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THE ECONOMIC VALUE OF INTELLECTUAL PROPERTY: ERODED AND MADE INSCRUTABLE BY SINGLE MARKET LEGISLATION

Paul Malcolm Taylor

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Submitted for the Degree of Master of Jurisprudence

University of Durham

Department of Law

1st October 1998

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Abstract

An examination of the effectiveness of measures of European Community law to harmonise intellectual property protection throughout the Community, focusing on two consequences of these measures: first, the adverse impact on the commercial value of the intellectual property in the hands of the proprietor or licensee and, secondly, the implications for the due diligence enquiry of the scope of protection conferred by intellectual property rights undertaken whenever an interest in intellectual property is acquired.

The position of the national law of Member States following accession to the Community is examined, in particular its limits to confer monopoly or quasi monopoly protection on the intellectual property proprietor. The effect of international cooperation (such as the Berne Convention) in shaping national law is considered by way of essential background to determine the extent to which obstacles to the implementation of Community principles result.

Particular attention is given to the inter-relation between the provisions of the Treaty of Rome and national law, insofar as the free movement principles of Articles 30 to 36 and the competition law prohibition of Article 85(1) conflict with the scope of intellectual property rights conferred nationally.

The role of Commission Regulations conferring exemption from Article 85(1) for intellectual property agreements is illustrated by reference to Commission Regulations EC 240/96 (concerning technology transfer agreements) and EC 418/85 (concerning research and development agreements). Finally an assessment is made of the effectiveness of selected Council Directives (91/250 EEC and 93/98 EC concerning computer software and duration of copyright) as harmonisation measures, taking into account existing sources of law and the needs of emerging technologies.
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INTRODUCTION
INTRODUCTION

A. THE VALUE OF MONOPOLY OR QUASI-MONOPOLY RIGHTS AND THE NEED FOR DUE DILIGENCE

The commercial value of intellectual property is determined (inter alia) by the scope of the monopoly or quasi-monopoly rights conferred on the proprietor, whose competitive edge depends on being able to prevent others committing acts of infringement. The purpose of due diligence investigation, carried out on the acquisition or disposal of intellectual property, is to verify for the purchaser, licensor or licensee of intellectual property the extent of that protection. For each category of intellectual property (copyright, design right, registered designs, know-how, patents and trademarks), it is necessary to establish the nature of protection conferred, in particular, the extent of restricted acts that amount to infringement, the duration of protection, any statutory exceptions that might be relevant, any potential licences of right and other inherent limitations to the full enforcement of restricted acts that are otherwise conferred by that intellectual property right. The process of verification therefore begins with identification of all intellectual property and an assessment of the commercial value of the rights conferred. The sources of law referred to in the remainder of this Chapter, each of which will be considered individually in succeeding chapters, have shaped the way in which the law of intellectual property has been harmonised internationally but particularly within the European Community (the "Community"), and impose limitations on the use and exercise of intellectual property. An assessment of the impact of such measures upon the commercial value of intellectual property is essential when carrying out due diligence investigation and yet in practise such an assessment is not feasible. This study will focus on the effectiveness of measures aimed at harmonising intellectual property law, on their adverse impact on the commercial value to the proprietor, and on their consequences for the process of assessing the scope of intellectual property protection.
B. INTERNATIONAL CONVENTIONS

In Chapter One, the role of Conventions and other forms of international cooperation will be examined by way of background to provide the essential context for the Community-specific harmonisation measures that are the main focus of this work. Those harmonisation measures comprise the Treaty of Rome ("the Treaty"), Commission Regulations and Council Directives.

C. THE TREATY OF ROME

The Articles of the Treaty that deserve special attention, because they limit the exclusive rights of the intellectual property proprietor, are Articles 30 and 36 (which provide for the free movement of goods) and Articles 85(1) and 86 (which prevent any anti-competitive practices or abuse of dominant position). Treaty provisions will be the subject of Chapter Two.

Articles 30 and 36 serve to define the limits on which infringing acts common to all intellectual property rights may not be relied upon to prevent free movement of goods throughout the Community. This has important consequences for the marketing strategy of any business dependent upon intellectual property and is a matter that therefore requires detailed investigation when any interest in intellectual property is acquired. Due diligence will focus on the need to ensure that a strategy is adopted that maximises the profit potential of intellectual property. This might involve withholding sales from markets that are subject to low prices if they would undercut sales in other markets where high prices prevail (following parallel importation into the higher priced markets). Articles 30 and 36 also have implications for due diligence enquiry of businesses engaged in parallel importation of goods embodying third party intellectual property, to determine the extent to which parallel importation is possible, against the wishes of the intellectual property owner.
Articles 85(1) and 86 are Treaty provisions which apply primarily in a different arena, namely, competition law. Articles 85(1) and 86 determine the contractual terms and other practices by which intellectual property may be exploited, once again imposing limits on what would otherwise be the full commercial freedom of the proprietor or licensee. As Treaty provisions, they deserve comment in Chapter Two. However, as the permitted terms of exploitation in agreements caught by the Article 85(1) prohibition have been clarified by the European Commission by means of Commission Regulation, the bulk of the discussion on the subject of Articles 85(1) and 86 will be found in Chapter Three, which focuses on Commission initiatives by way of Regulation.

D. REGULATIONS

Two Regulations concerning the application of Article 85(1) to selected intellectual property agreements will be examined (patent and know-how licences first\(^1\), and research and development agreements next\(^2\)) with particular regard to the obstacles they create to a clear determination of enforceability as a matter of competition law. Any party to an intellectual property agreement (whether the proprietor or licensee) will want to ensure, for example, that the terms of territorial exclusivity will be upheld, and the proprietor in particular will want to ensure the enforceability of other contractual terms aimed to protect the value of intellectual property.

The role of Regulations in Chapter Three is seen to be positive and necessary given the theoretical breadth of Article 85(1) but the task of due diligence, of confirming the enforceability and protection of the commercial value of intellectual property rights, is considered to be greatly hampered by the

\(^1\) 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 (1996) OJ L31/1

narrowness of Regulations. The Commission’s approach is considered to be insufficiently generous and clear for this purpose.

E. DIRECTIVES

The final chapter, Chapter Four, will consider the value of Council Directives as more specific measures aimed at harmonisation and the realisation of the internal market by removing obstacles based on differences between national levels of intellectual property protection. Directives ultimately determine (when enacted in national legislation) the scope of protection available to the proprietor. As an assessment of the commercial value of intellectual property in the hands of the proprietor (or licensee) is at the heart of due diligence, the impact for due diligence of the changes introduced by the chosen Directives will be examined. Three Directives will be selected for this purpose. The Directive concerned with software protection has been chosen since it was the first in a series of Directives targeted at the harmonisation of copyright. Its significant limitations will be highlighted but that Directive will be compared favourably against the later Directive which attempted to harmonise the duration of copyright protection throughout the Community. It is submitted that the later Directive has made the process of due diligence so complicated as to be virtually unattainable, certainly impracticable, even if it achieves certain theoretical aims.

Finally, the Directive on the legal protection of biotechnological materials has been chosen as a means of taking this review full circle. It illustrates the tendency, with emerging technologies, for legislation to adhere to established patterns of intellectual property protection rather than sui generis protection,

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perhaps wrongly. It illustrates the need for Directives to take full account of other sources of law. In the case of the Directive on the legal protection of biotechnological materials, the appropriateness of protection based upon the European Patents Convention 1973 will be examined.

F. SUMMARY

In short, this study will examine the effectiveness of harmonisation measures beginning briefly with the initial steps towards international cooperation, before proceeding with a more detailed examination of Community-specific measures in the form of the Treaty, the most important landmark as far as treaty cooperation is concerned, giving rise in due course to Regulations and Directives. The effectiveness of such measures will be examined for their impact (intended or unintended) on the commercial value of intellectual property and the process of due diligence evaluation.
CHAPTER ONE:
INTERNATIONAL COOPERATION

"He who wants to know himself should offend two or three of his neighbours"
INTERNATIONAL COOPERATION

A. INTRODUCTION

Certain international cooperation in the sphere of intellectual property has taken place independently of the aims of achieving the internal market pursuant to the Treaty of Rome ("the Treaty"), (for example, the Berne Convention for the Protection of Literary and Artistic Works 1886, revised Paris, July 1971 ("the Berne Convention")) and is responsible for some of the present obstacles to Community harmonisation. Even international cooperation undertaken with Community harmonisation as one of its express aims has been piecemeal and only partially effective. This chapter aims to introduce those examples of international cooperation whose legacy, in the context of the Community-specific measures, has been to hamper harmonisation as discussed in the chapters that follow.

B. THE BERNE CONVENTION

The Berne Convention took the initiative in international cooperation by minimum standard-setting in the field of copyright throughout and beyond Europe. The Berne Convention is one of the first (and surviving) examples of trans-national regulation of intellectual property and is still being revised to take account of emerging technologies6.

One of the most important principles established in the Berne Convention is that of "national treatment". It is the requirement that contracting states give to foreign authors of qualifying works the same level of protection that they confer on their own nationals. Of critical importance in the Berne Convention are the derogations to that principle. The first is that of "reciprocity" which

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6 Discussions continue amongst a Committee of Experts at the World Intellectual Property Organisation to address the issue of new digital technologies, particularly gaps that exist in the protection of works delivered and used by electronic transmission
entitles Berne Union countries to reduce the level of protection given to the works of an author of a non-Union country, to the level prevailing in that non-Union country. In turn, if a Union country takes advantage of the principle of reciprocity against the non-Union country to reduce the level of protection, other Union countries may similarly reduce the level of protection offered to the non-Union national, irrespective of whether the works of their own nationals are adequately protected in the non-Union country.\(^7\)

The Berne Convention remains the cornerstone of copyright protection internationally. In spite of the Directives that will be discussed at length in Chapter Four, copyright remains an area in which the substantive law is harmonised least, giving rise to anomalies concerning the exhaustion of those rights and insuperable difficulties in the due diligence task.

C. THE EUROPEAN PATENT CONVENTION

International cooperation in the field of patents came in the form of the Patent Cooperation Treaty 1970 (the "PCT"), which was established to coordinate patent searches. Its purpose was to overcome many of the variances that existed across national patent systems with patents of different scope filed in different languages. The PCT, in short, assisted the search for prior art. It is therefore largely procedural. If an application is made under the PCT, a so-called "international application" will ultimately result in national patents (rather than in an international patent). Searches will identify the viability of the application for novelty and obviousness and avoid wastage of costs. After the searches are made, the international application is passed to the appropriate national patent offices.

The Convention on the Grant of European Patents (the "EPC") was the first substantive measure taken in the field of patents to harmonise national patent
laws, even though patents continue to be granted and maintained nationally. The EPC resulted in an alternative route for patent applications involving the national patent offices of all countries (as before) and in addition the European Patent Office (the "EPO") in Munich which administers the grant of "European patents" in which various European countries may be designated for patent protection. A European patent does not in fact exist as such; it consists of a national patent in one country with matching sister patents in other European countries.

There therefore presently exist two parallel procedures for applying for patents. The purely national British system and the EPO system. Both may be pursued simultaneously although the British patent is cancelled when the EPO grants a European patent with the United Kingdom as a designated country. The EPO system has the advantage of being cheaper for multi-country designations (since a single translation will suffice until grant whereas each national system will require the application in its own language) but is generally slower than national systems, and suffers the disadvantage that single specification applications may not take full advantage of the differences that exist between the national patent systems.

The EPC has resulted in procedures for streamlining patent applications and has greatly facilitated the assessment of the likelihood of success of patent applications in numerous countries. However, for so long as there exist substantive variances in eligibility for patent protection and patent scope, patent law remains unharmonised. Also, for so long as the "first to invent" systems such as in the United States and the "first to file" systems in Europe.

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8 The EPC also contemplates a single patent across a single European territory (unlike European patents which are still a collection of national patents). This is not yet in force in spite of revision in 1989 (CMND 1452) to provide for a uniform appeal procedure on issues of validity and infringement. The greatest obstacle is the requirement for translations to be available in each Community state in the official language which is cost prohibitive unless applications are ultimately intended to be filed in all of those countries.
and much of the rest of the world are unharmonised the value of the EPC is inevitably limited.

D. THE PARIS CONVENTION, GATT AND TRIPS

The pressures for ensuring overseas protection for intellectual property and non-discrimination overseas led to the Paris Convention for the Protection of Industrial Property, 1883 (Revised at Stockholm, 1967) (the “Paris Convention”) and also the principle of national treatment in the field of patents, trade marks and industrial designs. That principle is summarised in Article 2(1) as follows:

"Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant or may hereafter grant to nationals."

There are presently 133 members of the Union. Important as the principle of national treatment is, the Paris Convention does not regulate or even attempt to harmonise the level of protection to be given by each member country except to a limited degree. For patents, designs and trade marks, the Paris Convention established a priority procedure for determining the priority date to be given to applications for registration made in Union countries. Little, however, is said in the Paris Convention concerning patent eligibility or principles of morality, obviousness, duration or infringing acts, nor of the eligibility rules for trade mark protection.

The importance of the principle of national treatment should not be underestimated given that it has also been formally adopted by the World Trade Organisation (the "WTO") which came into effect on 1st January
1995. The WTO replaced the General Agreement on Tariffs and Trade ("GATT"). Members of the WTO agreed in Article 3(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") as follows:

"Each member shall accord to nationals of other members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property."

Although the Paris Convention did not provide for minimum standards of protection or any substantive provisions which might lead to harmonisation of the laws of member countries, Article 1 of the TRIPs Agreement does impose obligations on member countries to provide minimum standards of protection in domestic law and these are elaborated in Part II, concerning eligibility for protection, scope of protection and subject matter, relating to patents, trade marks and industrial designs. Part III goes on to deal with enforcement measures by both nationals and foreigners.

At 1st March 1998 less than 23% of the 130 WTO members had implemented those minimum standards of protection. Compliance may not be complete until 2006. Even if that response might be regarded as disappointing, TRIPs will ultimately give a greater level of uniformity of protection than the Paris Convention or even the TRIPs predecessor, GATT. The result is cooperation at a rudimentary level to avoid discrimination between nationals and foreigners in order to encourage all participating countries to conform their laws of protection of intellectual property, and ultimately to facilitate trade between those countries.
International cooperation in the field of intellectual property by means of the Berne and Paris Conventions and most recently by GATT and TRIPs therefore forms the essential backdrop to the more detailed discussion which follows concerning the European measures taken to establish and maintain the internal market and are supplemented by the provisions of the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (the "Rome Convention") and the Protocol Relating to the Madrid Agreement concerning the International Registration of Trade Marks (the "Madrid Protocol"). It is interesting to note furthermore that neither GATT nor TRIPs contains anything inconsistent with principles of exhaustion of intellectual property (discussed in Chapter Two). In fact, Annex 1C of TRIPs expressly states that (provided that the rules of national treatment and most favoured nation treatment are preserved):

"for the purpose of dispute settlement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."11

E. SOURCES OF EUROPEAN COMMUNITY ("EC") LAW

EC law has various sources which operate in different ways. The ultimate and originating source is the Treaty. The aims and organs of the Treaty are established in Articles 1 to 8. Article 2 expresses these aims succinctly:

"The Community shall have as its task, by establishing a common market and progressively approximating the economic policies of the Member States, to promote throughout the Community a harmonious development of economic activities, a continuous and balanced expansion, an increase in stability, an accelerated raising of the

11 Article 6 of TRIPs
standard of living and closer relations between the States belonging to it."

In order to give effect to these ambitions, Article 5 of the Treaty provides that:

"Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from actions taken by the institutions of the Community."

This duty also includes "sincere cooperation". 

Part Two of the Treaty establishes the principle of free movement, the central Article for these purposes being Article 30 that guarantees free movement of goods:

"Preventative restrictions on imports and all measures having equivalent effect shall... be prohibited between Member States."

The Single European Act of 1986 added Article 8 which expresses the additional aim of establishing the internal market by 1992 without internal frontiers to the free movement of goods, services, persons and capital. All impediments to free trade throughout the Community must therefore be removed.

