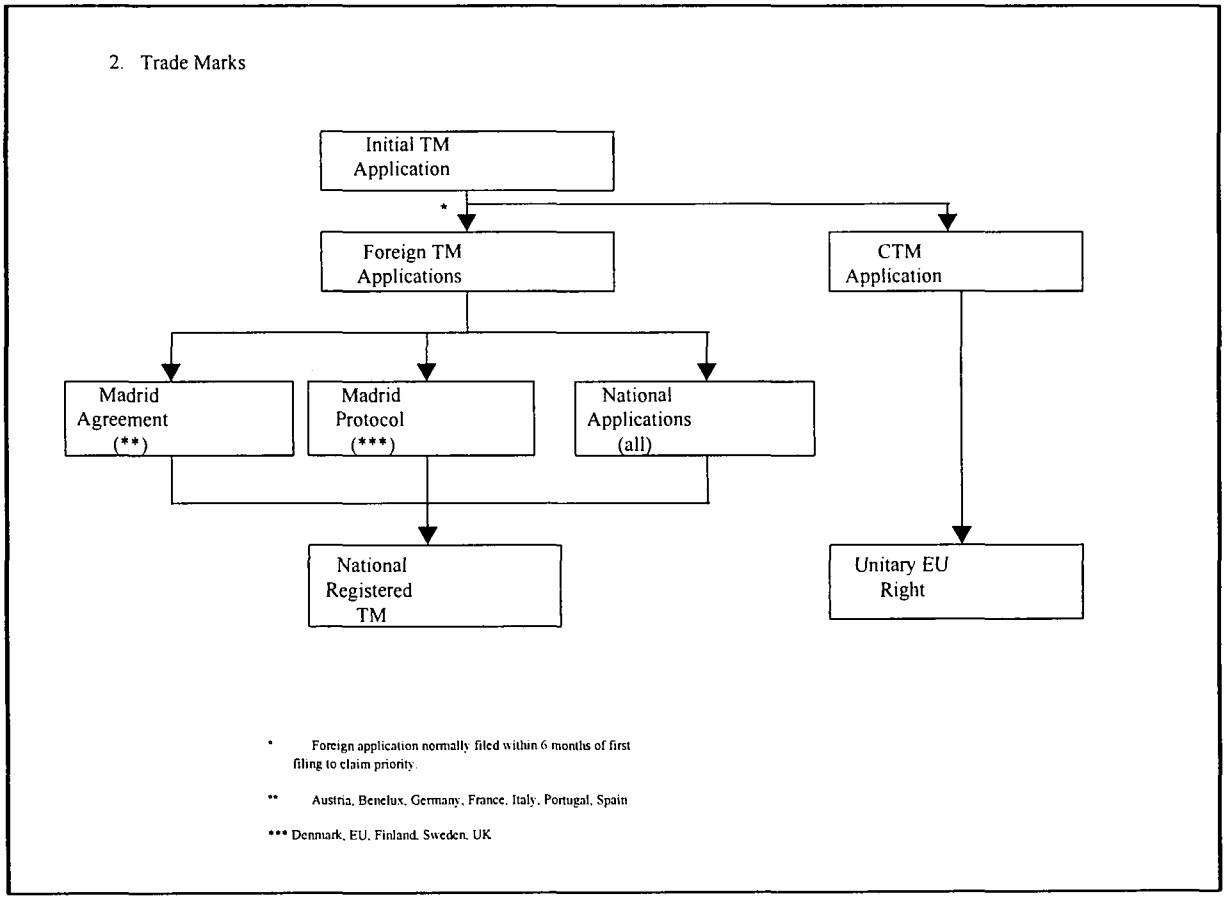
10.2.1. National route

The traditional route is to file trade mark applications in all the individual countries where registration is required. This route is particularly important to the company that wants the trade mark in only a few countries and not, for example, in the whole of the EU. This route will involve the use of trade mark agents in each country with the immediate expense of local fees.

10.2.2. International registration

This may be via the so-called Madrid Agreement and Madrid Protocol routes, routes which are applicable to some countries only. It is thought that Greece and Ireland will join the latter shortly. Other countries, not EC members, are members of one or the other of the Agreement and Protocol so that the use of these may be of interest where broader country spread of registration is required. Using these routes, which have their own rules, a trade mark can be obtained in each of the countries.

Figure 10.2. Routes to trade mark registration

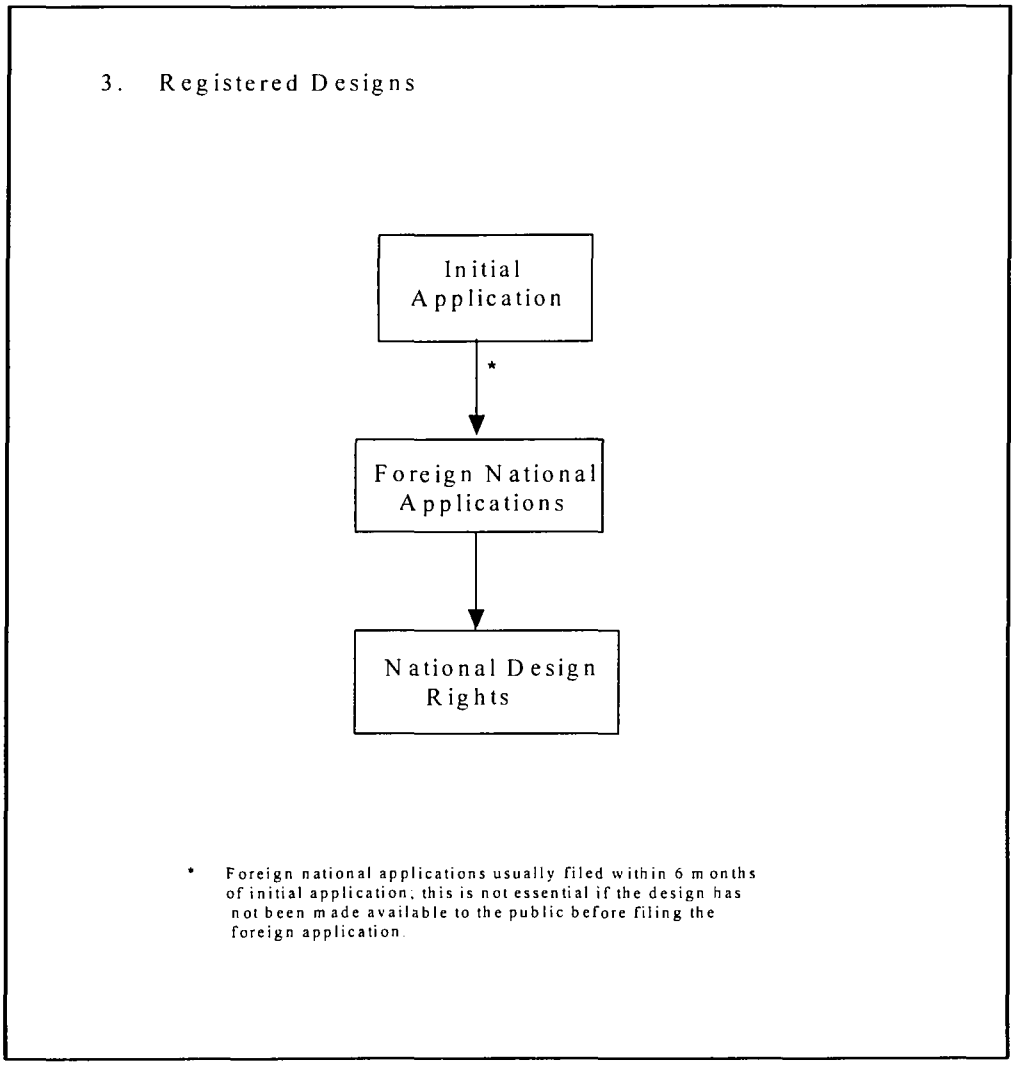


10.2.3. Community Trade Mark (CTM)

The CTM Regulation came into effect at the beginning of 1996 and the office for applications (Office for Harmonization in the Internal Market – OHIM) is located in Alicante, Spain. The regulation enables the registration of a single trade mark for the whole of the EU.

10.3. Registered designs

Figure 10.3. Route to design registration



Registered designs cover the shape, pattern or ornament applied to an article by an industrial process. To be the subject of registration, the design must be novel, and not a variant known in the trade at the time of filing. The application for registration of a design is made at a local patent office with a representation, such as a drawing and/or photograph, of the article together with a statement of claim relating to what protection is sought for; it may be for the whole or only part of the article in the representation. In the design IP law, the priority period is six months, and hence corresponding applications are made in individual countries generally within that six-month period in the same way as described above for national patents (see Section 10.1.1). However, there are no translations because a representation is pictorial, and hence the costs of application and registration are quite low.

There is no homogeneous registered design law in the EU.

10.4. Utility models

Utility models enable inventions which are novel over what is already known, but which are much less inventive than the invention in a patent, to be protected. There is no international convention for utility models. Such protection is therefore entirely national and not available in every EC Member State. Indeed, they were intended to provide low-level protection pending the grant of a patent; for example, under earlier German patent laws (e.g. 1968) a patent was granted not for inventions which were not only non-obvious, but also had an inventive merit and technical advance – a patent was therefore only granted for really inventive inventions, and so in order to provide some protection pending patentability resolution, the utility model was introduced (*Gebrauchmuster*). In the Netherlands on the other hand, where patents were also very difficult to obtain because of very strict criteria for obviousness, no utility model law existed. In the UK, where there was a lower level of obviousness, no utility model law was present (or indeed required).

The utility model law varies considerably across the EC: whether it exists; where it does; what can be protected and for how long. Utility models are much less important than patents and are generally used locally rather than internationally. They are perhaps used more by SMEs which exist in a given country because in that country a utility model will be cheap to obtain as no translation is required; on an international scale, however, they still suffer from the problems found in the national route to patents because the specification, which itself has to be carefully drafted, requires translation. It should be noted in this context that the level of obviousness for patents required by the EPO (and, therefore, by the national laws in EC Member States) is much lower than that found under pre-EPO type patent statutes in Germany and the Netherlands.

11. The motor industry

11.1. The role and importance of IP protection

IP rights are of major importance to the motor industry in the EU, primarily in the protection of trade marks in which resides the 'image' of the manufacturer, but also in protecting designs, and increasingly, with growing sophistication, in protecting patentable inventions.

The motor industry is of considerable importance in the EU. Large plants are found in many Member States of the EU, with associated impact on primary and secondary employment. Large manufacturing plants are located in six EU Member States and component manufacturers are found in those and in a number of other EU Member States. Companies are often multinational, having plants in a number of EU Member States, and there is substantial movement both of parts and of completed vehicles.

Major motor manufacturers no longer think nationally but in world terms. As one respondent said, at first there used to be different names and models in different countries, then there were the same models (with variants) and different names, but increasingly now, the same names and models are used world-wide.

Some figures relating to the EU motor industry are as follows:

Turnover (1990)		178 bn ECU
World production (1990)	EU	15.2 m units
	Japan	13.5 m units
	USA	9.8 m units
	Others	10.5 m units
EU trade (1989)		
Total export of automotive products		37 bn ECU
EU automotive trade balance		+17 bn ECU

Employment (vehicles and parts) (1993)

Belgium	France	Germany	Italy	Spain	UK	Total
52,292	315,014	730,787	177,232	135,722	204,450	1,615,497

Source: Eurostat.

New registrations ('000)

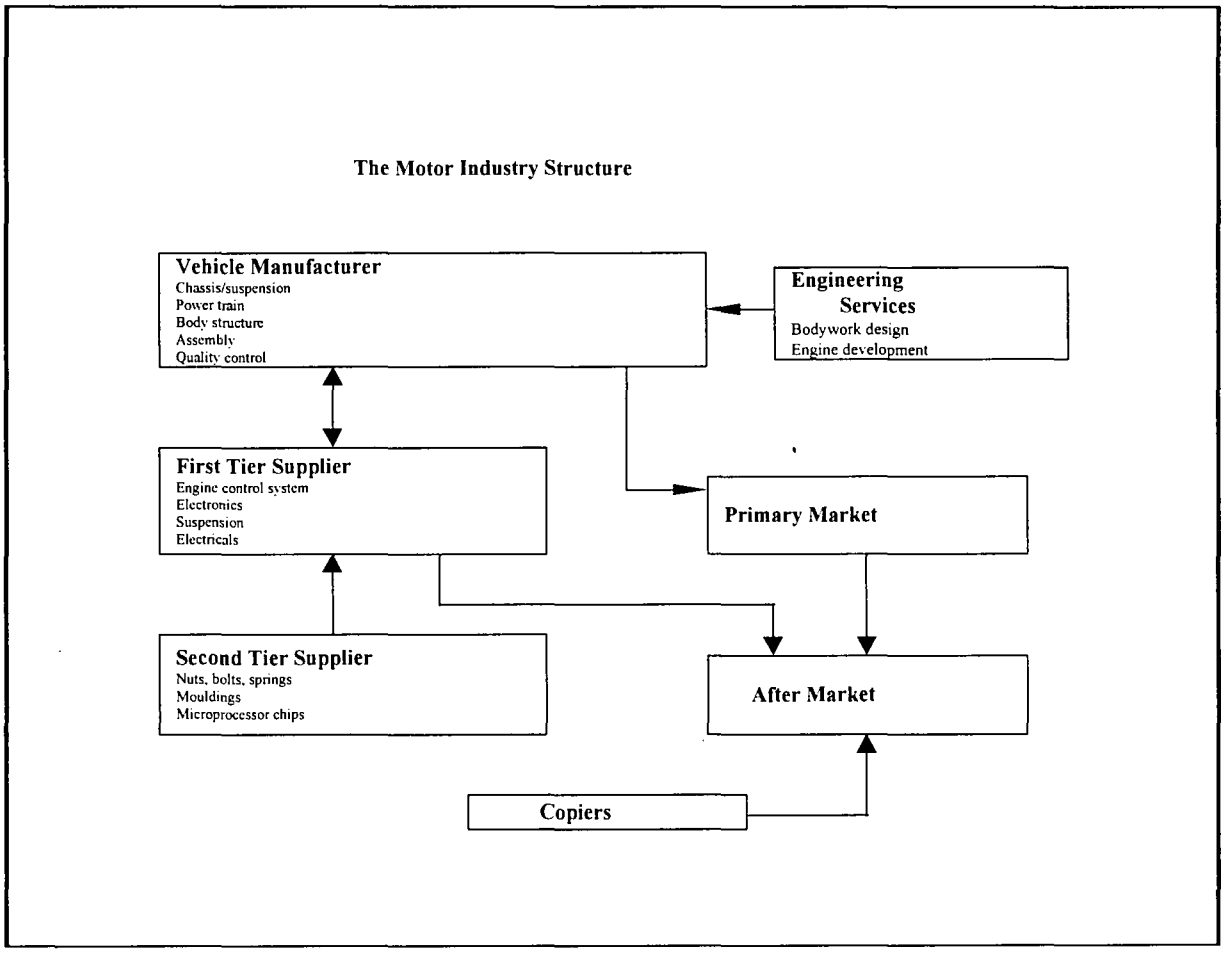
	1990	1995 (forecast)
Passenger cars	12,214	13,774
Light commercial vehicles	1,352	1,446
Heavy goods vehicles	313	308

Source: ACEA.