Free movement is also accomplished by means of the competition principles established in Articles 85(1) and 86 of the Treaty which prohibit practices that restrict competition or constitute an abuse of dominant position. A considerable amount of EC law has developed, concerning such matters as the

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12 Commission v Greece Case 68/88 [1989] ECR 2965

-13-
scope and duration of licence exclusivity and other contractual terms for exploiting intellectual property in line with those competition principles.

The Treaty also gives rise (under Article 189) to secondary legislation in the form of Council Directives ("Directives") (which direct Member States to enact their own legislation by a specified date to achieve a stated objective, but as a generality themselves have no direct effect), Commission Regulations ("Regulations") (which do have direct effect, without national enactment), Decisions (which amount to binding rulings on particular matters, usually given a narrow sphere of competence) and, finally, Recommendations and Opinions (which are not binding but are nevertheless influential). The supremacy of EC law is now recognised even in the case of direct conflict (MacCarthy's Ltd v Smith).

It is striking that the Treaty itself makes no mention of intellectual property other than in Article 36 which permits restrictions on free movement of goods if justified on the grounds of protection of "industrial and commercial property". The principle of free movement of goods ostensibly conflicts with the national protection afforded to intellectual property against "importation" as an infringing act, and Article 30 resolves the conflict. The interpretation of Article 36 has given rise to considerable case law from the European Court of Justice ("ECJ") to determine the extent to which intellectual property rights may be exempt from the free movement principle of Article 36.

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13 The status of Directives is an interesting one, in particular, the extent to which they give rise to rights at a national level before their implementation. The case of Alfons Lutjensen GmbH v Haupzollamt Sarrelleins [1996] ECR 205 established that a Directive is binding on national courts if its provisions impose a clear and precise obligation on Member States, it is unconditional (or subject to very clearly defined exceptions) and the Member State is given no discretion whether or not to apply it. These principles are not confined to Directives, but Directives are the most common source of claims for direct effect in national courts, for example, where the national legislature is slow in implementing Directive obligations which favour a Plaintiff.

14 [1979] ICR 785; [1979] 3 CMLR 44
Finally, the Treaty established as the main organs of administration, the Council of Ministers ("the Council"), the Commission of the European Communities ("the Commission"), the European Parliament ("the Parliament") and the ECJ. The Council's aim is to ensure coordination of economic policy\textsuperscript{15}. The Commission acts as the guardian of the Treaty, monitoring compliance and also instigating much legislation by means of Proposals which are put to the Council for consideration. The Parliament assumes a consultative function in its legislative role, requiring the Council to consult the Parliament in draft legislation. The Court of First Instance was established to hear appeals against decisions by the Commission and to review Commission decisions concerning penalties (under Article 173). Finally, the ECJ is concerned with Treaty compliance and the "interpretation and application" of the law\textsuperscript{16} and has jurisdiction to give preliminary rulings on such matters\textsuperscript{17} assisted by the Advocate-General whose non-binding opinion is given on all cases before the ECJ.

F. THE EUROPEAN ECONOMIC AREA AGREEMENT

More limited co-operation than established by the Treaty was achieved by countries comprising the European Free Trade Association ("EFTA"), formed in 1960. By 1989, the need became apparent for the inter-relation between the EFTA and EC countries to be formalised and in 1992 the European Economic Area Agreement ("the EEA Agreement") was signed. The parties to the EEA Agreement are the EC, EC Member States and EFTA countries\textsuperscript{18} and the geographical coverage of the European Economic Area (the "EEA") is the territory represented by those countries. The EFTA Agreement applies

\textsuperscript{15} Article 145 of the Treaty
\textsuperscript{16} Article 164 of the Treaty
\textsuperscript{17} Article 177 of the Treaty
\textsuperscript{18} Article 2(c) EFTA Agreement
the basic principles of free movement of goods and services to the EFTA states by reflecting in Articles 11, 12 and 13 of the EEA Agreement the provisions of Articles 30, 34 and 36 of the Treaty. It also applies similar competition rules by reflecting in Articles 53 and 54 of the EEA Agreement the substance of Articles 85 and 86 of the Treaty.

However, although a great body of text of EC law is adopted by annex to the EEA Agreement ("acquis communautaire of the EEA Agreement"), the interpretation to be given to the EEA Agreement differs from that given by the ECJ to the Treaty provisions because the objectives of the Treaty, unlike the EEA Agreement, are the achievement of the internal market and the other aims outlined above. Even if the text of certain crucial provisions of the EEA Agreement and Treaty are identical, their interpretation may be different.

The core provision of the EEA Agreement concerned with intellectual property is Protocol 28 which requires members to render their national law compatible with EC law on such matters as the level of intellectual property protection to be conferred on proprietors, free movement and exhaustion of rights as developed by the ECJ. Article 3 of Protocol 28 also requires the EPC provisions to be met in substance, and Article 5 requires compliance with the Berne Convention, the Paris Convention and Rome Convention.

The inter-relation between the Treaty and the EEA Agreement can give rise to anomalies and difficulties of interpretation. Protocol 28 of the EEA Agreement provides as follows:

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19 Currently Iceland, Liechtenstein and Norway

20 Opinion delivered pursuant to the second sub-paragraph of Article 228(1) of the Treaty, Opinion 1/91 [1991] ECR I-6079
"To the extent that exhaustion is dealt with in Community measures or jurisprudence, the Contracting Parties shall provide for such exhaustion of intellectual property rights as laid down in Community law."^21

It is clear from the advisory opinion of the EFTA Court in Mag Instrument Inc v California Trading Company Norway Ulsteen^22 that:

"The purpose and scope of the EC Treaty and the EEA Agreement are different ... the EEA Agreement does not establish a customs union but a free trade area ... the principle of free movement of goods as laid down in Articles 11 to 13 EEA applies to goods originating in the EEA, while in the Community a product is in free circulation once it has been lawfully placed on the market in a Member State. In general the latter only applies in the context of the EEA only in respect of products originating in the EEA. In the case at hand, the product was manufactured in the United States and imported into Norway. Accordingly it is not subject to the principle of the free movement of goods within the EEA."^23

It was therefore a matter for the EFTA countries to determine their own policy concerning international exhaustion in relation to goods originating outside the EEA. They remain free to enter bilateral or multilateral treaties with third countries for the purpose of that trade and this might conceivably create anomalies in future with the principles of exhaustion if developed by the ECJ in a manner inconsistent with those treaties.

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21 Article 2(1)
22 Case E - 2/97 advisory opinion of 3 December 1997
23 Paragraphs 25 and 26
All of the above instruments have played a crucial role in shaping the law of intellectual property, at certain points eroding intellectual property rights, at others obscuring them, but at all times the purpose of EC law has, to one degree or another, been that of achieving harmonisation throughout the Community.
CHAPTER TWO:
HARMONISATION BY TREATY

(Articles 30 and 36: Free Movement of Goods)

"Buy at a fair, but sell at home"
HARMONISATION BY TREATY

A. INTRODUCTION

Harmonisation of intellectual property has been necessary because of significant differences that have existed (and continue to exist) in the national laws of Member States, not only concerning activities within their boundaries (infringement) but activities outside as well (exhaustion). While that process (which is largely achieved by means of Directive and discussed in Chapter Four) continues, the European Court of Justice ("ECJ") interprets and enforces the provisions of the Treaty of Rome ("the Treaty") in such a way as to balance the free movement requirements of Article 30 of the Treaty with the requirements of intellectual protection recognised in Article 36.

1. Articles 30 and 36 of the Treaty of Rome

The scope of any monopoly or quasi-monopoly conferred nationally by means of intellectual property protection must be read subject to the principles of free movement established in Article 30 of the Treaty. Article 30 has already been referred to but requires elaboration. It contains a simple prohibition against quantitative restrictions on imports and exports between Member States as well as measures having equivalent effect. The language is so broad ("all restrictions on imports and measures having equivalent effect shall... be prohibited between Member States") that it is necessary to make an exception for intellectual property rights which typically include as infringing acts the act of importation. For example, infringement occurs on the importation of infringing copies of a design in the case of copyright and design right works, the importation of infringing products falling within product or process patent claims of the country of importation, the importation of

24 Sections 22 and 227 of the Copyright Designs and Patents Act 1988
25 Sections 60(1)(a) and 60(1)(c) of the Patents Act 1997
goods bearing a registered trade mark of the country of importation\(^{26}\) or the importation of goods to which a registered design of the country of importation has been applied\(^{27}\). The ban on importation without the consent of the rights holder is clearly a matter caught by Article 30.

Article 36 of the Treaty of Rome provides the necessary gateway for the exercise of intellectual property rights. Article 36 reads,

"The provisions of Article 30 [to 34] shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy, or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States."

At the heart of what is termed the "doctrine of exhaustion" is the inter-relation between the non-importation restrictions of intellectual property rights and Articles 30 and 36. In the early case of Deutsche Grammophon Gesellschaft mbh v Metro-SB-Grossmarkte GmbH & Co KG\(^{28}\), the ECJ stated,

"If a right...is relied upon to prevent the marketing in a Member State of products distributed by the holder of the right or with his consent on the territory of another Member State on the sole grounds that such distribution did not take place on the national territory, such a prohibition, which would legitimise the isolation of national markets,

\(^{26}\) Section 10(4)(c) of the Trade Marks Act 1994

\(^{27}\) Section 7 of the Registered Designs Act 1949 as amended by Section 268 CPDA 1988

\(^{28}\) Case 78/70 [1971] ECR 487

-21-
would be repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market."

It is to be noted that Article 222 of the Treaty preserves the national effect of intellectual property law by stating that it shall "in no way prejudice the rules in Member States governing the system of property ownership".


Intellectual property is territorial in nature, formulated and enforced by the laws of the state which confers protection. For example, a patent offers protection on the patentee only in the country in which the patent has been granted. At its widest, a patent is only national in scope (to prevent things being done in that state) in spite of the European Patent Convention ("EPC") harmonisation measures and even terminology which refers to a "European Patent". Protection is merely conferred state by state in territories according to the rules of each state which confer monopoly or quasi-monopoly protection.

Each state has also historically developed principles concerning the point at which those rights are said to be exhausted. For example, in the United Kingdom, once a patented product is sold, the purchaser could deal with it anywhere in the world subject only to restrictions of which the purchaser is given notice (Betts v Willmott).

"When a man has purchased an article he expects to have control over it, and there must be some clear and explicit agreement to the contrary

29 Paragraph 12
31 [1870] LR6 Ch App 239
to justify the vendor in saying that he has not given the purchaser his consent to sell the article, or to use it wherever he pleases as against himself. 32

Betts v Willmott is clearly an old case and must now be read subject to the limits on the freedom of patentees to impose contractual restrictions under Articles 85(1) and 85(3) of the Treaty. Nevertheless, Betts v Willmott does reflect the general principle in the United Kingdom that once sold anywhere in the world, any subsequent use of a patented product will not amount to infringement. As a result, once goods are first marketed, in the absence of lawful contractual restrictions, the purchaser and others in the supply chain following the purchaser are free to deal in the goods without their activities amounting to infringement. However, an implied licence is only to be taken as granted by the patentee, and not an assignee or licensee of the patentee (Manufacturers de Glaces SA v Tilghman's Patent Sound Blast Company). 33

The principles stated in Betts v Willmott (and in subsequent cases 34) have been confirmed more recently in Roussel Uclaf SA v Hockley International Limited & Another 35 in which Jacob J. stated that it is open to the patentee to stipulate limitations on any implied licence and these will be binding on the person supplied, as well as on subsequent dealers in the product, provided that notice of those limitations is brought to the attention of every person down the chain. This judgment is not immune from criticism 36 and reflects a Common Law approach to the doctrine of exhaustion. Applied at the national level, the

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32 Penultimate paragraph of the Judgment at page 245
33 [1884] 25 Ch D1
34 National Phonographic Co of Australia v Menck [1911] 28 RPC 229; Gillette v Bernstein [1942] 1 ChD 45
35 [1996] RPC 441
36 For example, it is at odds with the decision in Badische Anilin und Soda Fabrik v Isler [1906] RPC 173 that "if a person innocently buys a patented invention from a licensee and uses it not knowing that there are limits on the licence ... he is equally an infringer"
doctrine in effect results in worldwide exhaustion, subject only to limits on any implied licence that are effectively imposed by notice on dealers to prevent export or reimportation.

By contrast, many continental European countries (such as Germany) have resisted any concept of international exhaustion of patents, preferring instead to entitle the patentee to resist imports of products first sold outside their borders.

Inconsistency has therefore developed across the national laws of Member States concerning the application of principles of exhaustion; in particular whether international exhaustion is to be recognised and, if so, to what extent. In some countries (again Germany), international exhaustion has not been applied in the case of patents but has in the case of trade marks (at least until the implementation of Council Directive 89/104 EEC to approximate the laws of Member States relating to trade marks\(^\text{37}\) (the "Trademark Directive"). Inconsistency within nation systems adds to the inconsistencies that already exist across different national systems.

3. The Emergence of Exhaustion under Articles 30 to 36

It is striking that the doctrine of exhaustion developed by ECJ case law on the subject of Articles 30 to 36 has historically focused little attention on the operation of the national law. The case of Silhouette Internationale Schmied GmbH and Co KG v Hartlauer Handelsgesellschaft mbH\(^\text{38}\) ("the Silhouette Case") highlighted the fact that the effect of inconsistent national treatment of international exhaustion would be that,

\(^{37}\) OJ (1989) L 40/1

"the same products could be the subject of parallel imports into one Member State but not into another, a result incompatible with the internal market."\(^{39}\)

The ECJ's historic insistence upon confining its case law under Articles 30 to 36 to the immediate context of the Community, as confirmed in EMI Records v CBS United Kingdom\(^{40}\), rather than the world market, might be criticised for its conservatism, especially given the barriers that manifestly result between Member States if they are permitted to adopt different rules for international exhaustion under national law:

"The exercise of the trade mark right in order to prevent the marketing of products coming from a third country under an identical mark, even if this constitutes a measure having an equivalent effect to a quantitative restriction, does not affect the free movement of goods between Member States and thus does not come under the prohibition set out in Article 30 et seq of the Treaty."\(^{41}\)

The clarification of the position of different national rules, fundamental to the achievement of a single market, is a significant recent advance in the development of the doctrine of exhaustion under Articles 30 to 36.

The following sections of this chapter will analyse the effect of the application of Articles 30 to 36 upon the value and scope of intellectual property protection, the need to establish a marketing strategy that takes best advantage of Articles 30 to 36 and the consequences for due diligence assessment, taking in turn patents, copyright, registered designs and trade marks.

\(^{39}\) Paragraph 42 Opinion of Advocate General Jacobs delivered on 29 January 1998

\(^{40}\) Case 51/75 [1976] ECR 811

\(^{41}\) Issue 2 paragraph 10 of the Judgment of the ECJ
B. PATENTS

1. The Significance of the Patent Monopoly

The commercial pressure for parallel imports and patent protection are best illustrated by the market factors that apply in the pharmaceutical industry, for three main reasons. First, the costs of research, development and of obtaining regulatory approval are considerable for bringing a medicinal product to market and accordingly the price of pharmaceutical products (and therefore potential profit) is generally high. The start up costs and other barriers to entry for a would-be parallel importer are low. Secondly, pharmaceutical products are generally small, light and easily transported, making them a ready candidate for cross-border trade. Thirdly, the incentive for parallel importation exists in many countries because of price differentials that have resulted from government price control measures adopted pursuant to their national healthcare policies. The price of products in one country may therefore be fixed at a level considerably higher than that in a neighbouring country. Price differentials are likely to be further accentuated by variations in patent protection available in different countries. In general, prices for pharmaceuticals will be lower in unpatented countries because no patent royalties are payable on their sales. This is demonstrated by the drop in prices that typically occurs when products become generic upon expiry of their patents.