It is useful to consider the structure of a large volume motor manufacturer so as to be able to place the role of IP more accurately. Most motor (vehicle) manufacturers in the EU have approximately the same structure. No manufacturer carries out all the procedures involved in motor manufacture or makes all the components and sub-assemblies, many of which are manufactured by 'first-tier' suppliers, whose components are often supplied by 'second-tier' suppliers. Hence, there are chains of suppliers to the motor manufacturer, which is a primary supplier to itself of some parts as well as the final assembler of the motor vehicle. The chart below shows the relationships between the motor vehicle manufacturer and the suppliers of

sub-assemblies, parts and services, and the key interactions in the very important, so-called 'after market'.

Figure 11.1. Motor industry structure



Thus, although the concept of the vehicle is for the manufacturer to decide and determine from its knowledge of the market, the vehicle manufacturer may sub-contract important areas, such as aspects of body design. It is essential, for instance, that the new vehicle not only have customer appeal, but that there is close control of costs in a very competitive market; that the time to the market of the new vehicle must be as fast as possible, and that it is phased to ensure that timing relative to other models from the same manufacturer does not create unacceptable workload or investment peaks. Also, it is necessary that quality control is effective to ensure that the vehicle does not give rise to excessive warranty work or recalls after sale, because, apart from being costly, the reputation of the manufacturer would inevitably suffer.

In many of the above relationships, the vehicle manufacturer and the supplier will be co-operating in the design and specification of the part or assembly in question. For example, in the design of an ABS braking system, there will be close co-operation between the vehicle manufacturer and the first-tier supplier. Similarly, considerable development has been carried out in coatings and paints. The development of car shapes is ever continuing, not only for safety reasons but also for aesthetic effect and reduction of wind resistance. Research and

development takes place to invent new engines, in particular in the areas of fuel economy and emissions.

In the above relationships, IP is owned and generated by the vehicle manufacturer and the suppliers, and by both in a field of collaboration. The second-tier supplier will almost certainly own IP in its area of expertise, and any components so supplied will be under that IP. Hence, in the motor industry, IP is used in agreements between the individual companies, suppliers and subcontractors – rather in the same way as in defining the parameters in a transfer of technology agreement – in the supply of components and sub-assemblies, and in the manufacturing aspects. The IP establishes rights and ownership of the technology. IP is very rarely used offensively in this essentially co-operative environment. However, strong IP rights are required so as to define the proprietary nature of the technology.

Both the vehicle manufacturers and suppliers have a considerable interest in spare parts. The market for spare parts is low in the first few years after the sale of a motor vehicle. This is sometimes referred to as the 'after market'. The manufacturer warranty usually covers the replacement of parts and components for some years after the sale; body rust and corrosion warranties may last even longer. Thus, the international market for spare parts is not attractive to a copier until a few years after the first sales of a given model, but by then it may be quite large. Copiers are generally only interested in the after-market of large volume cars. The spare parts of the vehicle manufacturer have the same high quality as the original, but there is the potential that copy products are inferior in finish, strength and performance, with a concern for safety which may not be apparent until a year or so after replacement. The short-term attraction to the consumer of copy parts is lower cost, resulting from the absence to the copier of the original design costs. The motor manufacturers have expressed the concern that IP should be available for those parts which they have invented and designed, often at considerable expense, subject to those inventions or designs meeting the same criteria as to inventiveness or distinctive character as apply to other industries.

Thus the motor industry finds IP important.

11.2. Types of IP used and their relationship

11.2.1. Patents

Patents are useful for a number of reasons. They clearly protect inventions of the vehicle manufacturers and of the suppliers in areas of major technological importance such as vehicle features or components. Many patents are filed on test gear and inventions relating to production, which may not be seen or deduced from the vehicle itself. These are classical reasons for obtaining patent protection. However, in this industry the patent right is useful in establishing ownership of the technology and in cross licensing that technology between manufacturers and suppliers, so increasing the financial return from the associated research and development. In this industry, patents are generally obtained through the EPO, but it is usually sufficient to designate only the major vehicle manufacturing countries. Much of the technology will relate to manufacture, and thus the patent right is of major importance in countries where manufacture takes place, or is likely to take place.

11.2.2. Industrial designs

Design protection is important in the area of spare parts, but the increasing trend towards a free market in spare parts in the after-market through legislation which allows copying in the 'must fit – must match' area is depressing to the industry, and deprives the innovator of return where the design can be important and the result of extensive development investment.

11.2.3. Utility models

Utility model protection is of little importance. This unexamined right is seen as having a negative value in not adding to industrial progress but merely serving to confuse, by increasing the difficulty and uncertainty of searches. There is a strongly held view by some vehicle manufacturers that full patent protection is available for inventions of very limited novelty and invention, and that the nuisance that such patents already cause could be multiplied many times by a utility model right which would grant protection even more readily to even less meritorious inventions.

11.2.4. Trade marks

Trade marks are a crucially important property in the motor industry. Indeed, they may be one of the most important assets of a company, where the trade mark can be associated with the quality and reputation of a particular vehicle and its components. It is quite likely that a single trade mark of a company might embody the whole of the technical and inventive excellence of a company; indeed a premium of only 5% of turnover for such a mark would still be a considerable sum. Such trade marks would be held in all EU Member States, and closely policed.

11.3. Factors affecting the importance of IP protection as a strategic asset

IP is variously a measure of inventiveness, of the state of development or reputation of a company, and is therefore of value. In the motor industry, there is greater interest in having a portfolio of patents covering an area of technology, and other IP, to create a climate for stimulating general innovation and a competitive advantage. This may be in distinction to other industries, such as the pharmaceutical and agrochemical industries where a single patent may be sustaining a multi-million ECU market. There is generally no great interest in the rapid grant of patents, since development is quite slow compared with the rate of normal grant; indeed, relevant patents may actually have expired before significant production using the invention occurs. Although homogeneous patent law and reliable enforcement are desirable, the CPC is of little interest and it is doubtful whether this industry would use it because protection is not required in non-manufacturing countries.

Trade marks are, however, of major importance to a motor vehicle manufacturer. There may be a number of these trade marks for a given manufacturer, such as a house mark (Ford, Seat, Volvo, etc.) and marks for a given model (Sierra, Punto, Cavalier). All these marks are symbols of the quality, reputation and business of the vehicle manufacturer and are carefully policed. In particular the house marks, and others, are used on spare parts, to assure the customer that the spare parts are genuine, originator products. The trade mark can be valuable in preventing counterfeiting and ancillary unauthorized use by others.

Of considerable concern is the changing situation regarding design protection for spare parts and the encouragement being given by consumerist and insurance companies to copy parts designed by others. This problem may be alleviated if the copier has to invest large sums in production plant or if the copy is of such low quality that the copy is rejected, but poorer IP protection is not encouraging for the innovator and deprives return for further investment. Trade marks and the recognition of brands in the market provide very useful recognition of quality of the innovator.

The usefulness of IP to the motor industry is summarized in the following table:

Table 11.1. Usefulness of industrial property

Factor	Patent	Design	Trade mark
Effectiveness of protection	Good	Good[1]	Good
Promotes technical advances	Yes	No	No
Assists in regulation of safety, emission, fuel economy	Yes	To some extent	No
Brand name protection	No	No	Crucially important
Impact on spare part sales	To some extent	Yes[1]	Yes
Influence on location of production base of proprietor and competitor	Yes	Yes	No
Use in transfer of technology	Yes	No	No

[1] But already undermined, e.g. by the UK Copyright, Designs and Patents Act 1988.

11.4. Factors affecting the choice of registration procedure

A major factor is whether the IP is likely to be useful as a commercial asset. This means that the country where the IP is obtained has to be important in respect of the particular IP. Thus a trade mark will be obtained in every EU Member State, but a patent very likely in only some, such as Germany, France, Italy, Spain and the UK, and the country scope of a patent will be decided on a case-by-case basis in order to 'block off' key markets. The same argument applies on a world scale: only key world markets will be covered for patents. The route chosen will also be cost dependent. It is likely therefore that the CTM will be used for trade marks, but a choice will be made between the national and EPO routes to the patent right depending on the number of countries selected for the right – about three or more being in general the break figure favouring the EPO over the national route, because of cost and single prosecution, with the PCT route to the same being used if protection is required in at least two countries outside the EU. Design registration is national, as being the only general route available at present, and is obtained in the larger markets; utility model protection is hardly used.

The above discussion relates to the obtaining of the IP right; enforcement is a further factor to be taken into account and this is far from homogeneous and satisfactory in the EU because of the disparate attitude of the national courts to enforcement. However, some IP is obtained in the anticipation that such a factor will improve in the near future.

11.5. An industry assessment of the effectiveness and impact of new measures

The most important advance in IP in Europe has been the EPC for two reasons; firstly, it has greatly assisted in making countries amend their patent statutes to a homogeneous level so far as term and patentability are concerned (seemingly the case law is generally becoming similar), and secondly, it has reduced costs to some extent, because unitary prosecution can be carried out, often by in-house attorneys, and translation can be deferred until it is more certain that the patented invention is, or is likely to be, of commercial interest. There is now no significant variation in, or inhomogeneity of, patent term or invention patentability in the EU for the motor industry. There are, however, concerns of inhomogeneity in the area of enforcement, and costs of obtaining patent property through the EPO are of major concern – the latter relates mainly to the cost of translations and of EPO fees.

The CTM is being used and is likely to be valuable for much the same reasons; it is desirable to have a single trade mark for the whole of the EU. It is, however, too early to comment definitively on the performance and utility of the CTM, and the related office (OHIM).

The Anti-counterfeiting Directive should, in principle, be of use to the motor vehicle industry, but there are concerns that it has not been effectively introduced by many Member States; this is a matter for local governments to resolve, and for the Commission to intervene where the required action is not forthcoming.

The Block Exemption Regulation on patent and know-how licensing eases some of the problems associated with the drafting and execution of the many agreements involved in the running of European, and global, businesses, which are the norm in the motor vehicle industry. Here, supply from integrated, multi-factory, international businesses is easier to organize without the risk of restrictive export clauses in the related agreements; with widespread cross-frontier trade in components and finished vehicles, it is essential that licences do not prevent exports and free circulation.

11.6. Implications of the changes for time and legal certainty

The past few years have been associated with many changes in IP in Europe. These have necessitated management of the changes which have cost implications and are always time-consuming. Nevertheless, there have been business and cost benefits as outlined above. Homogeneity of patent law, single prosecution, CTM are undoubtedly important advancements. However, further improvements are required – the industry feels that the cost of obtaining patent property is too great and that this relates to the cost of applications at the EPO and to the translations as the European Patent goes into the national phase. It is believed that only the claims and the abstract of an EP require translation at the national phase because they will give the scope of local exclusivity and a résumé of the invention. Also, some homogeneity in the determination of validity and in the definition of the infringing act and remedies against infringement is required; otherwise the exclusivity provided to the proprietor by the IP right is of much less value in an EU context and the benefits of homogeneous patent and trade mark law and legal certainty are significantly reduced.

11.7. Expected consequences of forthcoming measures

The draft Community Patent Convention is not considered to be useful to the motor vehicle industry, and it is unlikely to be used. It is foreseen to be expensive. It would provide the

innovator with unnecessary territorial protection. Its unitary nature would make the innovator more vulnerable, as the whole of the EU patent property would be susceptible to a rogue court decision.

'We will definitely not use it and do not expect anyone else in our industry to make significant use of it.'

The new draft Design Directive, although welcome in that it provides a generally useful homogeneous right, does not auger well for the motor industry. The draft repair clause allows immediate copying under licence with a royalty based on design costs. This would be counter-productive for the EU in discouraging the motor industry in the EU from protecting designs, so encouraging copying with minimal compensation. A high percentage of copies would be made outside the EU by low-cost sources as the motor industry continues to globalize its products. It would involve the industry in negotiating a multiplicity of small agreements, which would be time-consuming to conclude and police. The cost of the draft provision to the industry could be in the order of hundreds of millions of ECU per annum.

'The repair clause if enacted would encourage copying of our body parts with totally inadequate compensation. Cost to our business might be in the order of tens of millions of dollars per annum'. 'Assuming that the present Commission draft is accepted, with zero years repair clause, drastic reduction in the level of protection. Since the repair clause would take away most of our rights, legal certainty would be improved!!' 'The EU must be in line with other leading economies in IP legislation.' 'Delete the repair clause.' 'In view of the high quality and safety requirements and as a consequence of the high investments made, manufacturers have an enormous interest in the legal protection of design rights of spare parts. The proposals of the European Commission whereby third parties would be legally entitled to copy such protected designs as from day one, run in our view directly counter to product liability and safety regulations enacted by the same European Commission.' 'Design rights should be harmonized but not in a way making separate rules for certain kinds of goods like spare parts. Copying should not be encouraged.'

The matter of design rights for motor components is clearly one which evokes considerable feeling. On the one hand, there are the legitimate rights of the IP right holder, and, on the other, the consumer. Having regard to the warranty period provided by the motor manufacturers in respect of a new sale, the after-market for parts is small before the end of that period. A royalty based merely on design costs is not adequate or realistic. An equitable solution, which would not offend the provisions of TRIPs, would be to abandon the repair clause in the draft directive and provide therefore a design right for spare parts of 10 years from design right application (the minimum term provided by TRIPs); it would give the design right owner some return over a period of about seven years from first marketing, and give the copiers a substantial after-market when the vehicles are getting older.

The motor industry considers that the draft EU utility model legislation[4] is unnecessary. It is considered that an unexamined right will only clutter up industry with a right of doubtful validity. Furthermore, it is likely to be expensive because of the need for translations, a matter on which the Green Paper is curiously silent. A utility model still requires a verbal description and claims (which need to be professionally drafted) and is not like a design right which is

[4] Green Paper COM(95) 370 final.

largely pictorial or diagrammatic in its filed specification. Thus, it is foreseen that a unitary EU Utility Model Convention would suffer from at least all the disadvantages of the CPC. If the European Commission is seeking through this proposed measure to assist SMEs, then EU-wide measures are not required, but it should be left to administration of purely national statutes. However, utility models are generally thought to be unnecessary; the level of inventiveness necessary for the patent right is small, so that it is difficult to visualize the even smaller level perceived for a utility model and to define the boundary. Indeed, a utility model right might act unfavourably on the patent system and even bring the latter into disrepute. Such difficulties lead motor industry representatives to suggest maintaining the patent level of inventive step and abandoning any EU utility model with its even lower level of inventive step, and perceived disadvantages.

11.8. What industry wants

The motor industry is of the opinion that homogeneous IP law in the EU is a necessity in an international business, i.e. homogeneity of scope, term, validity and enforcement. This is not, however, the same as unitary, EC law. It requires flexibility as found, for instance, in the EPC. It would not find unitary EU-wide measures or conventions attractive. IP is not required in all countries in all instances, and so to have a unitary system is seen as an expensive waste, save for trade marks. The industry is further concerned that since the standards of enforcement in the EU Member States are very variable, it simply could not trust protection of valuable IP to the weakest court. IP rights must be respected by third parties, the importance of enforcement being recognized by the courts. The most important single improvement now would be to upgrade the strength of enforcement procedures in the EU Member States.

The industry does not see the necessity for additional utility model protection along the lines foreseen in the Green Paper. This unexamined mini-patent would appear to cause confusion to innovators, without any substantial advantage as to cost. Almost by definition, companies interested in utility model protection are likely only to require it in a few EU Member States and not on an EU-wide basis. The large majority of the motor industry considers that the proposal in the Green Paper should be abandoned; the minority suggest that the utility model proposals be amended to provide a novelty-examined right having a short term, e.g. five years. In that way the protection would cover small improvements having short-term interest. However, EU-wide protection for trivial inventions is not conducive to respected IP systems.