An essential part of the formulation of any marketing strategy will be the selection of countries for patent protection and subsequent maintenance. The patent strategy is crucial to research and development in the pharmaceutical industry in which product development may last a decade or more before a single sale is made, in which the number of drug "hits" is extremely low when compared to the "misses" and where the patent term is relatively short given that the underlying inventions are often made, and the patent term commences, many years before the product may be marketed. The result is
that a significant proportion of the patent term and corresponding patent filing and maintenance expense is occupied with pre-sales research and development, clinical trials, regulatory approval and similar. Supplementary Protection Certificates under Regulation 1768/92 go some way towards extending the life of pharmaceutical patents beyond their normal term in recognition of the long gestation period of patented pharmaceutical products. Regulation 1768/92 was aimed at prospering the pharmaceutical industry but in line with a programme of harmonisation heralded by the European Patents Convention ("EPC")43. Nevertheless, the lack of uniformity in the national patent law of Member States, compounded by government price intervention has led to the testing of the principles of exhaustion in a number of cases concerning pharmaceutical patents. It has become clear that the policy of the ECJ in such cases has been to construe any derogation from Article 30 (under Article 36) very strictly through adherence to notions of the "specific subject matter" of intellectual property.43

2. The "Specific Subject Matter" of Patents

In "Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc"44 ("Centrafarm v Sterling Drug"), the ECJ held that a claim of patent infringement could only be used as the basis of preventing importation of goods if necessary to protect the "specific subject matter" of the intellectual property. The "specific subject matter" of a patent differs from what might be described as the "function" of a patent. The function of a patent has been described as "a temporary exclusive right on a new product or process to reward ... creative effort".45 The limits to the exercise of that exclusive


43 See for example the measures discussed in Section 5 below

44 Case 15/74 [1974] ECR 1147; [1974] 2 CMLR 480

The issue of consent has its origins in the recognition that the patentee alone has the right to do, or authorise others to do, anything that would otherwise amount to patent infringement, including sales and importation. The right to first market (which encompasses both sales and importation) is not however exhausted when the patentee does not exercise that marketing choice voluntarily, as in *Pharmon v Hoechst*[^47], in which the reimported goods had been marketed pursuant to a compulsory patent licence because,

"such a measure deprives the patent proprietor of his right to determine freely the conditions under which he markets his products."[^48]

Consent is obviously adequately given by a proprietor by means of a licence or assignment. Consent is also considered to be given between entities under common control (*Centrafarm v Sterling Drug*).

The concept of the "specific subject matter" of a patent has acquired resilience through testing in awkward cases, particularly those in which the ECJ has considered it necessary to decide in favour of the free movement of goods,
thereby undermining the economic value of patents. The ECJ has done so even where market distortions are caused by government intervention.

3. Governmental Distortions

At the heart of the doctrine of exhaustion is the policy aim of allowing free movement of goods in accordance with market forces with the effect, among other things, of levelling price differentials across Member States. In the case of pharmaceutical products, government intervention may take the form of control of the prices of healthcare products or may take the form of legislation that is inconsistent with the rest of the Community in relation to the patenting of pharmaceutical products.

a. Price Controls

In Centrafarm v Sterling Drug it was accepted that a price differential of 50% that existed between the country of first sale and the country of resale was the result of government price determination. Nevertheless the ECJ was not prepared to allow Article 30 to be sacrificed in order to accommodate distortions caused by governmental measures.

"It is part of the Community authorities’ task to eliminate factors likely to distort competition between Member States, in particular by the harmonisation of national measures for the control of prices and by the prohibition of aids which are incompatible with the Common Market, in addition to the exercise of their powers in the field of competition."49

49 Paragraph 23 of the Judgment of the ECJ
This immediately calls into question whether a patent may still properly be regarded as an incentive for the investment required for industrial invention. Many statements of the ECJ suggest that it may. For example in *Centrafarm v Sterling Drug* the ECJ recognised (in the case of patents):

"that the patentee, to reward the creative effort of the inventor has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements."\(^{50}\)

However, the erosion of patent rewards is manifest in the ECJ’s decisions concerning government-imposed anomalies that result from price controls and patent policy.

b. **Non-uniformity of Patent Protection**

In the cases of *Merck & Co Inc.* v *Primecrown Ltd*, *Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd*, *Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd*\(^{51}\) ("Merck v Primecrown"), government interference created anomalies in the patent laws of Member States following the accession of Portugal and Spain. The case raised a number of fundamental issues concerning the scope and extent of the doctrine of exhaustion and gave the ECJ the opportunity to review its existing policy.

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50 Paragraph 9 of the Judgment of the ECJ

51 Joined Cases C-267/95 and C-268/95 [1996] ECR I-6285
The review began with the interpretation of the ECJ's judgment in the case of Merck & Co Inc v Stephar BV and Petrus Stephanus Exler\(^\text{52}\) ("Merck v Stephar"). In that case, Merck held patents in the Netherlands for a pharmaceutical product, but not in Italy, where patents were not then available. Merck claimed to be entitled to prevent imports from Italy on the basis that no rights can be said to be exhausted where they do not exist. The ECJ rejected this argument on the grounds that Merck had freely chosen to market the products in Italy. Patent rights could not be invoked to prevent parallel importation of goods sold, even in unpatented territories, by the patent proprietor or with his consent. Considerable emphasis was placed on the choice of first marketing in that case.

"It is for the proprietor of the patent to decide, in the light of all the circumstances, under what conditions he will market his product, including the possibility of marketing it in a Member State where the law does not provide patent protection for the product in question. If he decides to do so he must then accept the consequences of his choice as regards the free movement of the product within the common market, which is a fundamental principle forming part of the legal and economic circumstances which must be taken into account by the proprietor of the patent in determining the manner in which his exclusive right will be exercised."\(^\text{53}\)

The fundamental issue in Merck v Primecrown was whether Merck v Stephar was good law. Similar facts arose in Merck v Primecrown except that Merck relied on patents held in the United Kingdom to prevent importation from Spain and Portugal where pharmaceuticals

\(^{52}\) Case 187/80 [1981] ECR 2063 [1981]; 3 CMLR 465

\(^{53}\) Paragraph 11 of the Judgment of the ECJ (emphasis added)
were not at the relevant time patentable under the laws of those countries in spite of their accession to the European Community. Maximum prices were set at extremely low levels. Although the products were marketed in Spain and Portugal with their consent, Merck argued that patent rights could not thereby be said to be exhausted. They also claimed that the principle in *Merck v Stephar* should be limited in the case of pharmaceutical manufacturers because:

i. the effects of price control legislation in one country are otherwise exported to other Member States (following *Pharmon v Hoechst*)\(^{54}\);

ii. the monopoly revenues of the pharmaceutical industry would be sufficiently undermined at a time when EC measures had been supportive of the industry by means of the Supplementary Protection Certificate;

iii. there is at least an ethical obligation to make medicinal products available which does not leave pharmaceutical companies free choice to withhold them as part of a marketing strategy from unpatented countries.

The ECJ ruled that the fact that the products were unpatentable in Spain and Portugal but were in the United Kingdom could not be the basis for preventing imports of products from Spain and Portugal into the United Kingdom. The ECJ adopted what might be said to be a formal and legalist approach to these issues and refused to adjust the ratio of the *Merck v Stephar* decision founded on the principle that the patentee has free marketing choice and must bear the consequences of

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\(^{54}\) It was noted in *Pharmon v Hoechst* (n. 47 above) that schemes for compulsory licences are a matter for national legislation and that if the doctrine of exhaustion were to apply to permit exports of products made under a compulsory licence it would amount, in effect, to exporting the national patent legislation concerning compulsory licences.
that choice. The special circumstances pleaded for pharmaceutical companies did not qualify for a derogation from the rule in Merck v Stephar. However the ECJ commented that exceptions would be allowed in the case of marketing in a Member State under genuine existing legal obligations. Mandatory price control in Member States did not fall within that exception, nor did a mere ethical obligation.

At this point, two observations should be made. First, the ECJ is likely to have been persuaded that the problem caused by the transitional provisions relating to the accession of Spain and Portugal was one unlikely to dog the pharmaceutical industry for long since all Member States now allow for patentability of pharmaceutical products and the facts of Merck v Primecrown are unlikely to be repeated. However, the effects of the Merck v Primecrown decision are likely to be felt for the patent life of those products which are caught by the transitional provisions relating to the accession of Spain and Portugal, or any other country in the future acceding with patent laws which are unharmonised. Anomalies of accession are likely to be significant given that at present ten countries from Central and Eastern Europe have applied for membership of the European Union.

Secondly, the ECJ did not pursue an issue canvassed at some length by Advocate General Fennelly in Merck v Primecrown concerning the consequences of their decision in relation to the marketing plans of pharmaceutical companies. This is especially important given that the central issue in Merck v Primecrown is not purely an historic one.

"The current logical implications of Merck v Stephar not only encourage pharmaceutical companies to partition Spain and Portugal from the rest of the Community by withdrawing from

55 "Agenda 2000: For a Stronger and Wider Europe 1997, European Commission"
those markets, but this also constitutes a potential copyists' charter for those two markets which will last at least until research orientated pharmaceutical companies are able to bring through to the marketing stage on those markets novel and therefore patentable products.

4. Return from Investment and the Significance of Choice

The case is a significant development of the law concerning the patentee's return on investment and the effects of the decision are vital in the process of any due diligence investigation. The patentee under a compulsory licence at least has royalty revenue from the licence. The case of Merck v Primecrown concerns acts that would amount to infringement but for the lack of patent legislation in conformity with Community standards and results in no royalty return to the patentee in countries of first marketing. This has consequences for the patent system itself and raises questions concerning the significance of the point of first marketing for exhaustion purposes.

a. Investment Undermined

The undermining effect on investment is more far-reaching than the product sales in the unpatented territories. The effect of parallel imports will be to depress prices in protected countries (subject of course to governmental price controls).

If the only way to protect markets where products are patentable is to keep products out of countries where they are unpatentable, that is an unsatisfactory result for the Community. The ECJ suggests in Merck v Stephar that pharmaceutical companies are at liberty to make such decisions yet it is all too easy to imagine claims based on Article 85(1)

56 Paragraph 112 of the Opinion of Advocate General Fennelly
or 86 to confront such a marketing strategy. The only apparent motive for withholding sales is the protection of monopoly profit and it is doubtful whether paragraph 11 of the *Centrafarm v Sterling Drug* judgment (even though approved in *Merck v Stephar* and in turn in *Merck v Primecrown*) would avail a pharmaceutical company in such circumstances.

Investment in pharmaceutical research and development is therefore potentially significantly undermined by the court's decision in *Merck v Primecrown*. It is submitted that this must be a mistake given that Europe is a world leader in pharmaceutical development and Britain alone is at the forefront of biotechnological advances on which pharmaceutical applications are based. The disincentive is a considerable one and the industry cost to the developer patentee is high. It has been said that.

"In general...the case remains that parallel trade represents a direct transfer of profit from manufacturers to distributors with the final payer, whether the government, a sickness fund or the patient concerned being rewarded the least."  

It is submitted that this is only half the truth. There is not a Pound for Pound transfer between the proprietor and importer. The effect is more far-reaching. Even if on individual sales it might be said that profit is directly transferred to the parallel importer, in reality, the industry base may suffer to a degree that is indeterminate. That in turn goes to the root of the patent system and may indeed make the

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57 See Miller ER International Schallplatten GmbH v the Commission Case 19/77 [1978] ECR 131, [1978] 2CMLR 334 and discussion in Section 5 below "Significance of Market Conditions"

58 Quoted in Section 3b above (n. 53 above)

59 REMIT Consultants' report prepared for DGIV entitled "Impediments to Parallel Trade in Pharmaceuticals within the European Community" IV/90/06/01, OPOCE 1992
difference between a decision on the part of a pharmaceutical company to invest in patent development or to leave that particular product research. Advocate General Fennelly noted in *Merck v Primecrown* that while markets where rights are not recognised,

"should not be obliged to contribute to the recovery of research expenditure, they should at least not be used to undermine the ability to recover R&D costs on other markets."

b. The Right of First Marketing

What is important to the intellectual property proprietor is the value, in the hands of the proprietor, of product exploitation and not that in the hands of a subsequent reseller or user. It is the proprietor's monopoly or quasi-monopoly profit that attaches to the intellectual property and this is found only on sales by the proprietor itself or, if the proprietor opts for first marketing through an intermediary, on sales by that intermediary, with the proprietor's consent (for which the proprietor is remunerated at a rate that presumably reflects the monopoly power of the proprietor to grant that right). This view is confirmed by Advocate General Roemer in *Deutsche Grammophon v Metro* where he stated that

"here it should be decisive that the objective of the industrial property was attained when the goods were first placed on the market, since it was possible to use the monopolistic opportunity for gain. On the other hand, it would undoubtedly go beyond the objective of that right if the holder was permitted to control further marketing, in particular

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60 Paragraph 112 of the Opinion of Advocate General Fennelly

61 Case 78/70 [1971] ECR 487 (n. 28 above)
reimportation, and the free movement of goods was impeded."

Once protected products have been marketed by or with the consent of the proprietor, the proprietor might be said to have reaped the benefit of the monopoly, if the monopoly is expressed as the right to achieve the commercial return in sales revenue that stems from being the only source of that product. If sales in a particular territory are exposed to competition from identical products (which are imported from another territory) previously marketed by the proprietor or with the proprietor’s consent, then the proprietor has already received revenue on those product sales. To confer on the proprietor the further right of protection against competition from its own products, albeit from an indirect source, on which it has already derived sales or licence income, would be going further than the level of reward contemplated for the proprietor’s own development. It would amount to a form of double recovery.

By conferring on the intellectual property proprietor a right of first marketing, the proprietor has complete discretion as to how best to maximise the potential on direct sales or licence income i.e. income in the proprietor’s own hands. As the ECJ reaffirmed in Merck v Primecrown, intellectual property systems are not there to guarantee a reward "in all circumstances".

However, even if a reward for creative effort cannot be guaranteed in all circumstances, it is for the ECJ to determine what the circumstances for reward are. It is submitted that, given the impact on patent investment, there was sufficient room for the Court to uphold the interests of the patentee in the circumstances of Merck v

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62 Referred to in paragraph 93 of the Judgment of the ECJ in Merck v Primecrown
Primecrown in which two countries offer no possibility of realising the reward for creative effort and in effect provide circumstances for the reward in other countries to be undermined (by reason only of transitional non-compliance with the laws that exist elsewhere in the Community following harmonisation Directives). It is true to say that profit might have been obtainable in the unpatented countries in the proprietor's hands but not on the basis of reward in relation to the intellectual property or "its specific subject matter".

5. The Significance of Market Conditions

In Merck v Primecrown, Article 30 might be regarded as the tool for levelling the market for pharmaceuticals at the cost of the patentee when it should be the responsibility of the authorities to address national distortions. The ECJ stated that

"although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods. It is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules of free movement of goods."63

Those "authorities" have failed to provide free market conditions in which product movement is driven by free competition in spite of the fact that numerous Community harmonisation measures have been taken specifically in

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63 Paragraph 47 of the Judgment of the ECJ
the pharmaceutical sector. (For example, Council Directives 65/65 and 93/39\textsuperscript{64} and Council Regulation 2309/93\textsuperscript{65} created a European Agency concerned with Community-wide standards of quality, safety and efficacy and for product authorisation, Council Directives 92/28\textsuperscript{66} and 92/27\textsuperscript{67} were directed at marketing standards for the advertising and labelling of products, and Directive 87/21 offers an abridged procedure enabling the applicant to refer to "essentially similar" results from pre-existing medicinal product authorisations of other proprietors to avoid repetition of pharmacological and toxicological tests and clinical trials.) Nevertheless, national regulatory regimes remain firmly in place for pharmaceutical products to benefit governments as powerful purchasers. The result is that the price level of imported goods drives down the prices established nationally in the country of importation. In Merck v Primecrown, Advocate General Fennelly perceived that the effect is,

"to export not merely the product but also the commercial consequences of the legislative choice made by the exporting State to the importing State because the patentee has made a commercial choice to sell the product even in a less protected environment."\textsuperscript{68}

The economic structure of the market was dismissed by the ECJ in Merck v Primecrown and pharmaceutical companies were reminded by the ECJ of their decision to choose a marketing strategy to take account of the EC rules of


\textsuperscript{68} Paragraph 108 of the Opinion of Advocate General Fennelly
exhaustion. The risks of running directly into claims based on Article 85(1) and 86 are clear, and have recently been illustrated by the case of Merck, Organon, Glaxo v Commission. In that case, a sales system applied a 12% discount to wholesalers on sales of products destined for the United Kingdom. The discount was structured merely to reflect a scheme operated by the United Kingdom government and therefore did not apply to sales destined for other countries where no similar scheme exists. Following the threat of Commission proceedings, the discount scheme had to be abandoned. A similar situation arose in the case concerning the drug Adalat ("Adalat"). Nevertheless, the Commission fined Bayer AG a total of three million ECU for imposing a system of monitoring exports of their Adalat drug and limiting supplies to wholesalers to meet domestic demand only. The Commission inferred an agreement between Bayer and the wholesalers contrary to Article 85(1) on the grounds that the latter understood and were influenced by Bayer's "true motives" in imposed the monitoring system. That was in spite of the fact, as the Commission recognised, that,

"differences in price fixing methods and refund arrangements mean that there are wide disparities in pharmaceutical product prices in Member States." The significance of the judgment in Merck v Primecrown, in the light of these cases is three-fold. First, it would appear that enterprises are not as free as the ECJ might suggest, to adopt a market strategy that takes account of the economic market conditions of the pharmaceutical sector. Even if adopted unilaterally, the risks of inference of an agreement caught by Article 85(1) are high. Secondly, even if a strategy is devised with the intention of protecting

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69 Order of the Court of First Instance of 3 June 1997 Case T-60/96, [1996] ECR I-849

70 1996 (OJ) L201/1

71 Paragraph 55. However, the President of the Court of First Instance suspended the decision because there did not appear to be "at first sight" sufficient participation on the part of the wholesalers: Bayer v Commission Case T-41/96R [1996] ECR II-381
the proprietor against the effects of exhaustion, this will inevitably involve the risk of market partitioning to which the Commission is likely to take exception. Thirdly, it is to be expected that such a strategy, if not constituting arbitrary discrimination, would constitute a disguised restriction on trade between Member States. That is indeed the "true motive", albeit to avoid the dual effects of exhaustion and governmental fixed price differentials and yet is unlikely to be regarded favourably. No measures are currently proposed to harmonise government price regulation in the Community and the issue is therefore not short-lived.

C. COPYRIGHT

The function of copyright has been stated to be "to protect the moral rights in the work and ensure a reward for the creative effort" of the author. By contrast the specific subject matter of copyright is "the exclusive right to reproduce the protected work". It will be seen that many of the issues already discussed in the context of patents are equally relevant to copyright although on occasion the ECJ has differentiated between the two in its analysis. In Merck v Primecrown, the ECJ differentiated between forms of exploitation at least to separate the reproduction right from the rental right. This enabled the ECJ to decide in favour of free movement of goods on the facts of Merck v Primecrown and to provide an answer to arguments based on the earlier case of Warner Bros Inc and Metronome Video ApS v Erik Viuff Christiansen ("Warner v Christiansen") on policy grounds. Warner were proprietors of the copyright in the James Bond film, "Never Say Never Again". Christiansen purchased a video cassette of the film in London and took it to Denmark to rent it to the public. Although rental right did not exist

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73 Magill/Television Listings EC Commission Decision 89/205 [1989] CMLR 757
in the United Kingdom at that time, a rental right separate from the reproduction right did exist in Denmark (and had already been granted to Metronome). Warner relied on this right to prevent rental of the cassette in Denmark. The ECJ held that,

"where national legislation confers on authors a specific right to hire out video cassettes, that right would be rendered worthless if its owner were not in a position to authorise the operations for doing so. It cannot therefore be accepted that the marketing by a film maker of a video cassette containing one of his works, in a Member State which does not provide specific protection for the right to hire it out, should have repercussions for the right conferred on that same film maker by the legislation of another Member State to restrain, in that State, the hiring out of that video cassette."\(^{75}\)

The point was argued in Merck v Primecrown that patent rights cannot be taken to be exhausted by sales in Spain and Portugal where no such rights exist. The flaw in this argument was said, by the ECJ, to be found in the "specific subject matter" of copyright which distinguishes it from patent rights. According to Advocate General Fennelly in Merck v Primecrown (which in this respect the ECJ followed):

"the specific subject matter of a patent right may not be divisible in the same way as copyright into several individual acts restricted by copyright. But each of the several rights is an item of industrial or intellectual property whose existence flows from the law of a Member State."\(^{76}\)

\(^{75}\) Paragraph 18  
\(^{76}\) Paragraph 133
In other words, only the right of reproduction was exhausted in \textit{Warner v Christiansen} but not the different and separate performance right (which in any event would be dealt with under the free movement of services provisions of Articles 59 to 66 of the Treaty). He went on,

"The essence of the rights (if, admittedly not the extent) conferred in two parts on a copyright owner (the exclusive right to reproduce and to perform) and in one part in respect of a single act of marketing by a patentee are indistinguishable."\textsuperscript{77}

This raises a number of issues. First, whether it is correct in the treatment of patent rights to focus on first marketing of products when a separate parallel system of patent protection distinguishes product patents from process patents. It has been suggested by \textit{Torremans and Stamatoudi} that,

"the specific subject matter of a patent can only be compared to the specific subject matter of a copyright in relation to the sale of copyrighted products; not in relation to its performance aspect. The latter comes closer to the provision of a service rather than the supply of material goods."\textsuperscript{78}

However, it is submitted that this ignores the fact that a patent process is capable of being likened to a service if it does not involve the supply of material goods in its exploitation. This should not mean that the specific subject matter of patents is confined to product marketing. Take, for example, biological media used by water authorities to purify sewage according to a microbiological patented process. The media may be used as a product, an end in itself, for which it might be appropriate to speak of exhaustion only through marketing if the choice is made to sell it. Equally

\textsuperscript{77} Paragraph 133

\textsuperscript{78} \textit{Torremans and Stamatoudi} (1997) 9 EIPR 545 "Merck is Back to Stay"
however, if licensed as part of a purification process, it may be more appropriate to liken it to a service, as there is no product sale.

Secondly, to return to the reward aspect of exhaustion, in the case of Warner v Christiansen the profit was held to be attributable only to sales and not rentals, in view of the separation of the rental and sales markets. The presence of different markets with different rules and prevailing prices separately applicable to patented products and patented processes should also compel the same reasoning to apply to patents, against the judgment in Merck v Primecrown. Nevertheless, the ECJ seems ready to make such a differentiation in the case of copyright and not patents. In the case of Coditel SA v Ciné Vog Films SA, Ciné Voq was granted exclusive film and television rights to the film "Le Boucher" in Belgium and Luxembourg which excluded television showing for 40 months from film release. A parallel licence was granted by the same licensor to a German broadcast company who showed it on German television during the 40 month period binding Ciné Voq. A third party, Coditel, recorded and retransmitted the film shown on German television to cable subscribers in Belgium. It was held that television transmission was a performing right (a service falling within Article 59 of the Treaty), not dependant on physical deliverables, on which revenues are based on the number of broadcasts made. The owner therefore had a legitimate interest to protect in authorising a television broadcast of the film only after it had been exhibited in cinemas for a certain period of time. The right to insist on fees for broadcasting the film was said to be part of the "specific subject matter" of the right. Strategies demarcated along national boundaries with royalties based on usage were therefore held to be necessary to enable the proprietor to regulate royalty collection as part of the specific subject matter of the performance right.

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This distinction is likely to be perpetuated in future harmonisation measures and the appropriateness of this approach must be questioned. The Proposal for a Directive entitled "Copyright and Related Rights in the Information Society" (adopted by the Commission on 10 November 1997) has the aim of harmonising rights of distribution and exhaustion within the Community of tangible forms of the work of authors such as CDs, tapes and CD-Rom. Perhaps the greatest shortcoming of the Proposed Directive is that it excludes altogether from its scope delivery of material on line, treating non-tangible delivery perhaps artificially as a service or akin to a performance.

Thirdly, it is noteworthy in the case of Warner v Christiansen that Warner had deliberately withheld sales of the video cassette in Denmark. The fact that the ECJ found in favour of Warner does perhaps lend some support to the view that the intellectual property proprietor does have the power to make marketing decisions, which the ECJ will respect, in order to avoid the adverse market consequences of the right being exhausted. The free choice of the intellectual property proprietor might then be maintained in such a way that it may act in its own best interests in making marketing decisions. This is a theme consistently threaded through the cases ending in Merck v Primecrown, extending back to the case of Musik-Vertrieb Membrau GmbH et K-tel International v GEMA-Gesellschaft für Musikalische Aufführungs- und Mechanische Vervielfältigungsrechte from which came the statement that the intellectual property proprietor (in that case an author acting through a publisher),

"is free to choose the place, in any of the Member States, in which to put his work into circulation. He may make that choice according to his best interests, which involve not only the level of the remuneration provided in the Member State in question but also other factors such

80 COM (97) 628 Final
81 Joined Cases 55/80 and 57/80, [1981] ECR 147
as, for example, the opportunities for distributing his work and marketing facilities which are further enhanced by virtue of the free movement of goods within the Community.\(^n\)\(^{82}\)

In other words, it is apparently open to the proprietor to make the point of first marketing the most propitious, but as with all intellectual property, it is not open to the proprietor to object to the subsequent free movement across other states that follows from exhausting that intellectual property right. The critical trigger point remains that of exploitation by the proprietor or with the proprietor's consent. Marketing consent in the case of copyright occurs by way of licence or assignment (as with other intellectual property) but it is not considered to be given in the case of expiry of protection. In EMI Electrola GmbH \textit{v} Patricia Im-und Export and others\(^{83}\), reliance was successfully placed on copyright subsisting in Germany, to prevent reimportation from Denmark where the copyright had expired (since the Danish sales were not made with the proprietor's consent). Measures have been taken by Directive to level distortions base on copyright duration\(^{84}\) and their effectiveness will be considered in Chapter Four. It is submitted that those measures are piecemeal and, at the same time, the ECJ's case law inconsistent, illustrated by the ECJ's treatment of exhaustion of patents and copyright, which does not fully acknowledge the convergence of technologies that in reality render the form of delivery increasingly irrelevant.

D. REGISTERED DESIGNS

The principles of exhaustion as applied to copyright apply equally to registered designs (although the decided cases are fewer in number). This has

\(^{82}\) Paragraph 25 of the Judgment of the ECJ

\(^{83}\) Case 341/87, [1989] ECR 79

been confirmed in *Keurkoop BV v Nancy Kean Gifts BV*\(^85\). However, those cases concerning motor car spares (for example, *Consorzio italiano della componentistica di ricambio per autoveicoli and Maxicar v Regie nationale des usines Renault*\(^86\)), which upheld national law giving a design proprietor protection against spare parts importation, must be regarded with some suspicion. In the same context, the case of *AB Volvo v Erik Veng (UK) Ltd*\(^87\) is relevant but largely superseded given the sweeping changes to European design laws that followed. In that case however, design "specific subject matter" was defined as "the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design."\(^88\)

### E. TRADE MARKS

#### 1. The Subject Matter and Function of Trade Marks

Principles of exhaustion relating to trade marks are determined by the fact that the function of a trade mark is said to be that of identifying the origin of the goods i.e. the manufacturer.

In *Centrafarm BV et Adriaan de Peijper v Winthrop BV*\(^89\) ("*Centrapharm v Winthrop*") (the trade mark equivalent to the patent case *Centrafarm v Sterling*), the essence of a trade mark (apparently combining both its specific subject matter and function) was said to be:

\(^85\) *Keurkoop BV v Nancy Kean Gifts BV* Case 144/81 [1982] ECR 2853 [1983] 2CMLR 47

\(^86\) Case 53/87 [1988] ECR 6039; [1990] 4 CMLR 265

\(^87\) Case 238/87 [1988] ECR 6211; [1989] 4 CMLR 122

\(^88\) Paragraph 2 of the Judgment of the ECJ

\(^89\) Case 16/74 [1974] ECR 1183
"the guarantee that the owner of the trade mark has the exclusive right to use that trade mark for the purpose of putting products protected by the trade mark into circulation for the first time, and it is therefore intended to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trade mark."\(^{90}\)

It was held that the proprietor of the Dutch trade mark was not entitled to prevent importation of goods bearing that mark which had already been marketed by it in the United Kingdom. The ECJ stated that trade mark rights could not be relied upon to prevent importation,

"when the product has been put on the market in a legal manner in the Member State from which it has been imported, by the trade mark owner himself or with his consent, so that there can be no question of abuse of infringement of the trade mark."\(^{91}\)

This issue of consent, once again, is a critical one but has been restated differently in different cases.

2. Consent

In *Van Zuylen Freres v Hag AG*\(^{92}\) ("Hag I"), the ECJ ruled on the basis (now seen to be wrongly reasoned) that trade mark rights could not be used to prevent importation of goods with the same mark, "having the same origin". It was then considered by the ECJ that confusion could be avoided by measures that would not affect the free movement of goods (presumably

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\(^{90}\) Issue 2, paragraph 8 of the Judgment of the ECJ

\(^{91}\) Issue 2, paragraph 8 of the Judgment of the ECJ

\(^{92}\) Case 192/73 [1974] ECR 731; [1974] 2 CMLR 127
labelling and similar devices) and would not otherwise lead to market partitioning.

In **SA CNL-SUCAL v Hag AG**⁹³ ("Hag II") the ECJ took the opportunity of restating the principles established in **Deutsche Grammophon v Metro**, **Centrafarm v Winthrop**, and **Pharmon v Hoechst**, focusing again on the absence of consent on the part of the trade mark proprietor as the determining factor (rather than a concept of common origin). Likewise, in the case of **IHT International Heiztechnik GmbH and Uwe Danzinge v Ideal-Standard GmbH and Wabco Standard GmbH**⁹⁴ ("Ideal Standard") concerning the voluntary separation of trade mark ownership by means of express trade mark assignment, in line with **Hag II**, the critical importance of consent was emphasised. However, in **Ideal Standard** the ECJ drew a useful distinction between the "essential function of the trade mark" and "the specific subject matter of the trade mark". The "essential function" of the trade mark was said to be that of identifying origin and protecting the consumer assumption that goods bearing the same mark are made by a single source responsible for quality control. The "specific subject matter" was said to protect trade mark proprietors against competitors' theft of goodwill and reputation.

### 3. Trade Mark Legislation

The above cases were decided before trade mark law had become harmonised in the Community. Formal measures are increasingly taken to enshrine principles of exhaustion in the legislation of Member States. This can have a significant impact on the interpretation of principles of exhaustion beyond the immediate context of trade marks. Council Directive 89/104/EEC of 21

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⁹³ Case C-10/89 [1990] ECR 1-371

⁹⁴ Case C-9/93; [1994] ECR 1-2789
December 1988 to approximate the laws of Member States relating to trade marks\textsuperscript{95} ("the Trade Mark Directive") contains the following requirements:

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

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.\textsuperscript{96}

The Trade Mark Directive was implemented substantially in this form into the United Kingdom law by means of Section 12 of the Trade Marks Act 1994. Section 12 states:

"(1) A registered trade mark is not infringed by the use of the trade mark in relation to goods which have been put on the market in the European Economic Area under that trade mark by the proprietor or with his consent.

(2) Sub-section (1) shall not apply where there exist legitimate reasons for the proprietor to oppose further dealings in the goods (in particular, where the condition of the goods has been changed or impaired after they have been put on the market)."

The similarity between the Trade Mark Directive and the Act is striking.

\textsuperscript{95} (1989) OJ L40/1

\textsuperscript{96} Article 7
Owing to different labelling requirements and pharmaceutical practices in Member States, trade mark protection might be used by a trade mark proprietor to prevent a change of condition necessary to allow products to be sold from one country into another. The ECJ has therefore been keen to ensure that trade marks are not used as a device for doing so and has developed clear principles concerning repackaging and trade mark substitution.

4. Change of Condition

a. Repackaging

At the heart of the repackaging cases has been the extent to which Article 36 may entitle a trade mark proprietor to rely on principles of trade mark infringement to prevent importation of goods which have been repackaged but nevertheless bear the proprietor's trade mark.