Whilst the motor industry supports harmonization of industrial design law, it has profound concerns about the Design Directive as presently drafted for the reasons given above, and seeks amendment to delete the repair clause. Indeed, the Commission original and revised stances on spare parts pay no heed to the risks, value, time scale of investment and expenditure on successful and failed development projects; the margins required to sustain healthy business for the foreseeable future must be realized, and the stance on spare parts to encourage plagiarists is to the considerable detriment of presently large and successful international businesses in the EU. There may be a very short-term benefit to consumers, but it is to the long-term detriment to them, investment and employment in the EU. The motor industry would rather the draft Design Directive be abandoned altogether than having a directive including the repair clause.

In conclusion therefore, the motor industry has three major requirements for IP in Europe:

(1) Harmonization in IP statutes in the EU Member States is essential, but this does not mean that there should be a single, unitary right for the whole of the EU; for example the EPC is broadly satisfactory, but the CPC is unnecessary and would not be used. There should always be a choice between obtaining IP rights through EU-wide and national routes, and that choice must be without prejudice.

(2) The motor industry considers that the enforcement of IP rights in Europe is very variable and needs urgent attention.

(3) The costs for obtaining and maintaining patents are far too high; this largely includes translation and renewal fees. The motor industry believes that these are the areas to which the EU Commission should pay most attention in the near future in order to satisfy the requirements of this industry.

12. The pharmaceutical industry

12.1. The importance and role of intellectual property

Some figures relating to the EU pharmaceutical industry are as follows:

EU production (1993)	52.3 bn ECU
EU trade (1993)	
Total export of pharmaceuticals	34.5 bn ECU
Total import of pharmaceuticals	23.5 bn ECU
Pharmaceutical trade balance	+11 bn ECU
EU employment (1993)	
Total	540,000
R&D	81,000
NCE introduction (1990-94)	
Europe	94
USA	84
Japan	77
Other	4

The pharmaceutical industry is one of world-wide scale, and of considerable importance in the EU. Within the innovative pharmaceutical industry, companies are largely vertically integrated, with all aspects of the product from research through to manufacture, production and marketing being carried out by one company, or its subsidiaries. There is some contract manufacture and there may be joint marketing agreements; sometimes, there are research collaborations. Generally, each company is self-sufficient and seeks to market its products world-wide. There also exists a large generic industry which markets products as they come free from patent protection; this industry is able to market copy products at much lower costs than the innovator, as they have comparatively none of the R&D risk and investment of the innovator. However, the generic industry favours strong patent protection, because without it there would be no innovation.

It has been said that the innovative pharmaceutical industry is wholly dependent upon the patent system.[1]

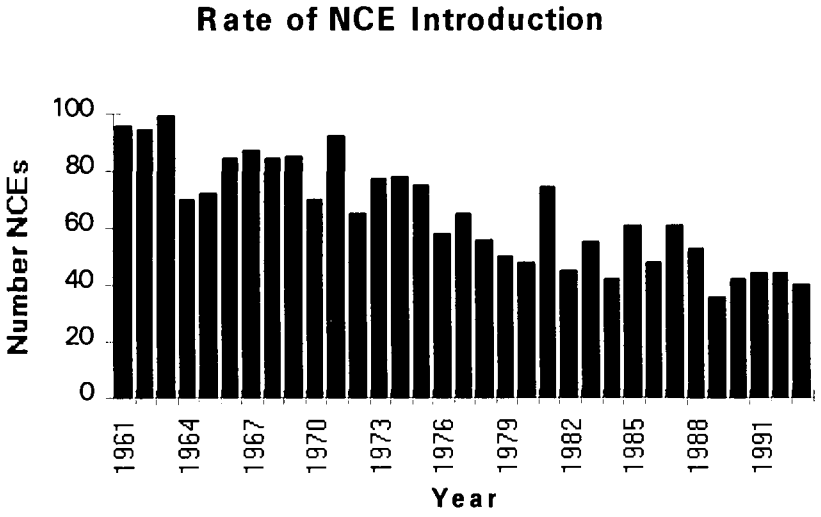
'Zeneca's business requires high levels of investment in the research, development, licensing and launch of new products, and the enhancement of existing products. This activity provides the dynamic for the Group's existence and growth, and the existing products and related intellectual property are the Group's most valuable assets.'[2]

The system provides an opportunity (and not a guarantee) for the innovator to obtain a return for the associated risk investment to keep copiers from early imitation of the innovation. New medicines are increasingly difficult and expensive to invent and develop to the marketing stage and after, and yet are relatively easy to copy. The world-wide situation requires attention because the industry needs to sell its products in the global market. For the patent system to be useful to the innovative pharmaceutical industry, three components are required: firstly, the chemical entity, the active ingredient, must be patentable; secondly, the patent must have an adequate term; and, thirdly, the patent must be capable of being effectively enforced and be free from dilution to the patent right, for example, by use of compulsory licences. If any one of

the three components is absent, the patent system is useless in assisting the innovative pharmaceutical industry. The patent system must also be considered having in mind these essential components.

Consideration of trends within the industry will assist in judging the usefulness of patent law. There are some basic tenets. Current research is paid for out of current sales; it would be prohibitively expensive to borrow and financially unattractive to lend 300 million ECU[3] or so in the pious hope that in 10-12 years a new medicine will have been produced, the profits from which will repay the loan and fund then current research. So, given the investment, there needs to be a patent life long enough after product launch to provide income to facilitate continuing development of the product and further research and development. It is increasingly difficult to invent new medicines; the disease states to be attacked are that more difficult than those treated by the medicines of yesterday; the innovator needs to know more about the disease state and the effect of the new medicine, and to satisfy increasingly stringent requirements of registration organizations around the world. The time taken between invention and marketing has therefore increased continuously over the last 30 years. As seen in Figure 12.1, the number of patented new chemical entities (NCEs) reaching the market has shown a decrease over this period in spite of increased expenditure.[3]

Figure 12.1. Rate of NCE introduction 1961-93



The normal cash flow trend for a typical range of pharmaceuticals in the US market introduced in the period 1980-84 is shown below in Figure 12.2.[4] The data in Figure 12.2 can be represented in cumulative cash flow terms (Figure 12.3), from which it can be seen that the break-even point in cumulative cash flow terms is about 18 years after invention, i.e. after patent filing. Thus merely to stand still, the patent system has to reflect these trends.

Figure 12.2. Cash flow for a range of pharmaceuticals in the US market

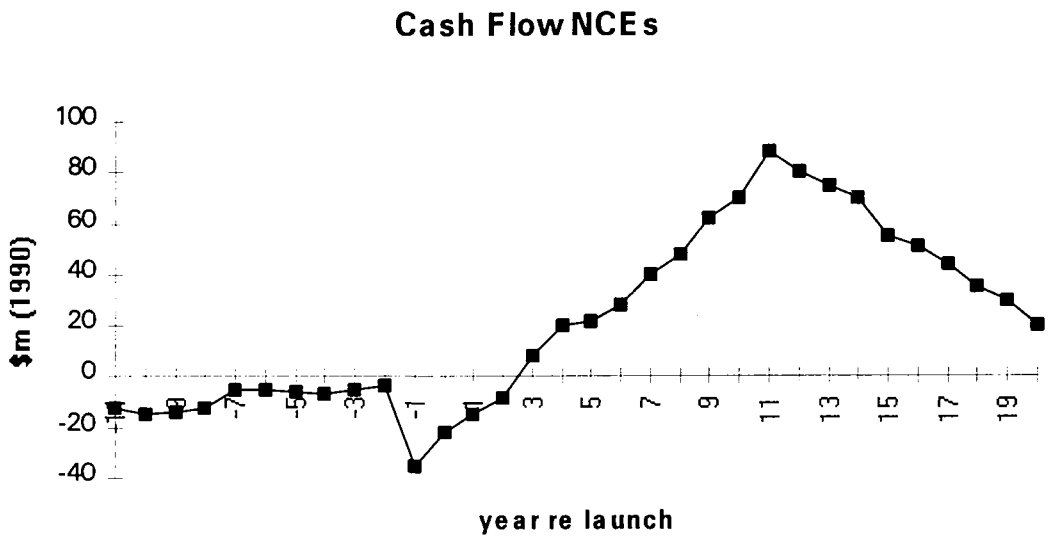
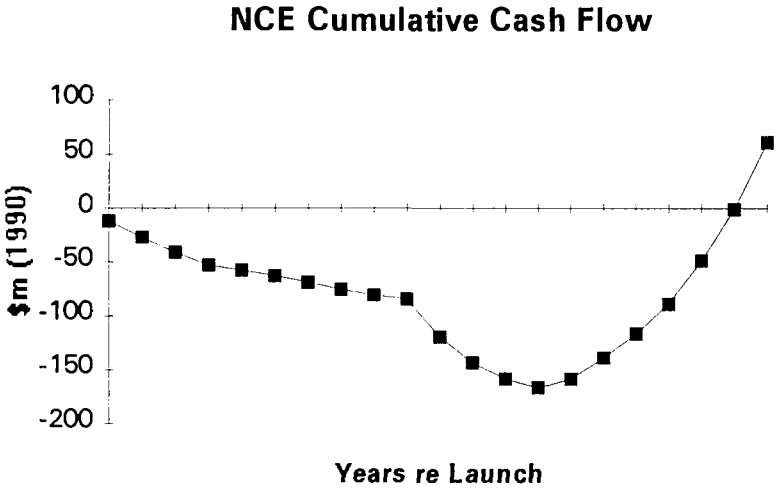


Figure 12.3. Cumulative cash flow



The useful patent term is shortened by the increasing time taken after patenting for the product to be developed; the effective patent life (EPL) can be quite short, although the patent term is generally 20 years from filing. Governments, who are the major purchasers of medicines in Europe, are always very cost conscious, so restraining the return to the innovator; the generic producers are increasingly actively encouraged, so reducing the return to the innovator after patent expiry. However, several events have improved the situation of the innovative pharmaceutical industry although they may take some years to have full effect. Protection of

the innovative new chemical entity (product patent) is essential. This is the real invention, and product patents are necessary to protect the investment in the related research and development associated with that new chemical. Such product protection must include the products from biotechnology, such as genes and gene fragments.

Because governments are the major purchasers of prescription pharmaceuticals and set their price in their Member State, the single market is fragmented. Major problems are therefore caused by the EC legal provisions concerning parallel imports. Whilst the basic concept of a single market is not contested by the industry, it has to be questioned whether parallel imports caused by or encouraged by government administered price fixing and reimbursement mechanisms in many Member States are tolerable.

The third requirement of the patent is enforcement. The pharmaceutical industry is deeply concerned with the variable performance of the national courts in EU Member States as discussed elsewhere in this study.

Design protection is of relatively minor importance, except for packaging, but trade marks play a significant role in connecting the innovator with the product. This is of increasing importance after patent expiry in order to maintain the recognition of the product of the innovator in the face of competition by generic pharmaceutical manufacturers. However, the importance of the trade mark is often reduced by the action of governments which encourage, and indeed sometimes demand, the use of the international non-proprietary name (INN) on labelling rather than the trade mark of the innovator; this may amount to a unique form of discrimination against the innovative industry.

Utility models play no role in the innovative pharmaceutical industry; however, if they were provided along the lines suggested in the European Commission Green Paper, the industry would be hampered by the presence of unexamined rights on very minor alleged inventions. The view of the pharmaceutical industry is that there should be no such rights in the EU.

12.2. Types of protection used and their relationship

12.2.1. Patents

There are two routes to patents in Europe at present: the European Patent Convention (EPC) and the national route in each Member State. These are described elsewhere in this study, and matters relevant to the pharmaceutical industry will be considered below.

12.2.2. European Patent Convention (EPC)

The EPC route is used almost routinely by all innovative pharmaceutical companies because they would normally require patents in all the EPC contracting states rather than just in four, which is generally reckoned to be the financial break-even point,[5] and the prosecution can be achieved by a single patent attorney, often already employed by the company. It is, however, unfortunate, to say the least, that some EPC contracting countries (i.e. Greece, Portugal and Spain) did not allow product patent protection until 1992; this is resulting in inhomogeneity, particularly within the European Union, which will last until 2012. The EPC practice is one of continuing development as would be expected in a dynamic organization; its influence, which already embraces almost all of Western Europe, is expected to extend to Eastern Europe as the patent laws come up to the EPC standard.

The EPO is developing its own case law which is extending to the member countries. Oppositions are a weak part of the EPC practice; they are considered to take too long, which adds to the uncertainty of the strength of the EP, and an opposition to a patent generally results in any infringement action being stayed. The EPO must resolve this problem, for example, by increasing staffing levels and the filing fee for lodging opposition. There is almost some support for Article 84 EPC to become a ground of opposition.

Attendees at the seminar considered that all biotechnological inventions should be patentable, including animal and plant varieties. For selection inventions, strict photographic novelty should apply if an inventive step is found.

It became clear from the seminars that the industry would strongly welcome a Community patent for reasons of cost and homogeneous coverage, but only provided it could have full confidence that patents could not be declared invalid for the whole EU by courts which were not sufficiently expert to ensure full respect. However, provided validity was determined by a mandatory opinion of the EPO, this obstacle would be overcome.

12.3. Trade marks

The Community trade mark is generally welcomed, but there are several problems which concern the pharmaceutical industry.

Firstly, approval for marketing a medicinal product in Europe is obtained through the appropriate national approval organizations or, more recently, through the European Medicines Evaluation Agency (EMEA). The EMEA *must* be used for approval of products of biotechnology and *may* be used for other innovative products. Those approvals include approval for the presentation of the medicine – product package, product insert – and the trade mark. The trade mark may be rejected during the approval process by the EMEA's Committee for Proprietary Medicinal Products (CPMP) on the grounds of risk to public health, in spite of having been registered and hence thought by the trade mark registries – the competent authorities in trade marks – to be distinctive and not likely to cause confusion. Such a rejection at a late stage could be a considerable problem. During the seminar it was suggested that the problem would be alleviated if the CPMP would raise objections to a trade mark in advance of a formal EMEA application.

Much more serious, the Commission – based on its interpretation of Regulation (EEC) No 2309/93[6] – requires a single trade mark throughout the EU for each application to the EMEA. Whilst companies in principle share the desire to have the same trade mark throughout the EU, this cannot always be obtained and is seen by the industry to have no relevance to the safety, quality or efficacy of the medicine. To remedy this difficulty, companies seek the possibility of choosing another trade mark for any Member State where real legal difficulties arise in the choice of a single trade mark (i.e. a trade mark that is available, commercially acceptable and legally valid throughout the Community).

Furthermore, they point out that the Community trade mark approved by OHIM is susceptible to invalidation by any court in the EU, after the marketing authorization has been granted, and so the whole marketing strategy of the proprietor will be in danger, even many years after first marketing, and therefore patients in Europe might even be deprived, albeit temporarily, of an EMEA approved medicine. Such an event would delay marketing in the EU pending the

approval of a new mark – to the disadvantage of trade and patients. The problem limits the attractiveness of the EMEA and could inhibit recourse to the centralized procedure.

Nevertheless, the Commission points out that all the companies concerned by the Community authorization procedure have – so far – managed to abide by this requirement, and, moreover, some have filed for a same product several applications, each with different single trade marks valid throughout the EU. However, in respect of the latter issue, the Commission has acknowledged that a single trade mark may be challenged in a Member State on legal grounds after it has been registered. This type of situation will require a 'practical solution' which the Commission is elaborating without questioning the principle of requiring a single trade mark.

There is, in addition, a problem in some countries in that the use of the same trade mark for prescription and non-prescription products having the same active ingredient is not permitted;[7] this is unacceptable as many prescription-only medicines later become 'over the counter' (OTC) products (e.g. Tagamet®, Zovirax®) following their initial and continuing marketing as prescription-only products. The reputation for efficacy, safety and the connection with the manufacturer are thereby lost, and there is no evidence that by retaining the prescription name there is any confusion to the public, either the patient or the pharmacist. Harmonization of this aspect is required.

The Harmonization Directive on trade marks has been particularly important and welcomed. So far as the CTMR is concerned, the industry requires trade marks throughout the EC and the volume of initial applications demonstrates wide interest. It is, however, still too early to judge the performance of the new system.

12.4. Factors affecting the importance of intellectual property

The importance of intellectual property is heavily dependent upon what is provided by the statute and the stance taken by the judiciary in enforcing those statutory provisions. Providing that the three crucial components discussed in Section 12.1 above are present, then intellectual property is supportive of the industry. If one is not present, the statute is in effect useless. All countries in the EC now have a 20-year term from application date for patents (except for Portugal which will shortly amend its law to the 20-year term for all patents existing at 1 January 1995), although there is some inhomogeneity in term from older patents (Austria, Germany); many countries have existing patents that have only process claims (Greece, Portugal, Spain) – this gives cause for considerable concern and will be the source of inhomogeneity until at least 2012.

The enforceability of intellectual property in the EU is broadly unsatisfactory – the ability to obtain interlocutory injunctions against infringers is unknown in many countries, and is the norm in very few. This problem of enforceability adversely affects the role of intellectual property in the EU. Before there can be unitary rights in patents in the EU, a satisfactory and acceptable procedure is required; one which needs to gain the confidence and respect of IP right holders. This matter is now considered to be the single most important matter facing the patent holder in the EU.

12.5. Factors affecting the choice of registration route

The choice of registration route for patents is largely dictated on a case-by-case basis. Usually the patentability of an invention in this area is known from searches carried out before filing.

If the invention is a new chemical entity, which will take many years to develop to a marketable product, which is usually the situation, then the route will be the EPO directly, or the EPO via the PCT with prosecution by in-house attorneys. If the invention will take a shorter time to develop, or will not require protection in many of the EPO Member States, then the national route, either direct or via the PCT, may well be the more attractive, in particular because the granted patent will not be the subject of opposition in the EPO. The use of the PCT will enable filing at the last possible date in the international convention year, a single filing date for all the countries designated in the application and a delay in providing translations. The term and patentability of subject matter (subject to the comment below) will be the same irrespective of the route, and enforcement will be subject to the national courts.

However, a close watch needs to be made on differences of EPO law from national law in particular in the area of patentability, and the filing route pattern will be chosen accordingly.

12.6. An industry assessment of the effectiveness of the new measures

'There is no doubt that certain recent EC measures are assisting the innovative pharmaceutical industry.'

12.6.1. EPC

The EPC has clearly resulted in increasing homogeneity in patent law (to grant) in Europe. Because of the inhomogeneity referred to above, changes to the doctrine of free circulation are required so that the market is not distorted to the detriment of patentees (and the public).

Costs of patenting have been reduced through there being a single prosecution at the EPO to a patent effective in the designated countries, rather than a piecemeal approach through local agents; even so the costs, particularly of translation, are a high proportion of the overall costs of patenting, and whilst these might be bearable by large international companies, smaller companies find them to be prohibitive.[8]

12.6.2. Supplcmcntary Protcction Certificate (SPC)

The SPC,[9] which is a new IP right, has the same effect as a patent, and is applied for individually in each country of the EU where a patent exists on a pharmaceutical product. The SPC has a maximum five-year term and provides a maximum 15 years EPL, the dates for the commencement of these being determined by the first product marketing approval in a EU country; the terms are a political compromise to take account of all interests in a complicated business area – and less than those originally proposed. Thus, the above figures are definitely maxima and can only apply to the country of first approval. There are complicated transitional provisions, which again lead to inhomogeneity in the EU market; this is further distorted by the SPC Regulation not coming into effect in Greece, Portugal and Spain until 1998 (without any transitional provisions), and hence not affecting patented medicines in those countries until a much later date. Whilst the SPC will help the industry, this inhomogeneity will adversely affect the usefulness of the SPC. The SPC Regulation is not perfect in its drafting and there are times when there will not be consistent interpretation of its provisions throughout Europe; what can be protected, when is the first approval, what are the rights are all very important subjects of uncertainty.

The industry believes that an SPC should be available to all industries which suffer a reduction in effective patent life because of regulatory or other statutory pre-marketing or use delay.

12.6.3. High Technology Directive[10]

This directive provides protection against use or copying of the regulatory data of the originator in respect of high technology products. This includes medicinal products and those obtained from biotechnology. The directive provides protection for 10 years from approval for the highest technology and 6 years for inversions resulting from less high technology. There is, however, considerable scope for local interpretation and resulting inhomogeneity. Thus, in Austria, Belgium, France, Germany, Italy, the Netherlands, Sweden and the UK, the protection for both biotechnology and conventional pharmaceutical products is 10 years; whereas in Greece, Portugal and Spain, it is 10 years for the former and 6 years for the latter, and Denmark, Ireland and Luxembourg are similar but require the existence of a patent.

Such protection is not as useful as that provided by the patent right, because the second applicant can obtain product marketing approval using its own data.

Such a directive provides only minor protection compared to a patent; a third party is still at liberty to file its own dossier (perhaps derived, at least in part, from published information from the innovator) relating to a product, and so to obtain its own full approval – only the patent right will reserve the exclusivity to the innovator.

12.7. Implications of the changes for time and certainty

Implications are not easy to discuss. The discussion above has described inadequacies found in present legislation. Action is also needed, in some cases urgently, in respect of the forthcoming measures described in Section 12.8 below. In the industry's view, there is at present a strong innovative industry in the EU, and the Commission and the governments of Member States must not bring into effect any legislation or procedures which jeopardize the future of this industry. A continual watch needs to be kept so that beneficial changes can be made if there are adverse perturbations to the *status quo*, in particular by actions in the USA or Japan or by governments in the EU.

Relating to a particular matter, there are pressures from the generic industry to allow clinical trials on a patented pharmaceutical product to take place before patent (or SPC) expiry so as to allow the generic version to be marketed immediately upon expiry; such pressures must be firmly resisted. This would be counter to the provisions of GATT TRIPs, but an additional matter to be taken into account during consideration of the SPC term.

12.8. Expected consequences of forthcoming measures

12.8.1. GATT TRIPs

One of the many agreements concluded in the Uruguay Round of GATT was Trade Related Aspects of Intellectual Property Rights (TRIPs). This laid down minimum provisions for the law of many IP rights in the countries which become members of the WTO, the successor to GATT for those countries who subscribe to all the above agreements. In the patent area, TRIPs requires that patents shall be available for all areas of technology without discrimination; there shall be no discrimination between imported and locally-produced goods, and there are strict

provisions relating to the granting of compulsory licences. The acts which constitute infringement are stated, and there are also provisions defining remedies and procedures for infringement actions. It is clear that the patent provisions in the patent statutes of all EU Member States require amendment in respect of compulsory licences to conform with TRIPs; as yet, only Italy and Spain are doing so, although Germany requires only clarification. Industry views it as essential that all these TRIPs provisions are included in the local statutes of EU member countries immediately and that the requirements of new patent law are effective immediately – not only for applications filed thereafter, but also for applications filed earlier, provided that serious investments and commitments are safeguarded. Furthermore, the EU and the governments of its Member States should encourage other WTO members to amend their statutes in a timely manner.

12.8.2. Biotechnology inventions

It has been said that biotechnology will be the basis for the third generation of new pharmaceutical products. That may be a little exaggerated since there is still considerable scope for classical organic chemistry in the industry, but biotechnology will open new vistas. It will make complicated organic molecules, such as polypeptides, more readily accessible, as well as open up new areas of treatment, such as gene therapy. Inventions in this exciting science must be adequately and fully protected by the patent system. If they are not so protected, then the science will remain academically interesting but will not be developed to the extent of providing new products of great benefit to mankind. In other areas of technology, it has taken the patent system some time to catch up; in chemistry itself, the patent system in every country, except the USA used to provide protection only for the chemical processes by which a new chemical was produced, but now it is increasingly the situation that the latter is protected. GATT TRIPs provides that there shall be no discrimination against any area of technology. At present, the Japanese, the US and the EPC provide for the patent protection of most aspects of biotechnology inventions, provided that the invention is novel and inventive, and capable of industrial application. It is vitally important for us all that this situation prevails.

12.8.3. Draft Biotechnology Directive

The first draft Biotechnology Directive, which would have laid down some ground rules as to the interpretation and scope of biotechnology patents in Europe, was defeated in the European Parliament in 1995. It would have clarified the law in this area of science and provided a greater degree of certainty, which is just what industry, and indeed the public, require. Without this, there is the danger that development of this industry in Europe will be discouraged and move instead to pastures where the law is more certain, for example, Japan and the USA. An area where patents must be allowed is that of genes and gene fragments, consistent with other requirements of patent law. The demise of the draft directive is to be regretted, as there is nothing to fear from the patent system in this area. It provides an opportunity for the patentee to obtain a reward for his labours; it provides the public with information. It does not inhibit academic research.

The second draft directive[11] is broadly satisfactory to the industry; it will encourage the industry in the EC and add to the portability of investment in the EC. However, any amendment which reduces the scope of protection would be unacceptable; some areas such as the farmers' privilege and the compulsory licence provisions between rights (patents and plant

varieties) seem to offend against the TRIPs provisions. Reversal of the burden of proof re 'known' products would be a useful addition; many products of biotechnology are known in the patent sense and hence the biotechnology patent is likely to be directed to a process; if reversal of the burden of proof is limited to processes for making new products, the usefulness of many biotechnology patents will be much reduced.

12.8.4. Community Patent Convention[12]

At first glance, the CPC might appear to be just what the innovative pharmaceutical industry would want as it provides homogeneity in the EU. However, this is far from the situation, and indeed the industry finds the CPC wholly unattractive because of their concern regarding enforcement in which, according to the 1968 Brussels Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, initial stages of patent litigation involving infringement and validity would be left to the national courts. Because enforcement is at present so variable in the EU Member States (recent interim injunctions, under appeal, in Spain are a very welcome and unique event),[13] there is considerable risk that the first action would be in a state having little or no tradition of effectively enforcing patents or a tradition of holding patents invalid. This could sterilize parallel actions in other EU states or find the patent invalid for the whole of EU. Other fears about the CPC include cost and lengthy procedures, though in the seminars it was stated very clearly that if the problem of invalidity by an inexpert court could be solved, the industry would favour positively Community-wide patents because of its desire to treat the EC as a single entity. The suggestion that a mandatory opinion on validity by the EPO should be required by the specialist designated national courts was regarded as a solution to the problem.

12.8.5. Draft Industrial Designs Directive

Whilst the industry is substantially unaffected by the present draft, it considers that the concept of automatic compulsory licences (re spare parts) is an ugly precedent, and for that reason, the industry is against the draft directive.

12.8.6. Anti-counterfeiting Regulation[14]

The US provides for patentees to obtain information on imports of patented products from outside the USA. An extension of this regulation to cover patented products would be welcome, and there seems to be no insurmountable problem in such an extension; even copying of the US practice, which appears to work well, would be useful.

12.9. What the pharmaceutical industry wants

Any industry wants security, certainty for the future. The pharmaceutical industry is no different. It therefore seeks intellectual property which will provide for its needs, with predictability for its patents. Without that security, in particular the three components discussed in Section 12.1 above, there will be no such industry, to the detriment of mankind – for example, no new medicines, poorer health, fewer jobs, reduced health care.

Considerable progress has been made in the quality of patent law in Europe. However, much of this progress has only been parallel to that necessary to ensure that patent law reflects trends in and complexities of the innovative pharmaceutical industry. Nevertheless, improvement is still required in the ability to enforce the patent right and considerable modification is required

in the patent laws of most EU countries to bring them to the minimum standard required of them by GATT TRIPs.

All pharmaceutical respondents welcomed the SPC because the 20-year normal term of a patent is too short for the industry; some concerns were voiced, namely, over inhomogeneity caused by different interpretations of the regulation in different states and by the transition provisions, and moves to allow clinical trials by third parties before the expiry of the patent and the SPC. The latter, since it has already been taken into account, would, if permitted, mean that the SPC periods would have to be extended accordingly and would fly in the face of decisions in Europe,[15] counter moves in the US[16] and recent decisions in Japan,[17] and would probably be counter to the provisions of TRIPs.

13. What factors impinge on the effectiveness of EU and European measures in IP?

13.1. Introduction

Key determinants of the effectiveness of EC and European measures to provide industrial property protection are the rights provided and whether those rights are respected and upheld. Subsidiary determinants relate to cost, speed, and convenience. This applies to the European Union and its individual Member States, as it does to any country. However, there are many components to these two broad features, and the situation in Europe is complicated by the varying standards presently found in the Member States, and the doctrine of free circulation in the single market, which tends to reduce the effectiveness of IP, particularly in certain businesses where there is not a free market. Thus, there are both national and EU provisions to consider.

Questionnaires to intellectual property practitioners and EPAs (in some countries called Patent Agents, Trade Mark Agents, etc.) in large companies and in private practice in the Member States were intended to discover what views are generally held in professional circles.

Intellectual property practitioners in private practice are in a very good position to estimate the different views among large and small companies as proprietors of IP rights, because they have to act for clients both large and small. They are in only a fairly good position to estimate views among competitors of proprietors because, being particularly concerned with application work for protection of IP rights, they undoubtedly are conditioned to thinking from the point of view of the proprietors of rights more often than from the view point of the proprietors' competitors, though, of course, they are involved on the latter's side in all cases that threaten litigation. Industry executives, on the other hand, tend to be both owners and competitors of IP rights.

The questionnaires involved 40 to 60 composite questions for each of patents, trade marks, utility models and industrial designs. They looked at the issues from the point of view of proprietors and, separately, from the point of view of competitors of proprietors. For private practitioners each question distinguished between large companies and SMEs. To us there was no fear that the answers would be partial, because the questions covered all the important issues with a degree of overlap.

Almost all respondents to the questionnaires wanted homogeneity in IP throughout Europe. This makes obtaining an IP right more straightforward and reduces both administrative and statutory costs. Such a right should then have the same scope and the same term in all countries. There should, as a result, be a common source of case law, so that both the proprietors of the IP rights and third parties know the effective scope and validity of the IP right. This would aid business in its investment plans and hence the population at large. However, an important part of the equation is the second major feature. Homogeneity in respect for the IP right is necessary, and it is essential that all courts throughout the EU to which IP matters are or can be referred have a true perspective of the value of IP rights so that there is a proper balance between interests, and that the judgment in one country is similar to that in any other. Without this essential feature, respect for IP suffers.

There is considerable inhomogeneity at present in the field of IP rights in the EU.