In Hoffman-La Roche & Co AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH97 ("Hoffman-La Roche"), Centrafarm acquired "Valium" marketed in the United Kingdom by Hoffmann-La Roche and repackaged it using the same Hoffmann-La Roche trade mark (owned by Hoffmann-La Roche in the United Kingdom and Germany) for sales in Germany. The ECJ emphasised the trade mark function (following Centrafarm v Winthrop) to be that of guaranteeing for the consumer (or ultimate user) the identity of the origin of the product so that the consumer,

"can be certain that a trade marked product which is sold to him has not been subject at a previous stage of marketing to interference by a third person, without the authorisation of the proprietor of the trade mark, such as to affect the original

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97 Case 102/77 [1978] ECR 1139
condition of the product. The right attributed to the proprietor of preventing any use of the trade mark which is likely to impair the guarantee of origin so understood is therefore part of the specific subject matter of the trade mark right.\textsuperscript{98}

Accordingly, the ECJ decided that the first sentence of Article 36\textsuperscript{99} would entitle a trade mark proprietor to prevent unauthorised importation of repackaged goods. However, the ECJ stated that any ban on imports could constitute a disguised restriction on trade caught by the proviso to Article 36\textsuperscript{100} and the ECJ listed the criteria which would prevent reliance on trade mark rights by the proprietor. The proprietor’s use of the mark would be caught by the proviso, if the proprietor were to adopt a registration policy or marketing strategy which contributes to the artificial partitioning of the markets between Member States, if the original condition of the product is not adversely affected by repackaging, and if the fact of repackaging is disclosed on the package itself and to the trade mark proprietor. In these circumstances, the trade mark proprietor could not object to reimportation based on trade mark rights.

The significance of the proprietor’s own marketing strategy is obviously critical in determining whether it imposes a "disguised restriction". The ECJ in Merck v Primecrown emphasised the proprietor’s supposed free choice of marketing strategy available in the light of the extent of intellectual property protection available. The ECJ in Merck v Primecrown did not give sympathetic attention to the allegation that was suggested could be levelled against the proprietor,

\textsuperscript{98} Issue 2, paragraph 7 of the Judgment of the ECJ

\textsuperscript{99} "The provisions of Article 30 shall not preclude prohibitions or restrictions on imports, exports or goods in transit...justified on the grounds of...the protection of industrial or commercial property"

\textsuperscript{100} "Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States"
that the strategy artificially partitions the market, where the strategy is driven by the inadequacy of protection in certain Member States. The matter, once again, is to be resolved by reference to the subject matter and function of the intellectual property right in question.

The criteria laid down in Hoffmann-La Roche were applied in the case of Pfizer Inc v Eurim-Pharm GmbH. The importer, Eurim-Pharm, placed substitute external wrapping on the product "Vibramycin", which had already been marketed by Pfizer in the United Kingdom in blister strips, in such a way as to indicate both the manufacturer and the fact of rewrapping. Pfizer was unable to rely on its trade mark in Germany (where the prevailing price was considerably higher) to prevent importation because in these circumstances, "no use of the trade mark in a manner liable to impair the guarantee of origin takes place".

The issue of "artificial partitioning" came under scrutiny in the more recent line of repackaging cases, Bristol-Myer Squibb v Paranova A/S and CH Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S ("Paranova"). The crucial parts of the judgment summarise the essential function of the trade mark, "which is to guarantee to the consumer or end-user the identity of the trade-marked product's origin by enabling him to distinguish it without any risk of confusion from products of different origin. That guarantee of origin means that the consumer or end-user can be certain that a trade marked product offered to him has not been the subject at a previous

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102 Joined Cases C-427/93, C-429/93 and C-436/93, [1996] ECR I-3457
stage of marketing to interference by a third person, without the authorisation of the trade mark owner, in such a way as to affect the original condition of the product.\textsuperscript{103}

The trade mark owner may therefore prevent any use which interferes with the guarantee of origin.

The ECJ related the issue of "artificial" market partitioning to the essential trade mark function by saying that partitioning is not artificial if it is done in order to preserve the guarantee of origin.

"By stating that the partitioning of the market must be artificial, the court's intention was to stress that the owner of a trade mark may always rely on his rights as owner to oppose the marketing of repackaged products when such action is justified by the need to safeguard the essential function of the trade mark, in which case the resultant partitioning could not be regarded as artificial.\textsuperscript{104}

The test of artificial partitioning is to be applied objectively, judged at the time before enforcement (presumably at the stage of formulation of a strategy for trade mark registration). The ECJ also concluded that the condition of a product would not be adversely affected (applying Hoffmann-La Roche) by the application of self-adhesive labels to flasks, phials, ampoules or the translation of written instructions for use in different Member States\textsuperscript{105}. The ECJ also took the opportunity of addressing the position of the parallel importer,

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\textsuperscript{103} Paragraph 47 of the Judgment of the ECJ
\textsuperscript{104} Paragraph 57 of the Judgment of the ECJ
\textsuperscript{105} In any event, it has been established in Pall v Dahlhausen (Case C-238/89 [1990] 1 ECR 4827) that national laws concerning packaging requirements will contravene Article 30 if they prevent the marketing of products because they are not packed or marked in a particular way
\end{flushleft}-54-
extending the Hoffmann-La Roche requirements of identification of the manufacturer to cover also a requirement that the new packaging must state the identity of the repackager and the manufacturer (to whom specimens must be made available upon request) in a form of print and language intelligible to a normally attentive person with normal eyesight, identifying additional items for which the trade mark owner is not the source. Also, the presentation of the packaging must not damage the reputation of the trade mark or its proprietor. Finally, the extent to which a parallel importer may repackage is obviously important, as the judgment only permits repackaging "insofar as the repackaging undertaken by the importer is necessary to market the product in a Member State of importation."

b. Relabelling

The case of Frits Loendersloot v George Ballatine and Sons LTD ("Loendersloot v Ballantine") appears recently to have confirmed the ECJ's willingness to permit relabelling, in that case of whisky bottles with the removal of the identification number of the bottle, the name of the importer and the word "pure", provided the relabelling does not defeat another legitimate purpose of the original label such as the identification of the manufacturer and chain of supply for product liability purposes and provided the relabelling causes "as little prejudice as possible to the specific subject matter of the trade mark right."

106 Paragraphs 67-78 of the Judgment of the ECJ
107 Paragraph 56 of the Judgment of the ECJ
108 Case C-349/95, [1997] ECR I 6227
109 Paragraph 46 of the Judgment of the ECJ
c. Trade Mark Substitution

Different rules appear to apply in the case of trade mark substitution rather than repackaging. Substitution may be relevant where the mark originally applied is confusing, is not lawful in the territory of importation, is not passed by the drug approval authorities, or is unfamiliar to pharmacies and doctors prescribing them.

In *Centrafarm v American Home Products Corporation (AHP)*\(^{110}\), quantities of the sedative "Oxazepamum", which had been sold by the proprietor of that mark, AHP, in the United Kingdom under the mark "Serenid D" were purchased by a parallel importer and resold under the mark "Serestra" in the Netherlands. In the Netherlands, AHP marketed the product under its mark "Seresta" with the same pharmacological properties but with a different taste. AHP successfully claimed infringement of the trade mark "Seresta" since this had been applied in the Netherlands without the consent of the proprietor. The ECJ confirmed that only the trade mark proprietor is entitled to give its products their identity by fixing the trade mark, and the guarantee of origin principle would be offended by anyone else doing so. The Court acknowledged that the deliberate use of two different marks to achieve artificial partitioning would amount to "a disguised restriction on trade between Member States" under Article 36 but that valid (not "artificial") justifications for the use of different trade marks in Member States might exist. Examples would be the existence of trade marks in a country of proposed sale, differences in the pharmaceutical packaging laws of Member States, or other plausible, explicable, cultural, environmental, political, social or legal variations.

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It is significant that rules of confusion for the purpose of trade mark law differ considerably from country to country. In Hag II, Advocate General Jacobs\textsuperscript{111} noted the abundance of confusingly similar marks and the likelihood that intracommunity trade would be significantly impeded. He noted that confusion judged by the German standard in Societe Terrapin (Overseas) Ltd v Societe Terranova Industrie CA Kapferer & Co\textsuperscript{112} would not amount to confusion in the United Kingdom. Therefore a German exporter could sell in the United Kingdom but a United Kingdom exporter could not sell in Germany. Rules of confusion still appear to be a matter to be determined at national level, as confirmed more recently in Deutsche Renault AG v Audi AG\textsuperscript{113},

"Community law does not lay down any criterion requiring a strict interpretation of the risk of confusion."\textsuperscript{114}

d. Advertising

In order to permit the practical implementation of the developed principles of exhaustion, it has now been clearly established that the parallel importer may undertake ancillary activities such as advertising. In Christian Dior SA and Parfums Christian Dior BV v Evora BV\textsuperscript{115} ("Christian Dior v Evora") the ECJ affirmed the practice of advertising Christian Dior products by a company which held less of a "luxury image" than Christian Dior, provided that it did not "seriously

\textsuperscript{111} Paragraph 591 of the Opinion of Advocate General Jacobs

\textsuperscript{112} Case 119/75 [1976] ECR 1039; [1976] 2 CMLR

\textsuperscript{113} Case C-317/91, [1993] 1 ECR 627

\textsuperscript{114} Paragraph 31 of the Judgment of the ECJ

\textsuperscript{115} Case C-337/95 [1997] ECR I 6013
damage" the reputation of the trade marks used or the goods. A luxury brand would not however be treated as "seriously damaged" merely by sales at a cheaper price than those chosen by the trade mark proprietor for a given territory.

F. TERRITORIAL EXTENT OF THE DOCTRINE OF EXHAUSTION

The implementation of the Trade Mark Directive has been the recent catalyst for important and long-awaited clarification of whether, at least in the trade mark context, rights are exhausted when first marketed outside the Community. Article 7 of the Trade Mark Directive is ambiguous insofar as it relates to the position of goods which have been first put on the market outside the Community. Article 7 may be interpreted as merely setting a minimum standard, requiring Member States to apply principles of exhaustion throughout the Community but leaving them free to decide whether to apply principles of international exhaustion beyond that. (Those favouring this interpretation maintain that Article 7 is merely a modification of existing ECJ case law, since the Court itself has stressed that Article 7 is to be interpreted in the same way as the Court’s case law on Articles 30 and 36. It is maintained that the aim of the Trade Mark Directive was limited and, in the absence of clear wording to the contrary, the discretion that countries previously had to apply international exhaustion, should remain.) Alternatively, Article 7 may be interpreted as a maximum standard, requiring Member States to apply principles of exhaustion only within the Community and not internationally beyond the Community. (Those arguing in favour of a maximum point to the third recital of the Directive’s preamble, which refers to the approximation of national provisions of law which most directly affect the functioning of the internal market and maintain that international exhaustion is one such principle which the Trade Mark Directive aimed to harmonise.)
This ambiguity potentially gives rise to considerable difficulties in assessing the value of trade marks and the scope of protection afforded by them. The consequences for due diligence examination are not immediately apparent but are far-reaching, as suggested by Carboni\textsuperscript{116}. She considered there to be no general doctrine of exhaustion beyond the confines of the EEA. She interpreted the Trade Mark Directive by referring to the \textit{travaux préparatoires} which preceded the Directive\textsuperscript{117} and concluded that these materials demonstrate that one purpose of these measures was to prevent discrimination of businesses within the Community where no reciprocal free movement measures apply in countries outside the Community.

"There is a real danger that undertakings whose principal place of business could well be in a non-Member country would prevent their products being imported into the Community at more favourable prices, which would be detrimental to Community consumers."\textsuperscript{118}

Her conclusion was that it is open to countries to extend exhaustion laws to permit imports from countries outside the EEA where the national law of the non-EEA exporting country permits reimports from the EEA. If reciprocal treatment to parallel imports was found between non-EEA and EEA countries then a defence may be available to the EEA importer of goods of non-EEA origin. However, as Carboni observed, this would "entail reliance on the expert evidence of a local lawyer from the country of origin of the parallel imports in order to establish the existence of reciprocity". This would add time and considerable expense to any due diligence investigation. It would require a factual investigation of all sales made in non-EEA countries and an

\textsuperscript{116} Anna Carboni "Cases Past the Post on Trade Mark Exhaustion: An English Perspective" (1997) 4 EIPR 198

\textsuperscript{117} The First Protocol (presented to the Council on 25 November 1980), Proposal for a Regulation (COM (80) 635), Explanatory Memoranda.

\textsuperscript{118} Commentary on Article 11 of the Proposal for the Regulation on the Community Trade Mark COM (80) 635, Explanatory Memorandum

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investigation, for each type of intellectual property right, of the laws of each country of the EEA and the availability of remedies, bearing in mind that the availability of remedies throughout the Community is an important area that is as yet unharmonised. Matters would be complicated by the fact that reliance cannot be placed on interpretation of Directive requirements by other EEA states (Wagamama v City Centre Restaurants)\(^{119}\).

Clarification of such fundamental ambiguity would greatly assist the due diligence process. The different interpretations historically given by different Member States bears out the complexity of due diligence without such clarification. The Trade Mark Directive has been interpreted by the Federal Supreme Court of Germany to mean that exhaustion in the EEA does not occur as a result of first sales outside the EEA (Levi Strauss v Knecht)\(^{120}\). According to that decision, legislation enacted in 1995 in Germany pursuant to the Trade Marks Directive may be relied upon to prevent importation into Germany of jeans first marketed in the USA. That legislation represented a clear reversal of the principles of international exhaustion which had been developed in Germany prior to its enactment. Before the Trade Marks Act 1994, the United Kingdom took an inconsistent approach to exhaustion in the United Kingdom by non-EEA sales. It appears that the Court of Appeal in Colgate Palmolive v Markwell Finance\(^{121}\) permitted reliance on United Kingdom trade mark rights to prevent imports of an inferior quality toothpaste where that amounted to misrepresentation of quality and consent could not be implied. However, consent to worldwide sales was found to be present in Revlon v Cripps & Lee\(^{122}\) in the marketing strategy of the trade mark proprietor under the well known slogan, "New York, Paris, London".

\(^{119}\) [1995] FSR 713

\(^{120}\) GGH, Urt v. 14. 12. 1995 -1ZR 210/93

\(^{121}\) 1989 RPC 497

\(^{122}\) [1982] FSR 85

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The historical disparities in national trade mark law are therefore crucial to an understanding of the importance of the Silhouette Case. Advocate General Jacobs recognised that in view of these disparities, it was necessary for the Trade Mark Directive to transform the impact of Community law on trade mark protection. He appealed to the aims and scope of the Directive having determined that the terms of the Directive themselves are not conclusive. In spite of the fact that there are obvious limits to the scope of the Trade Mark Directive, as it was not intended as a measure of total harmonisation, it nevertheless did set out to harmonise the essential conditions and consequences of trade mark protection and he recognised that the scope of the exhaustion principle is central to the content of trade mark rights. Turning to the effect of national disparities concerning international exhaustion, Advocate General Jacobs concluded that:

"The Directive regulates the substance of trade mark rights, and its provisions are designed to be substituted for the diverse national laws across the whole range of its provisions." If some Member States practise international exhaustion while others do not, there will be barriers to trade within the internal market which it is precisely the object of the Directive to remove. Accordingly, he agreed with the submission of various countries (which argued against any discretion to apply international exhaustion) that the same products could be the subject of parallel imports into one Member State but not into another and that this was clearly against the aims of the internal market.

124 Paragraph 39
125 Ibid
126 Paragraph 41
In his opinion, Advocate General Jacobs refers also to the text and intention of the Community Trade Mark Regulation^{127} ("Community Trade Mark Regulation"). The Community trade mark is perhaps the most developed of the Community's harmonisation measures because of its unique emphasis on "unitary character".

"A Community Trade Mark shall have a unitary character. It shall have equal effect throughout the Community, it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, nor shall its use be prohibited save in respect of the whole Community."^{128}

Article 13 of the Community Trade Mark Regulation is a mirror image of Article 7 of the Trade Mark Directive, providing for exhaustion only for goods which have been put on the market "in the Community". Advocate General Jacobs concluded that it is impossible to construe the Regulation as imposing international exhaustion, similarly with the Trade Mark Directive. The original Proposal for the Directive expressly provided for international exhaustion and was subsequently changed to limit it only to the Community. The Trade Mark Regulation, given its unitary character, cannot be intended to give Member States discretion whether or not to permit international exhaustion. In view of the history of the Directive, its purpose and the identical wording to the Regulation, Advocate General Jacobs concluded that Article 7(1) of the Trade Marks Directive is to be interpreted to entitle a trade mark owner to prevent a third party using the mark when importing goods into an EEA country after first marketing in a country outside the EEA.