13.2. The single EC model

A model for the EC exists in the form of the Community trade mark system and this model is among many proposals being considered for extension to utility models, and is being legislated for industrial designs in the relevant draft directive and regulation. So far as patents are concerned the essential features of the so far abortive Community Patent Convention are (except for appeal from nationally designated specialist courts to a special patent appeal court rather than to the ECJ) the same as the trade mark model.

Thus, the only EC model in existence or under real consideration is that represented by the Community trade mark system and this is so far untried.

This model essentially comprises parallel Community and national systems for IPR:

(a) The substantive laws of validity and infringement are the same in the national and the Community systems.
(b) Procedures for application and registration of national rights and for the exercise of them in the national systems are left to national laws and administrative rule.
(c) There are coherent and logical procedural rules for application and grant of IPR and for opposition to them (where the right of opposition is to exist), and for revocation of rights in the relevant Community registration office and in designated national specialist courts, acting for the EC as a whole.
(d) However, though such substantive law is harmonized, court and litigation procedures in the Community system with regard to infringement, revocation and remedies are left to national rules to be applied in nationally designated specialist courts, though in fact specialist courts do not exist in many Member States.
(e) Procedures on final appeal from nationally designated specialist courts are the EC established procedures for the court in question (the ECJ; or a specialist Community final court of appeal in the case of the Community Patent Convention).

13.3. Comment

13.3.1. Parallel national systems

The existence of parallel national systems is probably inherent in the Treaty of Rome, but in any case the abolition of national IPR would not be countenanced in any national quarter nor by industry. The existence of national IPR would seem to be an absolute prerequisite for justice for SMEs, and in actual practice it appears very unlikely (from the answers to the questionnaires, to say nothing of universal assumption) that this assumption would be challenged.

From the point of view of industry in general, it has not been suggested in any of our researches that the continued concurrent existence of national IPR would be a burden on industry and in so far as industry in general interacts with SMEs, it is reasonable to do so through national IPR systems.

Industries vary in their approach to IP and some will always make use of national rights in preference to Community ones. For instance, when protection in only limited geographical

areas is required, cost alone dictates the use of national rights. Each questionnaire respondent gives the relevant threshold of numbers of Member States which can best be covered by national rights. It appears that cost is the only criterion, and although challenged by questions as to whether there would never be strategic marketing or other reasons for fragmenting the single market by taking national protection rather than Community protection, on no occasion did any respondent admit this was a factor.

13.3.2. Common substantive law

The vital importance of a common substantive law of validity and infringement at the EC and national levels is noted and agreed by all respondents.

13.3.3. National procedures

National procedures for national rights were unquestioned, and indeed to call these in question would be beyond the proper scope of the Treaty of Rome.

13.3.4. Common EC procedures

Common procedures for the Community systems are natural and call for no comment. The only queries on the actual procedures (in actual operation only for trade marks in the OHIM) relate to cost and slowness, though naturally these queries are not based on experience at present.

13.4. A major problem: national and specialist courts

There is considerable disquiet among respondents to the questionnaires as to the reliability of nationally designated so-called specialist courts to try the infringement and validity of Community IPR. The degree of expertise available is questioned, and the likely uniformity of decisions is queried. The slowness and expense in a number of national courts is criticized and, although only one respondent said so in so many words, some of this disquiet must surely arise from lack of familiarity with national litigation procedures, in the broadest sense, in the various Member States (court rules, costs, types of remedies and national differences of attitude to the granting of remedies and language). One obtains familiarity with national courts second-hand, through local experts.

These fears relate, of course, to the fact that Community IPR covering all Member States will, if litigated, be determined in a single national court. Against these fears it must be remembered that in any large litigation where commercial interests are great, these will most certainly be of importance in a number of major Member States and therefore the proprietor of the IPR will be able to choose a court in a large and commercially advanced Member State in which to pursue his rights. It is unreal to imagine that a major infringement action could be brought only in a small or inexperienced Member State, because clearly in the case of a major infringement it will occur in many Member States, or at any rate all the large ones. If infringement only occurs in an inexperienced Member State, it is obvious that large commercial interests are not at stake, so in practice it is probable that the system of designation of national specialist courts will normally be effective and practical. The danger, however, is that a small and unimportant dispute affecting only a market in a small and unsophisticated Member State can yet result in invalidity being declared of an EC IPR for the

whole of the EC. The proposal that courts should be obliged in the case of patents to obtain an opinion of the EPO on validity was considered in the seminars to meet this fear adequately.

13.4.1. The Community Patent Convention

The draft Community Patent Convention would cure the shortcomings of the European Patent Convention with regard to fragmentation of the single market described in Chapter 10 by providing for a single EC patent infringement action which would be litigated in any one Member State where infringement had occurred, in specialist national courts designated for the purpose, with final appeal to a European patent appeal court, and with counter-claims by defendants for revocation for invalidity in the same courts. However, industry rejects this proposal because it will not contemplate revocation for the whole of the EC by a court which could be relatively inexperienced in a small, relatively uncommercial Member State, and it is true that a commercially insignificant infringement in a small Member State could lead to revocation of the patent for the whole EC. The first solution of respondents was that they should, in such circumstances, have the option of conversion of their EC patent into national patents in Member States other than that in which invalidity was found, along the lines of the Community trade mark conversion proposals.

This, however, could not work for patents because the grounds for patent invalidity and the facts on which invalidity are found are the same in all Member States, unlike the case of trade marks where, though the grounds are the same, the facts in the markets as to reputation etc. can be quite different. There could be no justification for conversion to national patents of a Community patent when the latter was found invalid in one nationally designated specialist court, because the ground of invalidity found would equally invalidate the patent in all Member States.

The final complaint of respondents is not that the facts in a patent case in one Member State are different and irrelevant to the EC as a whole (as can be the case with trade marks) but that the courts in some less sophisticated Member States cannot be relied on to give generally acceptable judgments. This is a very real problem. Unfortunately, it would not be possible to provide for different consequences according to the reliability of any particular court, and therefore the only conclusion would be that, because some specialist patent courts are unacceptable to industry to give EC-wide judgments, then none can, because discrimination between courts would be unacceptable. The consequence of this could only be that validity of an EC patent cannot be unitary. As a consequence, because of the assumed failings of certain national courts, the patent system must continue to fragment the single market. This is a very serious conclusion, particularly as the fault would only arise in practice in those possibly less common cases where infringement only occurred in a small or less commercial Member State. Because of this possibility, companies which would otherwise prefer EC-wide unitary patent rights would be prevented from adopting such rights. The whole patent system would be condemned to remain fragmented to the disadvantage of the single market. It should be noted that respondents from the less developed Member States themselves indicate reservations as to the capabilities of the courts in their own countries.

13.5. A solution

There are, however, possible solutions. One is that all designated specialist national courts should be obliged to call for an opinion on validity from the EPO (an option already existing

in the EPC, but not used). In these circumstances, such a mandatory opinion could be made binding, but even if it were not, less experienced courts would accept the opinion. Clearly, rejection of an EPO opinion would be grounds for appeal. The seminars established that this would meet the worries of industry. The matter was discussed at length in the seminars and industry showed that such a solution would meet their reservations for a unitary patent system which (where they want protection throughout the EC) they otherwise strongly support.

13.6. The Community trade mark

In the case of a Community trade mark being invalidated because of a fault in any particular Member State (for instance, the prior existence of a similar mark, or a language issue leading to a finding in that state of confusion, misdescriptive use or misleading character of the mark), the proprietor is entitled to convert his CTM into national marks wherever these objections do not exist. This thus diminishes the risk from insufficiently experienced national courts, though it does not totally remove the disadvantages.

13.7. Translations

The consequences of translation requirements are most acutely felt with respect to patents, but will, if other Community systems are put into effect, concern utility models, possibly nearly as acutely as in the case of patents, bearing in mind that the lesser amount of translation required may be matched by the lesser value of the right involved.

Experience so far is only with the European Patent Convention system. First, it must be remembered that to apply in each Member State separately would involve the maximum amount of translation. However, one of the advantages of a uniform EC-wide system should be economy in costs including, potentially, of translations.

Working on the basis of the actual, and indeed long-term experience, which exists for patents, and where the problem is the most acute, some conclusions can be drawn. In the first place, patent specifications are used in two ways: first, from an industrial point of view, and secondly, when necessary, from a litigious point of view. The competitors of a patentee wish to understand the technical advance claimed in a new patent and its industrial and commercial significance. For this a good abstract is all that is required, backed up by some of the leading claims (but not all dependent claims). Translations of these enable a full appreciation of the interest, value and commercial/industrial significance of the patent. The patentee for his part wishes to set his alleged advance in the context of the prior art sufficiently to underline his contribution. Again, a joint abstract and some leading claims are sufficient.

It is only if litigation is contemplated that the full text needs to be studied by the protagonists in their own working languages. Clearly, so far as an alleged infringer is concerned this requirement only arises when infringement is alleged. At this stage, the patentee should provide a translation in the language of a Member State which the alleged infringer prefers.

13.8. Criteria against which the utility of differing routes to industrial property protection may be judged

The criteria below reflect the tests, explicit or implicit, companies may apply in assessing the pros and cons of differing routes to protection of industrial property. It is against such criteria

that the potential value added, if any, of Community action in this field may be judged (but see below).

Table 13.1. Criteria for differing routes to industrial property protection

Criteria stage	Speed and convenience	Cost	Effectiveness	Territorial scope
Grant including opposition	**Is it easy to get?** How long to get protection? Is procedure reasonably simple? Is opposition long drawn out?	**How much does it cost at each stage?** Statutory fees Translation costs Patent Attorney Internal company costs Renewal fees	**Is the grant clear?** Clarity in procedure? Clarity of grant? Clarity of rights? Are rights generally respected without litigation? Are there significant risks in the application?	Local? National? EC? International?
Remedies, litigation & judgment	**Is judgment and remedy reasonably speedy?** How long to obtain judgment? Are the procedures reasonable?	**Is the cost of litigation reasonable?**	**Are the rights interpreted in the same way in each country covered?** In each country covered can the rights be effectively enforced? Are there expert courts? Is litigation transparent?	

EC IP rights are for the most part in a quasi-competitive situation in relation to national IP rights and their value will be assessed by companies in relation to criteria like those above. However, to justify EC action, further tests must be applied. It is not in general sufficient to show simply that against the current situation it would be possible for EC action to show advantages. EC action has also to be judged against constitutional criteria, namely:

Subsidiarity: is action at EC level required because protection is more effectively provided there than at national level?
Proportionality: are the measures required likely to be proportionate to the results to be achieved, notably the benefits to industry, and to society?
Necessity: is action really necessary at all?

In the case of industrial property, there is an unusual consideration. EC measures to provide unitary rights in this field normally presents an option, not a compulsion, as companies are free to utilize national methods or a European route where it exists. The element of competition and choice between the various possible routes must act for the benefit of the user, and it could be argued that the decision on subsidiarity ('at which level is action best taken?') may here be left to the user – though, of course, the tests of proportionality and necessity remain.

14. Assessment of the advantages and shortcomings of recent EC IP legislation

This chapter assesses EC and European legislation and planned legislation and makes a coherent distillation of relevant answers to the questionnaires and of comments made at the seminars. The chapter is split up into the individual IP rights, although some comments will be common to all IP rights, in which situation the generality will be noted; the chapter ends with consideration of pending or planned legislation and that which is not dedicated to any one IP right.

14.1. Patents

The patent scene in Europe is dominated by the EPC. Many laudatory epithets have been used in the preceding chapters of this study regarding the EPC. It has been, and continues to be, a unifying, homogenizing force in Europe and the EPC has been a template for the substantive national patent laws so far as patentable subject matter and term are concerned. It should be added that the EPO itself has established a good record in formalities, examination and information aspects, where the personnel are very helpful and courteous – that has had a knock-on effect in at least some of the national patent offices. The EPC is less expensive to use than national filings with break-even being about four countries.[1] However, some respondents use the EPO for less than four countries, possibly because the examination and opposition procedures of the EPC result in the patent being *prima facie* stronger than in countries where there are no such procedures.

Most respondents consider that the opposition procedures in the EPO are good value for money. Anyone can within nine months[2] of grant file an opposition to the granted patent on any one or more of the grounds prescribed.[3] However, a number of difficulties have arisen in respect of the EPO opposition procedure, not, however, with the decisions themselves:

(a) The present fee for filing an opposition is ECU 560; that is the only fee received by the EPO in respect of an opposition and it has to cover, for example, all the formalities, the three member opposition panel, and translations. Thus the Opposition Division has to be subsidized by other divisions of the EPO. Most respondents considered that the Opposition Division took too long to dispose of an opposition – it can take many years. The reason is that the Opposition Division is overloaded; there are too many oppositions, some of which are filed, it appears,[4] frivolously and this blocks the system. There is therefore a clear case for the Opposition Division to become self-supporting, to increase its level of staffing, and to adjust the opposition fee (at the time of writing about the same as a typical airfare to Munich plus overnight accommodation) to a more realistic figure. The delay in settling oppositions has important commercial consequences for a patentee who wants to exert the patent; such actions in national courts are generally stayed pending resolution of the opposition in the EPO. Hence, a serious commercial decision must be made if a product, which is the subject of a patent application, is to be marketed soon after filing, as to whether an EP application should be made with a risk of opposition, or national filings for all markets required, where opposition may not be possible or may be quicker in resolution.

(b) Several respondents remarked that the EPC opposition period should be shorter, e.g. until six months after grant. That would seem to be sensible, since potential opponents

have long known about the existence of the patent application (published 18 months after filing or priority date, whichever is the earlier); no respondent favoured any extension to the nine-month period (it would merely add to uncertainty and open the patent to successive or consecutive oppositions); similarly, no respondent favoured removing the opposition provision in the EPC, and several commented that they did not like the removal of opposition procedures from recent national patent statutes.

(c) In order to reduce costs to opponents and patentees at oppositions and other proceedings, it would seem reasonable to allow teleconferencing in place of personal attendance at oral proceedings; teleconferencing is becoming commonplace within and between companies to reduce travel expense and to use executives' time more efficiently.

(d) On technical points, there was majority support (see also [4]) for addition of a ground of opposition to include EPC Article 84; it is very strange that the EPO examiner can reject a patent application on the grounds that 'the claims shall define the matter for which protection can be sought (and that) they shall be clear and concise and be supported by the description', but that an opponent cannot, unless the opponent can argue that by being too broad, the claims are invalid on the grounds of obviousness. Article 83, which requires that 'the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art' is, on the other hand, ground for opposition. This means that once the EPO has allowed a claim, there is no way for any party to question that it exceeds the scope of the real invention disclosed. There have been cases where the EPO[5] has attempted to include attack on a claim under Article 83, but this is tortuous (the claims by covering inventions in the specification that have not been sufficiently described are therefore unduly broad) and not comprehensive (lack of support).