^{128} Article 1(2)
The ECJ followed the Opinion of Advocate General Jacobs by concluding as follows:

"[T]he Directive cannot be interpreted as leaving it open to the Member States to provide in their domestic law for exhaustion of the rights conferred by a trade mark in respect of products put on the market in non-member countries ... This ... is the only interpretation which is fully capable of ensuring that the purpose of the Directive is achieved, namely to safeguard the functioning of the internal market. A situation in which some Member States could provide for international exhaustion while others provided for Community exhaustion only would inevitably give rise to barriers to the free movement of goods and the freedom to provide services."\(^{129}\)

That level of clarification, although given in the context of trade marks, is of great value insofar as the reasoning applies equally to other intellectual property rights. As national disparities in the treatment of international exhaustion of any intellectual property right will inevitably result in barriers to trade within the internal market, the reasoning of the ECJ can be applied to other intellectual property rights. However, there have been no harmonisation measures apart from the Trade Mark Directive aimed at wholesale substitution for diverse national laws and doubtless there will be many more cases in the future arising out of the disparities in those laws.

G. DUE DILIGENCE ISSUES

The consequences of the developing doctrine of exhaustion are manifold when acting for the purchaser of a business, be that of a parallel importer or intellectual property proprietor. Due diligence investigation requires a detailed examination extending far beyond verification of the title and

\(^{129}\) Paragraphs 26 and 27 of the Judgment of the ECJ
ownership of intellectual property, including the detailed dealings of the rights in the business and related activities of that business. In addition, the effect of the rules of exhaustion on the value of intellectual property (in the hands of the proprietor) is extremely difficult to ascertain.

When acting for the owner of a business dependent on its ownership of intellectual property, a great many highly complex issues will need to be investigated. For example, in relation to patents, whether a policy of first marketing in the EEA has been adopted to maximise profits by excluding marketing or consent to sales in countries where the prevailing product price is low, whether by reason of lack of patent protection, price control or some other factor. An assessment of the particular policy adopted by a business would be unfeasible in the time typically available for completion of a business or company sale as it would require analysis of price and market conditions and the position of the proprietor’s (and competitors’) intellectual property in each country.

It might be assumed that it would be easy to determine whether consent has been given to marketing. However, consent to first marketing may have been given inadvertently. For example, a practice of licensing may fail to meet the requirements of any applicable block exemption Regulation, and be caught by Article 85(1) of the Treaty either because the express contractual provisions fail to meet the block exemption terms or the pre-conditions for exemption are not satisfied. It is arguable that the relevant restrictions (including territorial scope) are void and therefore consent has been given without territorial limit. Apart from the risk of fines and that the licensor may be unable to recover royalties, this may also place the licensor in breach of other licence agreements which are intended to be exclusive. Even then the likely effect of any consensual marketing in countries intended to be reserved to the licensor (or other licensees) will need to be examined. Inadvertent

130 Discussed below in Chapter Three
consent may also be given by the adoption of an "international" brand (Revlon v Cripps & Lee).

Assessment of copyright and design right works is made far harder given the wide disparities that exist across the national laws of Member States and lack of substantive harmonisation beyond the provision for minimum levels of protection provided by international corporation as discussed further in Chapter Four.

If acting for the proprietor of a trade mark, any practical barriers to re-importation must be legitimate. For example, any product identification must be for tracing purposes relating to such matters as safety or product liability and not as a deterrent against re-importation (Adalat, Loendersloot v Ballatine). The use of expensive packaging may be an effective deterrent against repackaging particularly if cheaper packaging would cause "serious damage" to the trade mark or goods (Christian Dior v Evora). There must be no artificial territorial division achieved by the use of different trade marks (Paranova), something that can only be judged by the presence of features that adequately explain any actual market division. All of these items are a matter of degree and do not lend themselves to due diligence assessment, yet it is essential to ensure that profit for the intellectual property proprietor is maximised.

In relation to all intellectual property rights (whether acting for the intellectual property proprietor or parallel importer) the complexity of these issues is further aggravated by the accession of new countries to the EU, especially the transitional periods of derogation applicable to those which are less economically developed. These are typically the territories in which low prices are most likely to prevail and provide lucrative parallel export markets but where protection may not exist equivalent to the rest of the EEA. There may also be products available in those markets prior to accession to which special rules apply. For trade marks, in spite of the Community Trade Mark
Regulation, the unitary character of the trade mark cannot be reconciled with prior trade marks held in acceding countries. Article 52 of the Community Trade Mark Regulation provides for invalidity of the Community Trade Mark in respect of earlier trade marks. A Community Trade Mark may conflict with a national mark held in an acceding country by a different owner. Either the owner of the trade mark in the acceding country, or the owner of the Community Trade Mark, if not both, will suffer by any resolution of the issue since both marks cannot co-exist within the Community following accession so as to confer rights on the proprietor in relation to acts of infringement. A close eye needs to be maintained on such issues, involving searches in all countries likely to accede in the foreseeable future. In the meantime, it is one area in which Community Trade Mark measures may be seriously hampered. If both marks are allowed to co-exist the unitary character of the Community Trade Mark is lost.

In addition, the distinctions between EC and EEA territorial coverage will continue to give rise to anomalies especially given the potential for differing rules concerning international exhaustion (Polydor Limited and RSO Records Inc. v Harlequin Records Shops Limited and Simons Records Limited\(^{131}\)).

Finally, commercial arrangements between the parties in the Community or EEA and acceding countries will be of considerable importance as well as other arrangements with effects in any acceding country, if they were conceived on the assumption that the territory remained outside the Community or EEA (as appropriate).

In short, harmonisation of intellectual property by these particular Treaty provisions has been effected at considerable cost to the intellectual property proprietor and has added greatly to the task of due diligence investigation.

\(^{131}\) Case 270/80 [1982] ECR 329
CHAPTER THREE:
HARMONISATION BY REGULATION

(COMpetition Law Regulations)

"Tender-handed stroke a nettle, and it stings you for your pains, grasp it like a man of mettle, and it soft as silk remains"\(^\text{132}\)

\(^{132}\) Aaron Hill (1685-1750 "Verses Written on a Window")
HARMONISATION BY REGULATION

A. INTRODUCTION

This Chapter will begin with the point at which Articles 30 and 36 (covered in the previous Chapter) meet Articles 85(1) and 86. It will examine the difficulties posed by Articles 85(1) and 86 in any due diligence investigation of intellectual property in licensing and joint venture transactions in the light of recent EC harmonisation measures adopted by way of Commission ("Regulation"). The importance of competition law to intellectual property due diligence is that the effect of Article 85(1) can be to undermine critically the commercial value of the rights held by a proprietor, licensee or joint venturer, operating as it does to render certain clauses in intellectual property transactions, or even entire agreements, void.

Articles 30 and 36 together define the extent to which intellectual property rights may be used by an intellectual property proprietor to rely on territorial barriers based on national protection. Articles 30 and 36 address the consequences to the intellectual property proprietor of first marketing products. However, Articles 30 and 36 only deal with marketing by the proprietor or by a licensee (ie. with the proprietor's consent).

Articles 85(1) and 85(3) together define in general terms the extent to which the intellectual property proprietor and licensee may enter into agreements conferring or reserving territorial exclusivity or which are otherwise potentially restrictive of competition. An agreement prohibited by Article 85(1) is automatically void and unenforceable under Article 85(2) unless exempt under Article 85(3); however, only those particular provisions which are prohibited by Article 85(1) will be void if they are severable from the remainder of the document (Société Technique Miniere (LTM) v
Maschinenbau Ulm GmbH (MBU). An infringement of Article 85(1) or 86 exposes undertakings to the risk of fines of up to 10% of the combined gross worldwide annual turnover of the groups to which they belong. Even if extensive indemnities are given by the vendor of a business to cover the costs of any fine, the purchaser will nevertheless risk being involved in lengthy proceedings and will suffer the uncertainty of not knowing the outcome of any Commission investigation or challenge to the enforceability of any intellectual property agreement acquired.

The Commission is empowered to grant exemption from the prohibition of Article 85(1) under Regulation 17 Article 9(1) following formal notification by the parties concerned, or (by virtue of Council Regulation 19/65) by way of block exemption regulations in respect of categories of bilateral exclusive agreements and licences of intellectual property, the aim being to enable the Commission to reduce its case-load of individual notifications.

In exercising its power under Council Regulation 19/65, the Commission has adopted the following Regulations in recognition that it is generally supportive of vertical licensing agreements that enable small companies to penetrate new markets or promote innovation: Regulation 2349/84 relating to patent licensing agreements (the “Patent Regulation”), Regulation 417/85 relating to specialisation agreements (the “Specialisation Regulation”),

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133 Case 56/65 [1966] ECR 337; [1966] CMLR 357
134 Article 15(2) of Regulation 17 OJ (1962), 13/204 OJ 1959-62, 87
135 Regulation No. 19/65/EEC of 2 March of the Council on application of Article 85(3) of the Treaty of certain categories of agreements and concerted practices (1965) OJ No. 36/533


Article 11 of the Technology Transfer Regulation

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"The rules governing patent licensing agreements and agreements for the licensing of know-how ought to be harmonised and simplified as far as possible, in order to encourage the dissemination of technical knowledge in the Community and to promote the manufacture of technically more sophisticated products"\textsuperscript{142}.

The Commission acknowledged\textsuperscript{143} that the grant of exclusivity is seen as a necessary incentive for the intellectual property proprietor to grant licences and for the licensee to invest in manufacture and marketing in the allocated territory\textsuperscript{144}. However, it is emphasised in the Technology Transfer Regulation that the principles of Articles 30 and 36 are not to be affected:

"The exemption of export bans on the licensor and on the licensee does not prejudice any developments in the case law of the Court of Justice in relation to such agreements, notably with respect to Articles 30 to 36 and Article 85(1). This is also the case, in particular, regarding the prohibition on the licensee from selling the licensed product in territories granted to other licensees (passive competition)"\textsuperscript{145}.

It is submitted that the measures taken by the Commission to regulate the terms of intellectual property agreements, have failed in their aim of providing certainty to parties due to the Commission's innate tendency to be conservative in any group or "block" exemption. This is best illustrated by its approach in the Technology Transfer Regulation. It is necessary to examine that Regulation in some detail before its effect and shortcomings can be appreciated.

\textsuperscript{142} Recital (3) Regulation 240/96
\textsuperscript{143} Recital (10) Regulation 240/96
\textsuperscript{144} Recital (12) Regulation 240/96
\textsuperscript{145} Recital (11) Regulation 240/96
B. TECHNOLOGY TRANSFER REGULATION

1. Introduction

It is noteworthy that the Technology Transfer Regulation emerged in anticipation of the pending expiry of the Patent Regulation which was to occur on 31 December 1994\textsuperscript{146}. The Commission draft which was first circulated in April 1994 met with vehement criticism and was rejected as unworkable largely due to the incorporation of market share criteria as conditions for exemption (originally territorial exclusivity would only be available to a party if it has a market share of less than 40%). The Regulation was so delayed that it did not in fact come into force until 1 April 1996. The market share test is still present in Article 7(1) in diluted form when compared with the original proposals, in such a way that exemption conferred by the Regulation is withdrawn if the effect of the agreement is to prevent the licensed products being exposed to effective competition in the exclusive territory from the same or similar products "which may in particular occur where the licensee’s market share exceeds 40%"\textsuperscript{147}.

2. Scope of the Regulation

The Technology Transfer Regulation applies\textsuperscript{148} to licences of patents on their own ("pure" patent licences), licences of non-patented technical information ("such as descriptions of manufacturing processes, recipes, formulae, designs or drawings"\textsuperscript{149}), ("know-how licences") and combinations of both, ("mixed

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\textsuperscript{146} Extended to 30 June 1995 by Commission Regulation 70/95. The Know-how Regulation was due to expire on 31 December 1999

\textsuperscript{147} Market share assessment is nevertheless still relevant for the purposes of Regulations 417/85, 418/85 and (for the purposes of "old agreements") Regulations 2349/84, 556/89 — see also Regulation 151/93 in the context of joint ventures

\textsuperscript{148} Article 1.1

\textsuperscript{149} Recital (4)
licences"). The licences may cover other ancillary intellectual property, in particular, trade marks, design right and copyright, especially software, but it is only appropriate to include this ancillary intellectual property when the additional licensing contributes to the achievement of the objects of the patent or know-how technology and the provisions relating to these items are only ancillary (i.e. the provisions relating to these additional items only contain restrictive obligations which attach equally to the licensed patents or know-how). Ancillary intellectual property is therefore narrowly defined, emphasising the limits of the Regulation to catch primarily only patent and know-how rights but not other intellectual property.

The significant step taken by the Commission in creating a combined Regulation for patent and know-how licences does recognise that in reality the two rights are essentially similar in nature and in practice are licensed together. The combination is creditable also in the transitional treatment to repealing the earlier Know-how Regulation and Patent Regulation because any licence that would have been exempt under either of those two Regulations would also be exempt under the more relaxed regime of the new Regulation.

Another positive result of the Technology Transfer Regulation is that it did away with the artificial analysis that had to be made in the past to determine in the case of a licence which included know-how whether the know-how was ancillary to patents, and covered by the Patent Regulation, or was more than ancillary and therefore eligible for exemption only under the Know-how Regulation. The two are now combined in a more flexible form but still differentiating between core patents and know-how for the purpose of determining the scope of permissible territorial restrictions.

150 Article 1.1
151 Recital (6)
152 Article 10(15)
153 See Article 1 and Recitals 3 to 9 and 12
3. Pure Patent Licences

Article 1.2 deals with the duration of territorial restrictions in pure patent licences. The licensor may be prevented from granting equivalent patent licences to others in the allocated territory\textsuperscript{154} and may be prevented from exploiting the patent itself\textsuperscript{155} for the duration of the patents (ie. for so long as they are maintained)\textsuperscript{156}. Similarly, for the duration of the patents, the licensee may be prevented from exploiting by any means the licensed patent in the licensor’s territory\textsuperscript{157} and may be prevented from exploiting the patent by manufacture or use\textsuperscript{158} or by active sales and marketing\textsuperscript{159} in territories licensed to other licensees of the licensor.

In addition, the licensee may be prevented even from making passive sales against unsolicited orders\textsuperscript{160} in territories licensed to other licensees but only during the period of five years from the date when the licensed product is first marketed within the Common Market by one of the licensees\textsuperscript{161} and then only to the extent that there is protection in those territories by parallel patents. Notice that first marketing is by one of the licensees and not the licensor itself, so that sales by the licensor do not extinguish that right.

\textsuperscript{154} Article 1.1(1)
\textsuperscript{155} Article 1.1(2)
\textsuperscript{156} Article 1.2
\textsuperscript{157} Article 1.1(3)
\textsuperscript{158} Article 1.1(4)
\textsuperscript{159} Article 1.1(5)
\textsuperscript{160} Article 1.1(6)
\textsuperscript{161} Article 1.2
4. **Pure Know-How Licences**

The position of pure know-how licences is dealt with in Article 1.3, permitting the same restrictions on the licensor and licensee except that the maximum duration of those restrictions differs. It is confined to a period not exceeding ten years from the date when the licensed product is first put on the market within the Common Market by one of the licensees except that this period ends five years from that date in the case of the restriction on the licensee putting licensed product on the market in territories licensed to other licensees in response to passive orders. It may not be within the knowledge of the licensor or any licensee precisely when first marketing occurred, as this may be known only by another licensee who has not communicated this to the licensor. Nevertheless, the date of first marketing is the critical trigger event for the permissible period of these restrictions. Each licence agreement should therefore require the licensee to communicate the date of first marketing though this is rarely ever done. The parties to know-how licences are therefore at risk that they are giving effect to restrictions beyond their permissible end-date and are conducting themselves under the agreement contrary to Article 85(1) even if the form of their agreement is compliant with the Technology Transfer Regulation.

An important proviso⁶² to exemption is that it only applies if the parties clearly identify all licensed know-how and subsequent improvements and it only applies for so long as the know-how remains secret and substantial. This is consistent with the definition of know-how in Article 10 as "a body of technical information that is secret, substantial and identified in appropriate form". The terms "secret", "substantial" and "identified" in turn are defined in such a way as to result in a requirement that the know-how must be secret in the sense that it confers a market lead (even if all component parts are publicly available) and it must be "useful" in conferring competitive edge, and

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⁶² Article 1.3
verifiable (so that it is distinguishable from the licensee's own technology which is to be kept free of restrictions). There is no doubt that this requirement of the Technology Transfer Regulation will assist the due diligence process, assuming that the parties have accurately identified the know-how, since this will be documented. However, if the parties have documented the know-how, but inaccurately or incompletely, they may be operating the limited restrictions that are only permissible in relation to qualifying documented know-how, in relation to undocumented know-how. Although the undocumented know-how may be capable of qualifying for exemption, it does not if it is not identified. Once again, even though the document on its face may comply with the Regulation, the unidentified know-how that is licensed de facto would not be licensed within the exemption and the conduct of the parties may therefore still infringe Article 85(1). This would not be verifiable on due diligence investigation.

6. Mixed Licences

The duration permitted for the same restrictions in mixed licences reflects a combination of the rules separately applicable to patents and know-how licences. The permissible period is the same ten year period as for know-how or, if longer, the duration of "necessary patents" in Member States where they are held\(^\text{163}\). Article 10(5) defines "necessary patents" rather inelegantly as, "patents where a licence under the patent is necessary for the putting into effect of the licensed technology in so far as, in the absence of such a licence, the realisation of the licensed technology would not be possible or would only be possible to a lesser extent or in more costly or difficult conditions. Such patents must therefore be of technical, legal or economic interest to the licensee".

\(^163\) Article 1.4
This test of whether a patent is a "necessary patent" depends on the capability of each licensee and may vary from one licensee to another. The same technology in the hands of one licensee may result in a ten year period of protection while, in the hands of another, the period of protection will be the patent term. Even in cases of a single licensee, an assessment of whether a patent is a "necessary patent" cannot be made by examining the documentation alone although an indication is likely to be given on questioning of the licensee.

The concept of "necessary patents" is one newly introduced by the Technology Transfer Regulation and is found nowhere else in any Regulation or Directive. It also unintentionally has the potential of putting unnecessary constraints on both licensor and licensee in relation to improvements.

6. **Improvements**

If technical progress is indeed to be made (as contemplated by the Technology Transfer Regulation) the licensor should be encouraged to disclose and license improvements in order to keep the technology at its cutting edge and most competitive. If the improvements are patented and yet are not sufficiently "core" to a product to constitute "necessary patents", the licensor runs the risk that the permissible restrictions may only be applied for a period of ten years\(^{164}\). The licensee on the other hand itself may wish to be clear that the restrictions only apply for ten years by claiming that the improvements patents are not "necessary patents". In doing so, the licensee risks termination of the agreement if it contains a white-listed clause envisaged by Article 2.1(16), reserving to the licensor the right to terminate the licence agreement of a patent if the licensee raises the claim that such a patent is not necessary. (Note that this is consistent with the white-listing of "no-challenge" clauses in Article 2.1 (15) entitling the licensor to terminate a licence if the licensee

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\(^{164}\) Though when the ten year period commences may be uncertain

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contests the secret or substantial nature of the know-how or challenges the validity of licensed patents even though these clauses were black-listed in the Know-how Regulation and Patent Regulation.

It is also worth bearing in mind in the same context that improvements clauses that extend the licence life are no longer black-listed\textsuperscript{165} unless a territorial restriction on either the licensor or licensee is extended\textsuperscript{166}. Article 2.1(4) directly addresses improvements in the white list by confirming as non-restrictive

"an obligation on the licensee to grant to the licensor a licence in respect of his own improvements to or his new applications of the licensed technology",

with two important provisos. The first is that where the improvements are severable, the licence must be non-exclusive so that the licensee is free to exploit them elsewhere freely (insofar as the licensor proprietary information is not thereby disclosed). If improvements are not severable, the licence may presumably be taken back on an exclusive basis although Article 2.1(4) does not expressly say so. In any event the question of severability is one of fact and would require care in examination. The second proviso is that any grant-back of improvements must be reciprocal i.e. the licensor must undertake to grant an exclusive or non-exclusive licence of improvements to the licensee. No explanation for the second proviso is given in the Recitals and it is considered that the requirement in Article 2.1(4) on the licensor to grant the corresponding licence of improvements is unusual. It is potentially restrictive of competition since it prevents the most propitious application of the technology by the licensor and this may not necessarily be justified by a licence of improvements made by the licensee. If the Commission was aiming

\textsuperscript{165} These were previously black-listed under Article 3.2 Patent Regulation and Article 3.10 of the Know-how Regulation

\textsuperscript{166} Article 3(7)
at fairness it is odd that it should do so at the cost of free competition. (Article 3(6) confirms that an obligation on the licensee to assign its improvements to the licensor is black-listed.)

7. **Quantity Limits**

Article 1.1(8) expressly exempts an obligation on the licensee to

"limit production of the licensed product to the quantities that the licensee requires in manufacturing its own products and to sell the licensed product only as an integral part of or a replacement part for his own products",

provided that such quantities are freely determined by the licensee. White-listed in Article 2.1(12) is a clause with similar effect which permits an obligation on the licensee not to use the licensor’s technology to construct facilities for third parties.

The purpose of this is explained in Recital 8, the objective being to facilitate the dissemination of technology and improvement of manufacturing processes in this instance where the licensee itself manufactures the licensed products or sub-contracts manufacture. It therefore excludes agreements solely for the purpose of sale. The Commission clearly exempts a restriction intended to confine the licence scope only to the licensee’s own requirements, whatever those might be. However, quantity restrictions in the case of sales agreements are not countenanced, and even measures to monitor "own" or "domestic" requirements, as in Adalat\(^\text{167}\), may be treated as Article 85(1) infractions. There seems little justification to differentiate an agreement granted by a patent proprietor to a patent licensee (for manufacture and sale) from an agreement granted by a patent proprietor, who undertakes its own

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\(^{167}\) Case T-41/96R [1996] ECR II-381 (n. 70 above)

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manufacture, to a distributor (for sales only) where both are used as a means of marketing patented products. If it is permissible in the Technology Transfer Regulation to limit production quantities in an exclusive patent or know-how licence to the licensee’s own requirements, the same should be permitted in an agreement between the patentee and a reseller.

8. The White List and the Black List

The white list and black list are critical in all Regulations (the black list particularly so because the inclusion of a single black-listed clause would preclude automatic exemption) but they do not deserve special mention because these provisions, on the whole, are self-evident and when found in any licence agreement during due diligence their scope may be matched, word for word, or in substance, to determine the status of the clause. If any clauses exist which are not expressly exempt under Article 1, which are not white-listed under Article 2, or black-listed under Article 3, they may be presumed to be eligible for exemption within the Regulation if the Commission confirms this under the more streamlined opposition procedure established under Article 4. The requirements for formal notification using Form A/B will usually be waived at the Commission’s discretion if the text of the agreement is submitted together with an analysis of market structure and an estimate of the licensee’s market share requiring considerably less information than Form A/B. Exemption may be claimed unless the Commission opposes it within four months, two months shorter than the six month period under the Patent Regulation and Know-how Regulation. At present, the opposition procedure is in limited use by parties to such agreements with under a dozen or so submissions in each year. The Commission’s lack of enthusiasm is likewise found in the fact that the opposition procedure was omitted altogether from the early drafts of the Regulation.

168 Article 4
9. Matters Not Apparent on Due Diligence

Even if the form of an agreement meets all the requirements of Article 1, contains any number of white-listed clauses in Article 2 and no black-listed clauses in Article 3, and even if grey-listed clauses (i.e. neither white-listed nor black-listed) are passed under the expedited opposition procedure, exemption may still be jeopardised and the parties exposed to the full consequences of infringement of Article 85(1) for reasons that are not apparent and cannot be examined by due diligence investigation at least on document inspection alone. The adverse effect on the value of the intellectual property would be considerable.

For example, under Article 3, exemption is refused where there exists a concerted practice (or unjustified requirement) between the parties resulting in refusal by one party to meet demand from users or resellers in its allocated territory who would market the products in other territories within the Common Market\(^{169}\) or where the parties make it difficult for users or resellers to obtain the products from other resellers within the Common Market, in particular by the exercise of intellectual property rights or other measures which

"prevent users or resellers from obtaining outside, or from putting on the market in the licensed territory products which have been lawfully put on the market within the Common Market by the licensor or with his consent"\(^{170}\).

The resonance of this wording with the case law on Articles 30 and 36 is obvious and it may be taken as placing limits on the freedom of the licensor of patents or know-how (or both) freely to establish a licensing strategy. In

\(^{169}\) Article 3(3)(a)

\(^{170}\) Article 3(3)(b)
particular, it may prevent a patentee, if the facts of Merck v Primecrown\textsuperscript{171} were repeated, from choosing a licensing strategy that avoids sales of products in territories unprotected by patents if they are protected elsewhere. Such a strategy in one or more patent licences might be seen as a measure making it difficult for users or resellers, for example in Spain or Portugal ("within the Common Market") to obtain the product from other resellers by the exercise of intellectual property rights. Article 3(3) reflects the Commission’s eagerness to ensure that products are freely available to resellers "within the Common Market" and it remains to be seen whether such a strategy would benefit from exemption under the Technology Transfer Regulation if implemented through an exclusive patent licence. Reliance no doubt will be placed by licensors on the expression "without any objectively justified reason" in Article 3(3).

It is worth noting also that Article 2.1(14) contains an important white-listed provision which permits

"a reservation by the licensor of the right to exercise the rights conferred by a patent to oppose the exploitation of the technology by the licensee outside the licensed territory".

This might be taken to be a reference to the principles of exhaustion, intended to clarify that direct sales by a licensee outside its allocated territory are not to be taken as exhausting the proprietor’s rights in the country of importation.

The consequences for due diligence are as follows. First, it cannot be known in the absence of further clarification of the decision in Merck v Primecrown or the Technology Transfer Regulation itself whether a licensing strategy which avoids marketing in a territory unprotected by patents will disapply the exemption that might otherwise be available. The Technology Transfer

\textsuperscript{171} Joined Cases C-267/95 and C-268/95 [1996] ECR I-6285 (n. 51 above)
Regulation has reminded us that it does not apply to pure sales agreements but it clearly contemplates clauses concerned with the marketing activities of the licensee and the extent to which they may be excluded from the "territory of the licensor." Assuming that the Article 1.1 restrictions are permitted within the time-limits in Articles 1.2, 1.3 and 1.4 and no further, the marketing freedom of the licensor is extremely limited. Article 1.2 states in the case of a pure patent licence, that exemption is granted only to the extent that and for so long as the licensed product is protected by parallel patents of the licensor, licensee and other licensees. If a territory is not protected by a parallel patent, for example, because the patent law of that country did not permit it at the time that the equivalent patent was granted in other countries, Article 1.2 may be construed to disentitle the proprietor from relying on any territorial restriction contemplated in Article 1.1. (One aspect of the Technology Transfer Regulation that is particularly welcomed is that the commencement date for the time limits is now the date of first marketing, rather than, under the Patent Regulation and the Know-how Regulation, the date of the agreement. If the change had not been made, the life of those restrictions might well have expired before first marketing of pharmaceutical products.) In short, many of the uncertainties of Merck v Primecrown apply equally to the Technology Transfer Regulation.

Secondly, as has been noted, Article 3(3) disapplies automatic exemption if there exists a concerted practice or requirement between the parties with the effects described in Article 3(3). This is a matter which is not likely to be apparent on the face of any document. Similarly, Article 3(4) disapplies exemption if the parties to the agreement, which is otherwise perfectly compliant with the Technology Transfer Regulation, were competing manufacturers at the time of the agreement, if the agreement contains customer or user limitations and similar. At least the clue to further investigation of that particular issue would be the presence of the clause

172 Article 1.1(3) to (6)
imposing the limitation. However, the same cannot be said of the preconditions for exemption in Article 5 or the circumstances for withdrawal of exemption under Article 7.

Article 5 disappplies exemption to the following: agreements between members of patent or know-how pools (even though pooling may not be evident), licences involving a joint venture where the parents are competitors¹⁷³ (except where the parties' combined market share for the relevant product is less than 20% for production licences and 10% for production and distribution¹⁷⁴), and reciprocal arrangements between competitors under which the licence is granted in exchange for an intellectual property or marketing licence — this exclusion recognises that the wider arrangement may not be apparent as it continues, "albeit in separate agreements or through connected undertakings."¹⁷⁵

Under Article 7, exemption is withdrawn in the most general of circumstances, namely where the effect of the agreement is to prevent the licensed products being exposed to effective competition in the licensed territory from identical or similar goods. This is said, in Article 7(1), to occur where the licensee’s market share exceeds 40%. It is submitted that, as with all market share criteria, this approach is extremely unhelpful and adds great uncertainty to the status of agreements expressly drafted to benefit from exemption. The Commission included market share criteria both in Article 5.2 and 7(1) in spite of the fact that it was the aspect of market share that raised so much protest against early drafts of the Technology Transfer Regulation and delayed its progress. Further, under Article 7(2), matters solely within the conduct of the licensee may result in loss of the exemption. Exemption is lost if the licensee refuses, without objectively justified reason,

¹⁷³ Because this is covered by Regulation 151/93
¹⁷⁴ Article 5.2(1)
¹⁷⁵ Article 5.1(3)
to meet unsolicited orders from users or resellers in the territory of other licensees. This is beyond the power of the licensor to prevent and it cannot be verified on document inspection alone. The matter may even not be within the knowledge of the licensor and so oral enquiry may not reveal it. Nevertheless, as a party to the agreement which does not thereby benefit from exemption, the licensor is exposed to the consequences of unenforceability, fines and so on.

Article 7(3), similar to Article 3(3), disapplies exemption if the parties, without apparent justification and without it being a requirement present in the agreement refuse to meet demand in the territory where the product is for resale outside the territory into other Common Market countries or where the parties otherwise make it difficult for users or resellers to acquire the products from other Common Market sources (whether by means of intellectual property rights or otherwise).

Article 7(4) concerns an unquantifiable effect which deprives an otherwise exempt agreement of sanctuary if the parties are competitors at the date of the licence and the best endeavours or minimum quantity marketing obligation on the licensee has the effect of preventing the licensee from using competing technologies. This is not a matter that can be tested by due diligence or even at the stage of entering into the agreement and yet the status of the agreement, particularly if reliance is placed on territorial restrictions, is critical. Added to this, the liability of the warrantor giving broad intellectual property warranties will be considerable. The commercial cost of loss of territorial restrictions is illustrated by Merck v Primecrown and the cost of warranty liability will be commensurate with that loss.

Finally, when an agreement is challenged and a decision is to be made whether its terms comply with those of a block exemption, the agreement
must comply in each and every respect if it is to be enforceable by a national court (Stergios Delimitis v Henninger Brau AG\textsuperscript{176}).

10. Conclusion

The single most important criticism of the Regulation is its uncertainty. Criticism initially focused on the use of market share criteria in the body of the white-list and black-list of clauses. Market share calculations are most uncertain when new technologies emerge yet it is precisely these technologies that will contribute most to technical and economic progress. The market in which fledgling science is first licensed is often extremely narrow and specialised and a reference to market share alone to determine market power is inappropriate where no sales of a given technology have taken place. The Commission itself is aware, for example, of the sensitivities of defining markets in which pharmaceutical products belong because they do not face direct competition and might be said to possess 100\% market share before a single penny of research money is recouped by sales. Nevertheless, the uncertainty of market share remains in various places in the Technology Transfer Regulation, albeit not in the core Articles 1 to 4. However, the preconditions for exemption and circumstances of withdrawal in Articles 5 and 7 are equally, if not more, uncertain in the context of due diligence since they concern matters that are incapable of verification except by an extremely expensive and time-consuming enquiry and even then the result would continue to be unresolved.