All industry respondents raised the problem of the cost of translations. This problem is not really one for the EPO because the requirement for translations is found in that part of the national statutes relating to the effect of a European Patent in that country.[6] The translations generally have to be filed within three months of the grant, although that period may be extendible. The cost of translation is very high and adds greatly to the expense of obtaining patent protection, even for a short specification. This is a subject which requires urgent attention if this cost is not to prevent widespread disaffection with the patent system in Europe: already small chemical companies are dissuaded from R&D to invent new chemical compounds because of the expense of patenting and safety clearance,[7] the latter – Notification of New Substances[8] – being interpreted variably in the EU. The translation is supposedly required to satisfy the disclosure part of the patent bargain. However, disclosure of the patent specification takes place with its publication in one of the official languages of the EPC (English, French or German) 18 months after filing or earliest priority date, whichever is the earlier. That disclosure of the specification makes the invention available to the public and destroys novelty of the invention to any later applicant anywhere. A full translation is only required when a patent is litigated; that occurs with very few patents (under 0.1%). The vast majority of translations are thus never used. It seems hardly logical therefore to require a translation into the language of every country where the European patent is to have effect. A halfway step might be to require a translation of the claims and a quality abstract. Another would be to introduce delayed examination; in this way applicants would have the option to prosecute to grant and full translation only those patent applications which experience showed were commercially attractive; other applicants may choose to proceed to early grant. A further suggestion was to encourage the use of electronic filing at the EPO so that translations could

(with increasing effectiveness) be obtained using one of the many PC translation packages that are available[9] (see below in Chapter 16).

A reduction in the burden of the costs of translation is urgently required (although not considered important by private practice), almost certainly at the EC level; maybe the requirement for translation could be deferred, if not until an infringement action, then until the first marketing of the product covered by the patent. It appears that a coherent and constructive solution is required; a recent review[10] does not provide any enlightenment. It may be that there is little that the EPO can do on translations; generally, the requirement comes from the statutes of the members of the EPC. It could be that an EC directive on the matter of translation would be the best way forward.

Another area of difficulty is the cost of application and renewal fees. One has only to consider the figures below, in Table 14.1, coupled with the relative populations of Europe, Japan and the USA[11] to realize that renewal fees and basic fees in Europe are far too high. Whilst the EPO could, and should, revise its fee schedule, the EPO has no suit in respect of renewal fees, which therefore require some central impetus for change.

Table 14.1. Population and patent costs

	Population (millions)	Full-term renewal fees (ECU)	Basic formal application fees to grant (ECU)[1]
EU	368.5	83,903	6,700[2]
USA	250.7	4,815	1,615[1]
Japan	124.7	27,487	985

[1] 50% reduction for SMEs.
[2] To grant; not including national phase.

It was felt that the general level of fees at the EPO is too high. This was particularly expressed by the national experts who felt that the fees for SMEs put the latter at a severe disadvantage against large companies. It is not seen why the fees paid should be dependent upon the number of states designated – it involves the EPO in no more work; why should a divisional application attract all the fees and at the time of filing? It is also suggested that, as in the USA, for SMEs all fees relating to their patent applications at the EPO be reduced by 50%.

The **Supplementary Protection Certificate** has been discussed above in Section 12.6.2. This new IP right in effect provides patent term restoration for medicinal products. The SPC is applied for at the national patent offices after marketing approval for the patented medicine has been obtained in that country.

The **Anti-Counterfeiting Regulation**[12] has been welcomed by industry in general; the motor industry experts considered that it should have been significant but was disappointing due to problems with effective implementation by Member States. It was also considered that the Regulation should be extended to patents, an area in which the corresponding legislation in the US is very effective.

14.2. Trade marks

The Community Trade Mark Regulation,[13] coupled with the Community Trade Mark Harmonization Directive,[14] is very important in the context of harmonization and facilitating prosecution of a single trade mark for the whole of the EU. The Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM) has been established in Alicante and has been open for the receipt of applications from April 1996. It is therefore too early to provide any experience as to how the Office is coping with applications and their examination, although the procedure appears straightforward. However, many respondents indicated that they would be using the OHIM, although coupled with parallel national applications.

'At present at national and Madrid level but in future we intend to use principally the CTM.'

'Possible, will migrate to CTMO (OHIM) for the important marks but will not let nationals go until CTMO (OHIM) is fully proven.'

The CTM begins its life with considerable goodwill and intention to use, because of many of the advantages seen in comparison with the EPO.

'The single trade mark for the whole of the EU will facilitate licensing.'

'It will reduce the variation in scope of protection found in EU Member States (e.g. Germany and Spain).'

A good trade mark is very, and surprisingly, difficult to 'invent'; the mark is often used before application for registration and hence even then has value in the marketplace. Therefore prosecution of the trade mark application must be swift and efficient; any opposition must be quickly settled. Generally, matters to be decided at the trade mark opposition stage are simpler to settle than in a patent opposition and hence there should not be such delay in settlement. It is very likely that there will be considerable numbers of oppositions in the OHIM because this will be a single, efficient method of challenging an EU-wide trade mark. Some respondents are concerned that the OHIM has attracted so many applications that prosecution and registration may be delayed. The opposition fee, set at ECU 350, is so low that many oppositions can be anticipated to be filed, bringing the risk that resolution of oppositions may be greatly delayed.

A further difficulty with the CTM is similar to that expressed below in connection with the CPC (Section 14.3.1), namely that the trade mark for the whole of the EU is susceptible to a decision of a court anywhere in the EU. Thus, a decision that a CTM is invalid would have meant that the mark is lost for the whole of the EU, although the fact that the trade mark may be automatically converted into a national mark in other Member States without any loss of priority makes this less serious. Particular difficulties in the pharmaceutical area are discussed in Section 12.3 above.

14.3. Planned legislation

14.3.1. Community Patent Convention (CPC)[15]

The CPC has little support from any of the experts consulted. Whilst it would appear that a unitary right for the whole of the EU might be attractive, there are a number of considerable objections to this route. Under the Brussels Convention,[16] action for infringement under the CPC would take place where the infringement takes place. This strikes fear into patentees

because the standard of some courts within the EU in patent actions, and all IP for that matter, is so unreliable, unpredictable, and often unacceptably slow and procedurally pedantic. In view of those difficulties it would be almost irresponsible for an IP manager to use the CPC, rather than the national (or EPC) routes to grant unless he can be assured that a court must follow an EPO opinion on validity. If the Brussels Convention were amended to allow the litigation to take place in the forum of the patentee's choice or in some other way, such as to establish a number of specialist IP courts in the EU, the CPC might have a better chance of being used. The solution found acceptable in the seminars was for validity to be subject to an opinion from the EPO. The CPC would in any event only be used by the larger companies who seek protection in all Member States. There remains the cost of obtaining the CPC patent, and the associated translations; failure to file one would render the whole patent unenforceable.

'As long as the Community patent can be invalidated by a low quality national first instance court, the CPC is of no value.'

14.3.2. Utility models

The Green Paper[17] makes a number of proposals for utility model (UM) protection in the EU. This might be in the form of a Harmonization Directive to harmonize UM protection in the EU and a Regulation to provide a parallel EC system along the lines of the CTM system.

It has to be said that whilst there is some support for UM protection from respondents, though none from the two industry sectors studied, the proposals in the Green Paper show some inadequacies. Firstly, the UM requires a specification, including claims, which need to be drafted with skill. It is not sufficient merely to base a UM on drawings. That specification requires translations. These requirements are very costly and similar to those incurred in a simple patent specification. The Green Paper does not address this problem. Secondly, the UM application requires, it is felt, some examination, such as a novelty search. Otherwise, there will be a morass of utility models granted, with very variable validity, which would be more of a hindrance than a help to industry, including SMEs, because the strength of the granted right would be uncertain both for the proprietor and third parties. The view was expressed that the level of inventive step in the patent system is already so low as not to require an even lower level.

'Quality of examination is essentially the same as patent.'

'Some prior art search ought to be made.'

'At least database search to be made.'

Thirdly, a register of utility models would have to be established to facilitate searching. Fourthly, some respondents questioned the need for UM protection (one at all) in any but the simplest inventions, and would not include chemicals, and noted that UM protection is only required in a few countries of EU, but not all, and should only last for a short time, e.g. five years, so as not to interfere with the patent right. Thus, there appeared to be a marked difference of views from the national experts and the two industries studied. Whilst there was general support for harmonized UM protection in the EC, there was little, if any, support for a unitary EU-wide right. The following remarks from the industry replies are illustrative:

'Unlikely that we would consider protection in each country by UM.'

'Re UM we are sceptical concerning the need for this, but if it is introduced in the EU it ought to be an examined protection to reduce legal uncertainty.'

'We will use it probably rather seldom and when there is no better alternative.'

'This tinkering could create additional burdens far outweighing any benefits.'

'Greatly reduced legal certainty due to proliferation of unexamined rights.'

'We think this will not benefit us and will cause unnecessary complication.'

'The UM system should not progress, at least not for chemical and pharmaceutical products and processes.'

'There is no need for a European UM or harmonized national UMs.'

'UMs for chemicals (including pharmaceuticals) would diminish legal certainty.'

'A UM will be bad not only for large industry but also for SMEs, since especially SMEs are not equipped to judge the validity of unexamined rights.'

It is has to be questioned therefore whether any UM right is needed. Does industry want it? Does the present situation inhibit the free circulation of goods or have any adverse effect on the single market? The Green Paper provides no evidence, nor has any been found from the respondents. The fact that a significant number of EC Member States have no UM provision seems to suggest that there is no problem at present. A far better suggestion might be to modify the existing patent system to provide for rapid grant and to modify the need for translations (see above); these would then furnish all the requirements sought for the proposed UM and yet another IP right would not be needed.[18] Indeed, the view was expressed that countries would find difficulty differentiating between the different levels of inventive step in a patent and a utility model.

14.3.3. Biotechnology Directive[19]

Following the rejection by the European Parliament of the joint text by the Conciliation Committee in respect of an earlier draft directive on the legal protection of biotechnological inventions, a revised directive is being considered by the European Parliament and by the Council of Ministers.

The new draft appears generally satisfactory to industry, provided that no substantial amendment is made during the various discussions and debates.

'The new draft has been published and as it stands is acceptable to industry.'

'If there is a reduction in the scope of patentable subject matter during its course through the EU institutions, then we would not want to see this progressed.'

The directive is required to ensure that EU industry is not disadvantaged compared with those in the US and Japan, and to ensure homogeneous interpretation of patents in this area is assured in the EU. Very often emerging industries and their technologies outstrip the IP provisions and the biotechnology industries is one such; thus there should be no artificial restrictions to patentability. One would immediately question whether a patent office has the competence to judge morality; it can hardly be immoral to encourage inventions which are designed to produce to new medicines to alleviate suffering and improve health;[20] indeed, to

discourage such research is itself immoral. Thus a strong patent system is required in this area, and the directive as presently drafted assists in this goal.

14.3.4. Patent protection for computer software programming

Here also, the EPC has been overtaken by technological advance and an effective definition of patent rights with regard to software through a directive harmonizing national law is required.

14.3.5. Industrial designs and models

The draft directive[21] seeks to harmonize the laws in the EU on registered designs, and the draft Regulation[22] provides a parallel Community system analogous to the CTM. As shown in Table 8.3, the national provisions in the EU are far from homogeneous and hence it is highly desirable to make the market more orderly in this important area of IP. Whilst homogeneity in provisions such as the definition of a design, criteria for protection, the term, provisions for nullity and scope of the right are welcome, the provisions relating to spare parts are unacceptable to the motor industry as discussed in Chapter 11, and to the pharmaceutical industry if a precedent for automatic compulsory licensing were thus established.

14.3.6. SPC for plant protection products[23]

This Regulation, which it was anticipated would come into effect by the end of 1996, is similar to the SPC for medicinal products, but will be very welcome to the industry. It will also assist in the interpretation of the first (pharmaceutical) SPC.

15. Has EU legislation on IP encouraged investment?

15.1. General considerations

Many factors affect industrial investment in a given country or group of countries, such as in the EU. All these factors will be taken into account when considering investment. However, no single factor will dominate the decision to invest. Some will influence the decision more than others, depending on the market and the industry.

Table 15.1. Examples of factors which affect investment decisions

External	Market	Internal
Political stability	World market	Strategy
Local services and geography	Local market	Staff expertise and availability
Local infrastructure	Growth	Ease of control
Political encouragement	Size	Competition – investment
Planning controls	Competition	Competition – management time
Inducements, e.g. public financing	Pace of change	Cash availability
Banking services	Others	Possession of IP right
Interest rates	IP rights	
Exchange control		
Availability of capital		
Currency stability		
Suitable work-force		
Education		
Social costs		
Available market for products of the investment		
Communications		
Legislation – including IP		

IP is one of many factors which will influence the decision to invest. Just as a patent right will not guarantee commercial success for a patented product but merely an opportunity for the patentee, the presence of strong IP rights in a country does not guarantee investment but increases the possibility that it will occur. The standard of local IP also gives an indication as to how an industry which values IP would be welcomed in a given country. Greece and Spain, for example, had no patent protection for pharmaceutical products (they both had process protection, but the court record on enforcement has until recently been abysmal). Greece and Spain do not have innovative pharmaceutical industries and have not been countries for inward investment. Thus in deciding where to make an investment, consideration is given to all relevant factors, of which IP may or may not be relevant, and a decision taken having regard to the best compromise of the relevant combination of factors.

It is easier to see whether IP legislation (or the lack of it) has discouraged investment. For example, respondents expressed clear concern that the EP attitude to biotechnology risked discouraging inward investment or even causing de-location from the EU. It will make sense for the EU to ensure that IP laws in the Community make it an attractive place for inward investment by companies in those industries where IP is important. As this study has shown, industries know the conditions and provisions they would like for IP, though these differ. In practice, there is considerable variation in the usefulness of IP within the various sectors of industry, and hence on its influence in investment. Without a patent system, there would be no

pharmaceutical industry and no new medicines: 'In the patent field, however, probably only the research based pharmaceutical industry is totally dependent on patents'.[1]

Similarly, although this study does not cover copyright, the following illustrates the present point: 'It can be fairly said that of the traditional copyright industries that their entire activity is intellectual property based'.[1]

Accordingly, Table 15.2 provides a quantitative indication of the proportionate values of IP; however, a full assessment would also vary by company and country.

Table 15.2. Proportionate values of industrial property to different industries

Industry sector	Patents	Trade marks	Designs	Utility models	Copyright
Electronics	YYY	YYY		YY	YY
Engineering	Y	Y	Y	Y	Y
Food	Y	YY			
Pharmaceuticals	YYY	YY			Y
Publishing		YY			YYY
Textiles		YYY	YY	Y	Y
Motor	YY	YYY	YY		

NB: In this table relative importance is: Y= of some importance YY = important YYY = of great importance.

Industries have a general perception of the economic value they place on the various types of IP. Attempts have been made to rank the importance of patent rights by industry[1] [2] based on the investment in R&D and the number of patent applications filed. Clearly companies would not file patent applications if they were not thought to be of value. These studies have ranked many industries and have found patents to be 'essential' in pharmaceuticals, 'very important' in chemicals and aerospace, and 'important' in motor vehicles and electrical engineering, but 'of little importance' in furniture, textiles and the retail trade.

It should also be borne in mind that the patent right may not be required for the whole of its normal term, and that the patent may be abandoned after only a few years of its life. That may be because the invention has proved to be of no commercial interest, or may have been superseded by an improvement not covered by the earlier patent. Only some 4.5% of patent applications filed resulted in patents which were maintained to the end of their normal 20-year term.[4] However, for some industries the 20-year term is not sufficient, for example, for pharmaceuticals and plant protection products.

In the UK, for designs, where the registration is in force for five years, extendible for two further periods of five years, the renewal pattern is given in Table 15.3. A similar reduction in maintenance of patents is found.

Table 15.3. UK designs filing and renewal rates

Registrations	1985	1990	1994
Filed	6,546	9,171	8,216
Renewed after 5 years	1,947	2,892	3,519
Renewed after 10 years	722	968	1,421

In many industries, brand marketing and the respective registered trade marks are of hugely important value in the marketplace and hence to the proprietor. The trade mark intensities have been reviewed[3] and it was found that the most trade mark intensive areas were classes 21, 28, 15 and 10 and the least were classes 12, 6 and 4.

All this gives an indication of how important industry considers IP to be in its particular sector. It gives no indication of the worth of IP in monetary terms. IP in terms of cost is usually written off against revenue expenditure as it occurs. We know of no instance where IP appears in a company annual report as an asset. It is therefore treated as an intangible asset, with varying degrees of importance to that industry, which will show in the sales figures and profit/loss accounts, but is not actually valued. The value of IP is reflected loosely in the company share price. It is commonplace for the share value of a pharmaceutical company to be affected adversely as the patent on a major product expires, or is found to be invalid. The value of IP is also important, together with know-how, in valuing a company at the time of take-over or merger or demerger. But this is not an exact science, and more based on 'feel'. One has only to consider the recent take-over of Rowntree by Nestlé to visualize the large, but unquoted and hitherto unrecognized, value placed on the Rowntree brand names. Thus, this study has not considered further the quantitative financial value of IP on the grounds that IP value is only clear at a point of crystallization, such as the sale of a brand, a licence or a company.

It is clear that the Community will benefit by providing IP rights which encourage industry and investment. In the patent field, the European Patent Convention has resulted in homogeneous patent law up to grant in all EU Member States. The Supplementary Protection Certificate is a useful procedure to national patent term restoration for the pharmaceutical industry – a similarly useful provision for the plant protection products will, it is hoped, become law by the end of 1996. The draft Biotechnology Directive will help to produce homogeneous law in that area if enacted. It is too early to comment on the performance of the unitary Community trade mark, but concern has been expressed about the ability of the OHIM to deal with the unexpectedly high volume of applications and, probably, oppositions. Registered designs could benefit from homogeneous national rights and maybe also utility models, but the latter appear to be less important to any industry. Enforcement of IP rights presents a real difficulty; not only is this often an expensive and lengthy procedure, but the courts in many EU countries are inexperienced in IP matters giving rise to concerns about the treatment of infringements. This is probably the most important area for the Community to rectify if IP rights in the EU are to be of benefit to industry. Without a solution satisfactory to industry, any unitary EU IP right will not be used by industry. A simple modification to the 1968 Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters may suffice.

15.2. Measures of patent activity

In an attempt to gauge the productivity of various industries in major countries, analyses are sometimes made of the number of patents filed. These analyses are fraught with difficulty and can give greatly misleading results unless the patent strategy and philosophy of each company and that prevalent in each country are taken into account. As one attendee at a symposium said 'the Japanese patent everything that moves'. German companies are also profligate filers of applications, probably because each application may have narrow scope. The UK companies are much less so. To take a number of examples of patent strategy: if one is a manufacturer of polyvinyl chloride, or any high volume plastics material, R&D will be directed at, for example, process improvements and end-uses for the polymer. One company may decide to patent the process improvements, but another may decide to keep them secret because to publish the process in a patent will publish unpoliceable know-how. One company may decide to patent end-uses for the polymer, another may decide not to patent but to ensure that it can sell its polymer to that end-use by publication and sales brochures. Both are sensible strategies, but the first company will have a much higher patent count than the latter. This would lead the unwary to conclude wrongly that the former had more productive research. It has been said elsewhere in this report that a major cost of patenting is in formal fees at, for example, the EPO and in translations. A wise patentee will, through prudent drafting, combine a number of 'inventions' into one patent application, so attracting one filing fee and one set of translations; that would give a lower patent count than a less prudent company. Some companies will only file on inventions which look commercially interesting. Unless one is aware of these variations, and any others, simple patent counts may be misleading.

In the EPO, the average number of designations per application in 1995 was 8.7[5]; in 1994 it was 7.9.[4] The 1994 Annual Report of the EPO[4] provides much detailed breakdown of patent statistics for 1994, the latest year for which they are available. Table 15.4 shows the country of origin of the EPO applications in 1994 (but the comments of the previous paragraph should be borne in mind), the percentage of those applications designating each EPO country, and Table 15.5 gives the corresponding data for granted patents. The pattern is interesting because it shows those countries which applicants considered were important and shows the necessity for the EPC type of patent right.

15.3. Special comments relating to small and medium-sized enterprises (SMEs)

It is appropriate to consider the IP requirements of smaller companies. These so-called SMEs include a wide range of enterprises, which many consider to be of increasing importance to the economy of the EU and to form the basis of increased employment. As they make many improvements in technology and market products and services, they, too, need IP to protect their investments and markets, and must know of IP as an information source. SMEs can be taken to employ fewer than 600 employees and the term includes the very small companies employing fewer than 25 and also the Institutes of Higher Education (IHEs) which also make inventions and many of which have marketing organizations to market products or to license others to market same.

An important feature about SMEs is that they have a much smaller and maybe less secure, financial base from which to operate. They have, by definition, fewer employees and hence are less likely than large companies to have staff or departments dedicated to a particular function, such as, for example, IP. This has at least three results. Firstly, they are heavily dependent upon outside assistance for such areas of expertise; secondly, costs of IP are likely to be

proportionately higher in terms of percentage of turnover; and thirdly, they are ignorant of IP as a source of technical information, knowledge of which could save on R&D costs by avoiding research on something already known.

Table 15.4. Originating country of EPC applications and their designations, 1994

Country	EPC applications	No of countries designated	Designations per application	% applications designating each country
AT	573	4,948	8.64	40.08
BE	695	6,598	9.49	45.77
DE	11,046	89,794	8.13	97.12
DK	334	3,803	11.39	33.86
ES	338	3,537	10.46	51.63
FR	4,384	36,186	8.25	91.47
GB	3,138	31,210	9.63	92.62
GR	19	175	9.21	26.55
IE	83	1,028	12.39	24.19
IT	2,046	18,270	8.93	72.61
LI	95	820	8.63	
LU	78	867	11.12	26.11
MC	15	157	10.47	17.61
NL	2,240	22,292	9.95	55.68
PT	9	89	9.89	22.99
SE	924	8,208	8.88	45.53
Total	**27,998**	**246,165**	**Av. 8.79**	
CH	1,981	19,183	9.68	
JA	10,422	50,245	4.82	
US	16,779	135,392	9.46	

However, there is an initial stage which must not be overlooked, namely that of knowledge of IP. It is very clear from interviews held with industry sectors and with IHEs that there is appalling ignorance of IP in SMEs. This is not surprising as it is not taught in any coherent manner. Whilst IP is taught, often only as an option, in many law schools, it is taught in few, if any, university science schools or on business degree courses. Large companies overcome this matter of ignorance by in-house courses to new entrants, run by the internal IP department, so that employees, at least at the graduate level, in all disciplines, have knowledge of IP and its relevance to the business of their employee. However, this is unlikely to happen in an SME because it will not have such a department and cannot afford the time and expense to send its employees on external courses. The result is that SMEs do not have an IP strategy and that ideas and markets of SMEs are not sufficiently protected, largely through ignorance. Accordingly, there is a need for IP education and for professional assistance at maybe a subsidized rate. Otherwise, a valuable source of knowledge which can benefit the EU as well as the SMEs is being and will continue to be lost.

It has been shown elsewhere in this report that the costs of IP in the EU Member States is much higher than, for example, in the USA. There, the statutory fees for an SME, for example application and renewal fees, associated with any IP are 50% of those for a large company. In the EU, statutory fees for an SME are the same as those for a large company. It would be a considerable help for SMEs in the EU to have a treatment similar to that in the USA. But there is still the problem of translations, already mentioned in this study.

Table 15.5. Originating country of EPC patents and their designations, 1994

Country	EPC patents	No of countries designated	Designations per patent	% patents designating each country
AT	535	4,473	8.36	40.48
BE	283	2,458	8.69	46.64
DE	9,645	73,362	7.61	97.35
DK	288	2,974	10.33	18.93
ES	103	893	8.67	45.12
FR	3,497	28,494	8.15	90.69
GB	2,088	17,614	8.44	93.43
GR	8	63	7.88	21.02
IE	34	372	10.94	0.16
IT	1,358	11,676	8.60	72.87
LI	67	565	8.43	
LU	37	331	8.95	27.13
MC	7	45	6.43	0.54
NL	1,284	10,626	8.28	57.12
PT	0	0	0	0.96
SE	661	5,564	8.42	49.59
Total	**21,433**	**172,753**	**Av. 8.06**	
CH	1,538	13,243	8.61	
JA	9,593	43,558	4.54	
US	9,691	70,807	8.96	

Many companies may for any one of a number of reasons require national IP rights rather than a right effective in the whole of the EU. That is true for SMEs where they may only require rights in certain countries of the EU. For that reason alone it is important that the national IP offices be maintained. National patent offices are, however, under financial difficulties because of the conflicting attractions of other routes to IP such as the EPO and CTM. In addition to the continued existence of national patent offices, it is also important for local IP firms to exist; in particular, but not only, in smaller countries these firms are also under pressure because of the activities of local industry and of a local patent office, and courts may not be sufficient for their maintenance.

Thus, the various IP needs of the important SME sector must be taken into account in any coherent study of IP in the EU. Resolution of IP matters in the EU must not be dominated only by the requirements of larger companies; to do so would be to the detriment of SMEs, from which larger industries may grow. However, the concerns and need for action are not limited to mere consideration of the statutes: education and subsidy are also required.

16. Impact of accompanying measures

16.1. Exhaustion of IP rights

In any State it is a rule, so far as intellectual property rights are concerned, that no goods or services shall receive the benefits of IPR protection more than once in their transfer from rights holder to ultimate consumer. So far as the EC is concerned, this basic principle has been adopted for the Community area. Therefore, the ECJ has established the rule that exhaustion of IP rights applies to the EC area as a whole. Thus, the benefits which the rights holder is able to obtain in releasing goods or services onto the market in any Member State where he has protection exhaust the IP rights in those particular goods or services for the whole of the EC area. The goods or services can then be resold in that Member State or any other Member State without infringing the IPR. If particular goods or services are released into the market in a Member State where the IPR owner has no IP rights, he may not obtain his IPR benefits when and if the particular goods or services are resold into a Member State where he has IP rights.

Any person in any country who infringes applicable IP rights by making or selling goods or services which do not originate with the IP owner or his licensees is liable to the penalties for infringement of the rights in wherever countries the IP rights exist.

Consequently, whether an IPR owner has a particular IPR in one or all Member States of the Community, or a single IPR for the whole of the Community the consequences of the law of exhaustion are of identical effect. In each case, his rights are exhausted as to any particular goods or services as to the whole or any part of the single market where he has IPR by his first putting them on the market in the area of the single market. As a consequence, exhaustion is not affected by whether the IPR are a collection of national rights or a single right covering the whole of the single market.

16.2. Competition law and block exemptions

The second principle of the Treaty of Rome which is relevant to IPR is that of competition. The rules for fair competition have been and are being established by the European Court of Justice and have been put into practical form by the action of the Commission in monitoring the fairness of competition. For the convenience of industry and commerce, the Commission has reduced many of these rules to a series of block exemptions from liability to register particular agreements for examination by the Commission. Needless to say, the conditions for block exemption do not necessarily represent the true legal position under competition law, because, in order to exclude all that is clearly not anti-competitive, these block exemptions err on the side of caution, by franking only activities which are clearly within the rules. It is left to the European Court of Justice to draw the accurate line between fair behaviour and abuse of monopoly.

Certainly, from the point of view of industry and commerce, it is easier to comply with the block exemption, and thus avoid registration and examination for legality of agreements, but it must never be forgotten that this is a convenience only, and the block exemptions most not be taken themselves to define what is and what is not an abuse. The competition rules or the ECJ have identical effect, whether they are applied to the effects of the exercise of only one or to a number of national IPRs, or to a single IPR for the single market area.

16.3. Discussion

The impact of exhaustion rules and the laws of competition, including their enforcement through block exemptions, have been essential to the attainment of a single, common, market. However, basically both rules are merely standard adaptations of the principles of IPR law to those of competition laws.

In the case of exhaustion of rights, in principle, an IPR proprietor was never intended to claim damages twice on the same actual infringing good, in different countries where he has rights, although he should, of course, be entitled to protective injunctions in each country where he has IPR. No doubt, in principle, such injunctions could be obtained, based on infringement actions in each country even though based on the same actual goods in a second country (if they had passed from one to the other), though the second court would probably not award damages a second time.

If indeed application of the rules of exhaustion mean that different actual goods must be the subject of actions in each Member State, in order to obtain injunctions in each state, this may be a change of law, but one of no substance.

In a second case it can be said that ordinary principles of the implied right of a purchaser to resell a patented commodity put on the market by the patentee has been extended by EC law, because where a person who is a patentee in certain Member States puts goods on the market which would infringe, but in a state when the patentee has no patent, he cannot sue on those same goods thereafter in a Member State where he has a patent. This, however, has been legal historical water under the bridges since the Merck case[5] of 1981.

The application of Articles 85 and 86 of the Treaty of Rome to IPR in themselves and through the mechanism of block exemptions merely identifies the proper limits of the impact of competition law on IPR, and when the relevant markets to be considered under competition law comprise more than the area of a single Member State, these articles represent a modification of what could have been the impact of national competition law even if the latter was identical to Articles 85 and 86 in the solely national geographic area. The introduction, however, of wider market areas than the national law in any Member State contemplated, it does not represent a modification of IPR laws themselves, but of course it does alter their impact on company behaviour. To put it another way, the application of the laws of competition to IPR in Germany would always have had a different effect in practice from a similar application of them to IPR in, say, Denmark, merely by reason of the size of the market being considered.

Hitherto, compulsory licences have been a feature only of national IPR laws, though they are available in the general armoury of EC competition remedies under Articles 85 & 86. The only proposed restriction on their operation has been the proposed exclusion in the draft Community Patent Convention of a ground in national patent laws for such a licence on the basis of a failure of the IPR owner to export to other Member States in cases where sufficient manufacture to meet demand already exists in the other states.

A new and wholly unprincipled modification of the principles of competition law and its impact on IPR has been proposed in the European Parliament's provision of automatic

[5] Case 187/80 *Merck & Co. Inc.* v *Stephar* [1981] ECR 2063.

compulsory licences in the case of industrial design protection for spare parts. Hitherto, a compulsory licence has, very naturally, only been proposed once abuse of competition law in monopoly has been found. The Commission has accepted this departure from principle. Any departure from general principles of this nature must always be cause for grave concern because of the potential precedent. However, in Parliament's defence it must be pointed out that they were responding to an equally serious proposed departure from general principle by the Commission in its original draft directive whereby they proposed an arbitrary exclusion from industrial design protection of a whole class of products, namely spare parts. This would have been a departure from principle no less serious and arbitrary.

17. The treatment of third-country products under EU systems of IP protection

17.1. GATT Trade Related Intellectual Property rights (TRIPs)

GATT TRIPs contains the minimum provisions that shall apply to the IP laws in members of the World Trade Organization (WTO), the successor to GATT for all those countries which take up the provisions of all the agreements concluded at the end of the GATT Uruguay Round. All EU Member States are members of the WTO; thus, the laws of EU Member States, and the EU itself in Community law, should conform with the provisions of the WTO Agreements.

A number of articles in the TRIPs Agreement govern and dominate all IP laws of WTO members. The TRIPs Agreement contains some general articles that apply to all IP and then some more specific articles found in the sections relating to specific areas of IP. The areas of IP addressed are copyright, trade marks, geographical indications, industrial designs, patents, integrated circuit layouts, undisclosed information and anti-competitive practices in contractual licences. Thus Article 1(3) of TRIPs states:

'Members shall accord the treatment provided in this Agreement to nationals of other Members';

and in Article 3(1):

'Each Member shall accord to the nationals of other Members treatment no less favourable than it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in' ... a number of stated international Conventions.

Thus, there shall be equal treatment in the EU given to the IP of nationals of other countries as that of the nationals of the EU Member States. This is an important principle which is reflected in the Paris Convention on Intellectual Property.

One can therefore construe that there should be no difference in the treatment of the products (goods and services) of nationals of non-EU Member States from the aspect of IP. Anyone can apply in the EU, for example, for a patent or a trade mark; 'A European patent application may be filed by any natural or legal person...' (EPC Article 58). And, indeed, there appears to be no difference. Products placed on the market in the EU receive that same treatment so far as IP is concerned, irrespective of source.

At no point in this study have third-country operators complained of any discriminatory treatment.

17.2. Free circulation and exhaustion of rights

There is one area, however, which merits further attention, namely free circulation of products, sometimes referred to as exhaustion of rights. As previously stated, once goods have been placed on the market in a given Member State by the owner of an IP right covering those goods, or with the permission of the owner, then those goods have free circulation within the EU, and the owner cannot use the corresponding IP right in another EU Member State to

prevent marketing in that state. This doctrine causes considerable difficulty to IP owners in certain industries if being challenged in respect of the pharmaceutical industry where there is no free market in a given Member State in pharmaceuticals, as the price locally is centrally determined by that government having regard to local conditions and its local healthcare strategy and budget. It is therefore thought unfair to have free circulation where there is not a free market. What must not be conceded is the doctrine of exhaustion of IP rights in the EU when the product of the IP owner has been put onto the market outside the EU – universal exhaustion. That is not a situation that any IP owner could tolerate, because the world market is so inhomogeneous in structure and price – many times different from even the EU.

18. The new measures: could they be improved?

It is only appropriate here to highlight, in brief, points which could be improved in the new and proposed measures. They have been the subject of detailed comment in many chapters of the study.

18.1. Costs

Applications, oppositions to applications and grants of IPR can be and usually are handled effectively to the satisfaction of IPR owners and their competitors, although there are complaints of undue cost, normally traceable to translation costs and bureaucratic costs required by Member States, partly because of their desire to keep viable national IPR granting systems in being. The costs are high, especially compared with the USA, and should be tackled. It is agreed that national systems are entitled to remain, that they are vital for SMEs and indeed for industry as a whole.

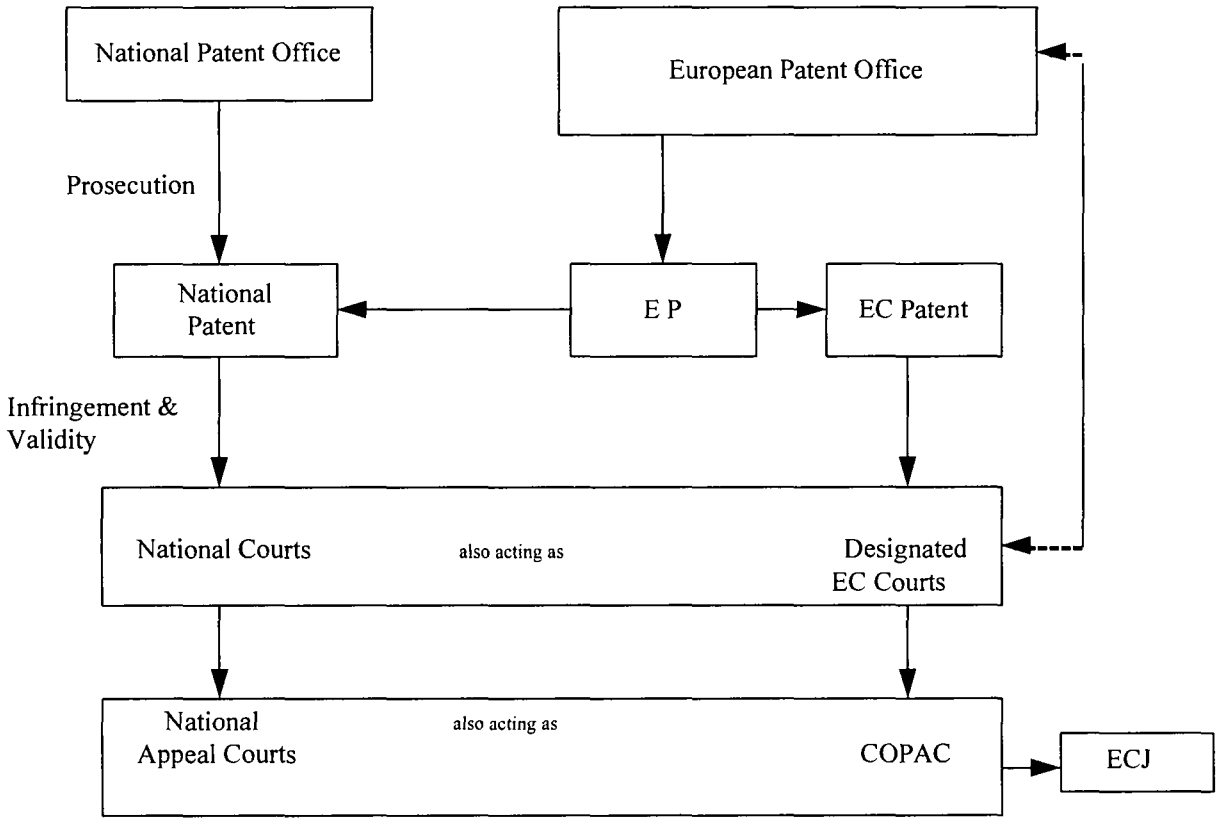
18.2. Enforcement at national level

The real shortcoming of the measures as they exist now, or are in draft form, is that they do not solve the problems of unsatisfactory enforcement of IPR in the national courts. There has been no proposal from any of our respondents or in the seminars for a truly Community-based court system for enforcement (except that for patents a Community appeal court might provide the first court of appeal and the ECJ the final court of appeal). It is accepted that, in the same manner, trials of infringement and validity must take place in suitable (i.e. specialist) national courts designated for the purpose (as in the CTM system and as proposed in the CPC). But it is not accepted that all these courts can be expected to give acceptable judgments on validity, when their decisions validate or invalidate a patent for the whole of the EC. Indeed, with patents, the failure of assurance of an acceptable judgment in validity is regarded as vitiating any Community system.

This issue arose in the written responses to the questionnaires and was therefore taken up in the seminars in detail and with full consideration of the issues. It was found quite clearly that if nationally designated courts were obliged to obtain an opinion of validity from the EPO, along the lines of Article 25 of the EPC, the objection was met and that keen support, which in any case was otherwise expressed for the CPC, was restored amongst all those who wanted EC-wide protection for their patents.

Such an opinion from the EPO could be provided for amongst the other provisions through which the CPC proposes to co-operate with the EPO (see Chapter II of the CPC). The following chart shows the perceived situation.

Figure 18.1. Future routes to patents in Europe



19. Conclusions

This study has considered actual and proposed activity in industrial property protection in the EU from the aspect of users of industrial property and those affected by IP, and considers two industries in particular, namely motor and pharmaceutical. The users are the industry itself in all its aspects and the practitioners in IP in the Member States, who obtain IP rights for their clients. An important area, namely copyright, has not been considered at the request of the Commission, even though industry considers this important aspect of intellectual property in its appraisals. Representations were made that copyright should be considered.

19.1. Industry requirements

The requirements of industry are extremely varied. Most require harmonized national IP laws in the EU in the areas of patents, designs and trade marks, but are not so concerned with utility models. SMEs in certain countries favour utility models, but in others they do not.

EC-wide IP rights are not always required by all companies or industries in all technologies in all Member States. There is therefore considerable support for nationally based IP rights as at present exist. There is wide support and enthusiasm for harmonization of national rights.

There is considerable concern that enforceability of IP rights varies significantly within the EU. This results from differing approaches by national courts and especially because of different degrees of specialized expertise in the complexities of IP, in specialized courts.

19.2. IP in the European Community

The following is a list of the more important laws and agreements which affect and control industrial property in the Community. Some of these are regulations and directives:

(a) Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention – EPC);
(b) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs), including Trade in Counterfeit Goods, concluded in Marrakesh in the context of the GATT Round;
(c) First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) (OJ L 40, 11.2.1989, p. 1);
(d) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1);
(e) Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ L 11, 14.1.1994, p. 1);
(f) Council Regulation (EC) No 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods (OJ L 341, 30.12.1994, p. 8);
(g) Commission Regulation (EC) No 240/96 of 31 January 1996 on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements (OJ L 31, 9.2.1996, p. 2);
(h) European Parliament and Council Regulation No 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ L 198, 8.8.1996, p. 30).

Proposed statutes are envisaged by:

(a) Proposal for a European Parliament and Council Regulation on the Community design (COM(93) 342 final);
(b) Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM(95) 661 final);
(c) Amended Proposal for a European Parliament and Council Directive on the legal protection of designs (COM(96) 66 final);
(d) Green Paper on the protection of utility models in the single market (COM(95) 370 final).

The report contains detailed concerns and criticism of all the above proposals.

19.3. General criticisms and comments

There is concern in industry, not shared by IP private practitioners, at the cost of IP in the EU. Costs are proportionately much higher than in Japan and the USA. This places some inventions, designs, etc. of all industry, and in particular of SMEs, in jeopardy of not being protected by IP merely on cost grounds. The costs are particularly evident in the furnishing of mandatory translations, and renewal fees will be a problem with any utility model legislation. There is also a difficulty over the speed of resolution of oppositions in the EPO, which can deter the use of IP in the EU Member States.

EU unitary rights for trade marks are well received. This is not so, prospectively, for the CPC patent for one specific reason. This relates to the fear of inhomogeneity in enforcement. This could be caused by an infringement action being determined by a court or in a country having a poor track record re IP rights, which finds invalidity, so removing the patent right for the whole of the EU. Action to rectify inhomogeneity in enforcement, with, it is hoped, a reduction in costs and complexity of proceedings, is required at Community level before industry could use a unitary right, and this action is seen as the most important area for attention by the Community, indeed a *sine qua non* for EC-wide IP in the Community.

The motor and pharmaceutical industries have specialist concerns with IP in the EU. The SPC has been welcomed by the pharmaceutical industry; it is hoped that inhomogeneity in interpretation has been rectified. The motor industry is concerned with design rights and spare parts.

All IP legislation must conform to the requirements of GATT TRIPs. However, the IP statutes of all Member States do not yet conform to GATT TRIPs although the 1 January 1996 deadline has been passed. This does not augur well for timely amendment of the IP laws in developing and Eastern Bloc countries.

19.4. Patents

Speed and cost of proceedings in the EPO are not seriously different from national proceedings. However, costs for EC protection are relatively high, compared to those in the USA and Japan. Translation costs are the chief burden for complex applications, though these are no less great than a series of national patent applications as well. The consideration for a patent is disclosure to the public of the invention, and where the EC as a whole is concerned, some argue this implies an obligation to disclose to all citizens without discrimination of

language. This is in line with a number of answers by respondents who fear discrimination on grounds of language. On the other hand, even national patents take account of patents and other documents in different languages. It appears that patents for some inventions will not be obtained by companies mainly on cost grounds. Cost – and translation costs – are an issue which industry wants addressed, though patent agents in private practice disagree.

EPO opposition proceedings are valued but found too slow. They should not be susceptible to deliberate delay and complication by later addition of new grounds in EPO proceedings.

The claims of a patent (all granted in accordance with the harmonized law of the EPC) are sufficiently clear to enable sensible decisions as to undertaking litigation or accepting licences between the patentees and their competitors.

The choice of applications in one, a number or all Member States will be based on the geographical scope of the protection required by the patentee, and this does not prejudice the single market. Therefore, the parallel operation of national patents and an EC-wide right if it existed would be entirely in accord with an efficient operation of the single market.

Court enforcement of patents is wholly unharmonized as to substantive law of patent infringement and as to remedies. Furthermore, there are no means of increasing convergence through a common court of final appeal. In addition, of course, a national court in which a case is tried only grants remedies for the Member State concerned. Thus, there is total fragmentation of the single market insofar as the enforcement of patents is concerned.

There are very considerable problems in finding a solution for court remedies which does not fragment the single market and yet which is acceptable to the parties. Owners of EC-wide patents, if they existed, could not contemplate losing their patent for the whole of the EC through one action in a Member State which may well not have a sufficiently expert court. It is possible to follow the analogy of the CTM system where loss of validity based on a fault relating to one Member State is remediable by the owner who can convert to national registration in all countries where this fault does not exist. There is no analogy here because objections to a patent are not based upon geographical considerations but upon world-wide novelty and inventive step.

One possible way of gaining legal certainty where there is any doubt as to the efficacy of them taking place in a Member State, is to refer revocation proceedings to the opinion and expertise of the European Patent Office. This is provided for in the Convention and undoubtedly a proper answer to the strong fears expressed by patentees that some national courts of doubtful efficacy might find a CPC patent invalid, is to alleviate them by mandatory reference of revocation proceedings to the EPO.

Assuming that validity is to be considered at the most expert level in this manner, it is likely that most patentees would happily leave the infringement to a relevant local national court where infringement occurred, as they have to in any case at present. The only greater risk for the patentee of such a system would be that a decision on infringement relating to a particular type of article in a case in one Member State would apply to that article throughout the EU.

19.5. Trade marks

The Community trade mark is widely welcomed and appears to be a useful IP right.

However, it is too soon to judge the performance of the OHIM; initial applications far exceed expectations leading to fear of delays. Equally, it is found that oppositions may flood the OHIM, leading to delay in registration which would be detrimental to industry. All this remains to be seen, and may be dealt with by appropriate action.

The new CTM system has sufficient attractions both for the 'one-stop shop' of the OHIM and for the common court system. Though there are the same doubts as to the effectiveness of all Member State courts in trade mark matters as in the case of patents, the risk is felt far less strongly because special expertise is less vital and because loss of a trade mark because of a fault in one or a few Member States is remediable by conversion to registrations in all the Member States not affected by that fault.

19.6. Industrial designs and utility models

The attractions of a single EC-wide right are in some cases recognized as being a positive alternative to a bundle of national rights. Designs on balance are considered a useful candidate for an EU-wide right, but there is no enthusiasm for a unitary utility model.

Neither in the case of industrial designs nor of utility models does a grant have sufficient strength to command high respect amongst competitors The problem of entering litigation or licence agreements is difficult to resolve on the basis of the grant. It must be decided on more commercial criteria than an assessment of the strengths and weaknesses of the grant itself in the event of a dispute. Some industrial respondents regard utility models as having negative value, arguing that a patent is much superior because it is examined.

19.7. Other matters: training for judges and for SMEs

Because homogeneity of enforcement of IP rights at national level is of the greatest concern, the EU could usefully take an initiative to provide courses, training and meeting opportunities for judges, with the aim of gaining greater uniformity of court decisions and procedure in the EC.

Whilst large companies train their staff in IP matters, SMEs have no such facilities. Enlightening SMEs as to the importance of IP in protecting their R&D and in using others' IP rights as an information source requires attention, because of the potential benefit to the EU from a more skilled and informed approach.

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