The difficulties of making a market share assessment are so great that the Commission itself has considered it necessary to publish a Notice on the definition of relevant markets for the purposes of Community competition law\textsuperscript{177} focusing principally on demand substitutability (ie. the ability of

\textsuperscript{176} Case C-234/89 [1991] 4 CMLR 329 ECR I-935

\textsuperscript{177} (1997) OJ 372/5 [1997] 7 ECLR 473

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customers to switch from one product to another in response to price rises) as the main determinant of market share over supply substitutability and potential competition. The need for economic tools demonstrates the complexity of the science of market share determination.

Another shortcoming of the Technology Transfer Regulation is that it is limited in scope, confined as it is to patents, know-how and ancillary rights. The Commission has in certain circumstances adopted Regulations which deal with all categories of intellectual property, namely the Specialisation Regulation and R&D Regulation but these likewise are limited in ambit and do not cover licensing agreements typically found in industry. It is perhaps because the Technology Transfer Regulation in its draft state met with such opposition that the Commission was reluctant to be too ambitious in its reforms or harmonisation measures even if the result is unsatisfactory both for lawyers and industry.

For example, there is no block exemption dealing with trade marks or copyright even though exclusive trade mark licences may be caught by Article 85(1), as demonstrated by Moosehead/Whitbread. In order to determine whether particular clauses in licences of trade marks or copyright infringe Article 85(1), a detailed review must be made of the case law concerning that particular right. In Moosehead/Whitbread, the Commission's reasoning provides extremely useful guidance but of course offers no exemption, leaving the parties with no choice when entering into exclusive arrangements potentially caught by Article 85(1), than to go to the trouble, expense and uncertainty of notifying them.

Finally, it is interesting to observe the comparison with the US intellectual property guidelines adopted by the US antitrust enforcement agencies.
"The EC Block Exemption and the USIP Guidelines reflect their very different jurisprudential ancestry. In the EC, the strict construction of the complementary roles of Article 85(1) and Article 85(3), coupled with a virtual anathema for provisions which restrict free movement of trade between Member States has resulted in much less balancing of such purpose and effect factors than in the United States. In contrast, the USIP Guidelines place great emphasis on the factual context in which the licensing operates, that is, its purpose and effect."

In fairness to the Technology Transfer Regulation and the regime of Article 85 as a whole, the emphasis of EC measures is and always has been on the market effect of particular agreements and practices. In that sense it is far more coherent that the formalistic approach of the United Kingdom Restrictive Trade Practices Act 1976 ("the RTPA") which will not catch agreements which cause competition mischief if drafted in a way that avoids the use of Section 6 or Section 11 restrictions. The new form RTP(C) used by the Office of Fair Trading requires relevant information and analysis but not to the extent of the burdensome Form A/B. Due diligence for RTPA compliance may be easier than Article 85(1) compliance by document examination alone. However, Article 85 is more commercially realistic as it is rooted deeply in market effects but that does nothing to assist an evaluation for compliance for so long as Article 85(1) is so broad and far-reaching, and the block exemptions so narrow, and remain conditioned on matters that defy verification.

C. COPYRIGHT LICENCES

It is clear\textsuperscript{180} that the Commission considers that the principles of patent and know-how licensing apply equally to copyright licensing, even if copyright licences that meet the rigours of the Regulation are, strictly speaking, not themselves exempt. However, certain types of licence will be outside Article 85(1) and no exemption will be necessary. Even exclusive licences may be outside Article 85(1) if they are "open", and exclusivity is indispensable to the launch of newly developed products on which considerable research and development expenditure has been invested, for reasons of market penetration as illustrated by LC Nungesser KG and Kurt Eisele v Commission of the European Communities\textsuperscript{181} ("Nungesser").

A licence is "open" where the licensor agrees not to grant further licences and agrees not to compete with the licensee in its exclusive territory, provided that no protection is given against competition by other licensees or parallel importers. The ECJ established that such an open licence would avoid Article 85(1) if the product licensed is new and unfamiliar, it requires market penetration by exclusivity to recoup significant research costs, and the licence is not for excessive duration. These matters are impossible to determine with any certainty and must be treated with care (as illustrated by Knoll-Hille Form\textsuperscript{182} in which product investment was not considered sufficient to justify exclusivity, although the Commission may have been influenced by the fact that both parties held sizable market shares).

Market share may also be an issue under Article 86 if the licensor is dominant, as demonstrated by IBM's tying practices which were condemned

\textsuperscript{180} Neilson-Hordell/Richmark. 12th Report on Competition Policy Page 73
\textsuperscript{182} 13th Report on Competition 183 Page 91
by the Commission\textsuperscript{183}; similarly, where barriers to entry exist and a copyright owner withholds valuable data which would open a market in compatible products or TV programme listings (Magill TV Guide\textsuperscript{184}). However, the ECJ in Magill indicated that it would only treat a refusal to license intellectual property as an abuse of dominant position in exceptional circumstances.

As far as software licensing is concerned, the Commission decided to deal with harmonisation by means of the Software Directive\textsuperscript{185} but did not take the opportunity of providing any further clarification or indeed block exemption for agreements relating to copyright in spite of the burgeoning industries in the software, multimedia and entertainment sectors.

\section*{D. TRADE MARK LICENCES}

As with copyright, the Commission has confirmed that guidance may be found in the Technology Transfer Regulation to exemptible terms and there is every reason to suppose that the principles of permissible "open licences" established in Nungesser will equally apply to trade mark licences. However, Moosehead/Whitbread serves to highlight that in reality the uncertainty continues as, in that case, the Commission decided that the exclusivity of the licence was caught by Article 85(1) because it has the consequence of excluding third parties from being granted the licence where they have the interest and ability to do so. This is surely the case with all exclusive licences even if they are "open".

No block exemption exists for trade mark licences and so parties who do not notify exclusive trade mark licences are at risk. Guidance on particular

\textsuperscript{183} IBM settlement (21st Report on Competition Policy)


\textsuperscript{185} Council Directive 91/250 EEC (n. 3 above)
clauses has been given in the case of Campari\textsuperscript{186}. Exemption was granted to restrictions guaranteeing quality control, an obligation to purchase essential secret raw materials from the licensor (herbs and colouring), obligations of confidentiality, a ban on sub-licensing or assignment, an export ban outside the EC (but only where reimportation was unlikely), and obligations on the licensee actively to promote the product. The Commission also emphasised that exemption needed to be sought for non-competition undertakings by the licensor\textsuperscript{187}.

In Moosehead/Whitbread, the Commission exempted an obligation to comply with the licensor’s manufacturing instructions to preserve quality, an obligation to obtain raw materials with specific properties (yeast) only from the licensor, obligations of confidentiality and requirements for joint advertising (provided independent advertising is not excluded). However, in that case, the Commission refused to exempt a no-challenge clause although the Commission appears to be relaxing its position on no-challenge clauses over the years, as reflected in the Technology Transfer Regulation.

In short, the position of trade mark licences is as uncertain as that of copyright licences. Any guidance offered by the Technology Transfer Regulation is only as good as that Regulation itself, which as has been noted, is open to a great deal of criticism.

E. **JOINT VENTURES**

In spite of the fact that Article 130 of the Treaty\textsuperscript{188} requires the Community to promote "research and technological development activities of a high quality", the steps taken by the Commission so far have been limited. These


\textsuperscript{187} Campari para 73, Moosehead para 16.2

\textsuperscript{188} Treaty on European Union Article G(38)
are confined to Notices which are of guidance only and one significant Regulation, the R&D Regulation which, as with the Technology Transfer Regulation, is subject to preconditions and market share stipulations which render a document review or other due diligence investigation at best of limited value.

The Commission's activity began with the Commission's Notice on Cooperation Between Enterprises\(^{189}\) but as the Commission's reasoning developed, it draw a distinction between concentrative joint ventures, which are the result of a permanent merger of a business, and cooperative joint ventures (of present concern) which are not generally economically autonomous and are the result of coordination between the joint venture parents over a limited duration\(^{190}\). As cooperative joint ventures can take any form, they do not readily lend themselves to automatic exemption and so the Commission has issued more general guidance in the form of the Notice on Assessment of Cooperative Joint Ventures\(^{191}\). The Commission distinguishes between the competition effects of the creation of the joint venture, which result from its mere existence, and the effects of ancillary contractual arrangements that surround it and which might be restrictive of competition. If the creation of the joint venture itself is outside Article 85(1), so also are the ancillary restrictions if they are a necessary means of achieving the joint venture aims\(^{192}\). The emphasis in determining whether restrictions are necessary and ancillary (and therefore permitted) is on restrictions that limit the freedom of action in the market of the participating undertakings\(^{193}\). The Commission has repeated a preference for separate research and

\(^{189}\) (1968) OJ C 75/3


\(^{191}\) (1993) OJ C43/2

\(^{192}\) Paragraphs 66 and 67 of the Notice on Assessment of Cooperative Joint Ventures

\(^{193}\) Paragraph 65 of the Notice on Assessment of Cooperative Joint Ventures
development activities by independent entities, since this is bound to result in
greater consumer choice (assuming separate products emerge), and is
concerned also to ensure that parties are not prevented by joint research and
development from getting a competitive advantage over each other. The
Commission will also favour a research and development joint venture
between non-competitors where independent product development by either of
them is unlikely (ODIN)\textsuperscript{194}.

The extent to which research and development joint ventures may go further
than the research and development stage to cover licensing of the research and
development results to the parents has been the subject of the R&D Regulation
(as amended by Commission Regulation 151/93) which grew out of
developments in Commission reasoning over many years as reflected in a
number of cases (such as Brown/Boveri and NGK\textsuperscript{195}, Carbon Gas
Technologies\textsuperscript{196}, Beecham/Parke Davis\textsuperscript{197}, and EMI/Jungheinrich\textsuperscript{198}.
These cases and principles illustrate the complexity and uncertainty of the
status of research and development agreements even if the Commission is
generally supportive of them. In order to clarify these principles in the case
of certain commonly found research and development agreements the
Commission published the R&D Regulation as a means of conferring
automatic exemption.

\textsuperscript{194} 90/410/EEC Commission Decision of 13 July 1990 relating to a proceeding under Article 85 of the EEC

\textsuperscript{195} Re the Agreements between BBC Brown and Boveri and NGK Insulators Limited (1988) OJ L301/68.
[1989] 4 CMLR 610

\textsuperscript{196} Carbon Gas Technologies 83/669/EEC Commission Decision of 8 December 1983 relating to a
[1984] 2 CMLR 275

\textsuperscript{197} Parke, Davis and Co v Probel, Reese, Beinterra-Interpharm and Centrafarm, Case 24/67 [1968] ECR
81, [1971] CMLR 104

\textsuperscript{198} EMI/Jungheinrich 17th report on Competition Policy (1987) point 119; [1978] 1 CMLR 395

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PARTICULAR R&D AGREEMENTS

The R&D Regulation applies to agreements for the joint research and development of products or processes with or without joint exploitation of the results. It therefore differs from the 1968 Notice in that it deals with applied research and development agreements (i.e. dealing also with the exploitation of results) rather than pure research agreements. The scope of exploitation originally permitted in the R&D Regulation was broadened by Regulation 151/93\(^{199}\) and is seen as a useful extension to what would otherwise have been a Regulation of such narrow application that it would have been of little practical value. Another useful aspect of the R&D Regulation is that Recital 14 expressly permits exploitation within the scope of other block exemptions with the result that (within the limits stated in the body of the R&D Regulation) these may in effect be bolted on to span both the research and development phase and subsequent exploitation phases with third parties, whether by way of patent licence or exclusive distribution.

Article 1 makes general reference to "research and development" and is intended to catch any form of joint venture contract without being specific as to its precise content.

The preconditions of exemption in Article 2 require the research and development work to be carried out according to a clearly defined programme, setting out its objectives and field\(^{200}\). All the parties must have access to the results\(^{201}\). If it is a pure research and development agreement all parties must be unrestricted in their exploitation of the results (except to the extent


\(^{200}\) Article 2(a)

\(^{201}\) Article 2(b)
exempt under Articles 4 and 5\textsuperscript{202}. Joint exploitation (and any exempt restrictions) must relate only to "results" which are protected by intellectual property rights or constitute know-how which substantially contribute to technical or economic progress such that the results are decisive for the manufacture of the contract products or the application of a contract process\textsuperscript{203}. Background technology will be included in this if "decisive for their manufacture". Assuming a document reflects these preconditions and is carefully drafted so they are not capable of being avoided (ie. the restrictions are suitably tailored and conditional) there still remains the continuing risk (as with all block exemption Regulations) that the parties put the arrangement into effect in such a way that the agreement as practised falls outside the scope of the R&D Regulation. For example, if the parties in practice bundle together as "results", within the meaning of Article 2(d), other intellectual property to which the parties are not entitled to apply the exempt restrictions, then the entire arrangement is jeopardised. This would be almost impossible to verify in due diligence.

Article 3 deals with the duration of exemption for agreements, depending on whether the parties are competing manufacturers. This itself is a matter of judgment and difficult to verify and could well change rapidly over time. It might even be precipitated by a change of control resulting from acquisition for which the due diligence investigation is conducted.

If the parties are competing manufacturers of products that will be improved or replaced by the contract products then exemption will be for the duration of the research and development programme and, if the results are jointly exploited, five years following first product marketing within the Common Market. If the parties are competing manufacturers, exemption is only allowed for the above duration (by virtue of Article 3.2) if at the time of

\textsuperscript{202} Article 2(c)

\textsuperscript{203} Article 2(d)
entering into the agreement the parties’ combined market share is less than 20% in the Common Market or a substantial part (for products that are improved or replaced by the contract products). The difficulties of market share assessment have already been highlighted. Following expiry of that period, the exemption will, under Article 3.3, continue but only for so long as the parties’ market share does not exceed 20%, this time where the market is differently defined (but in the more conventional way) to be the total market for products considered by users to be equivalent. This entails a separate market analysis from the one required under Article 3.2.

The R&D Regulation underwent amendment in 1992 such that if product distribution is entrusted to one of the parties, a joint undertaking or a third party, exemption may still apply (for five years) but only if the parties’ production of those products is less than 10% of the market for all such products in the Common Market or a substantial part. The exemption will continue the beyond the initial five year period in such circumstances provided the parties’ combined market share (in the conventional sense) does not exceed 11% in any two consecutive financial years. If it does, then exemption will end within six months of that occurrence. This suggests that market shares are readily ascertainable with certainty to a level of precision that distinguishes 10% from 11%. In reality, not only is it extremely difficult for a party to establish its own market share but the task is more than doubled by the need to make an assessment of the market share of the other party. The relevant information is likely to be highly confidential, guarded against public access, and enquiry is only likely to mislead (because answers will tend to suggest a lower market share than actually exists). The R&D Regulation, for its insistence that these matters are ascertainable is unreasonable.

205 Article 3.3(a)
A rehearsal of the content of the detail in the core Articles 5, 4 and 6 would bear out further the limitations of the R&D Regulation but would not warrant the space in a work of this length.

G. NOTIFICATION PROCEDURE

Mention of Articles 85(1) and 85(3) would be incomplete without reference to the notification procedure and its shortcomings. Form A/B requires such detailed information that its preparation typically occupies weeks of management time and of course considerable legal expense, all of which is disproportionate in the case of undeveloped or newly-launched technology, particularly when owned by start-up companies. The Commission's Notice on Agreements of Minor Importance\(^{206}\) provides a reason in such circumstances for not notifying an agreement but the uncertainties of market share definition and calculation are such that an agreement may easily be challenged, as being above the 5% or 10% market share \textit{de minimis} levels respectively applicable to horizontal and vertical agreements, if it concerns technology that is sufficiently innovative to be in a market of its own (or at least not directly substitutable with other products). Similarly, there remains the risk that a change of control of one of the parties to the agreement will place the market shares above those thresholds. Due diligence is frequently carried out in anticipation of a change of control or other transaction that will require a reassessment of the turnover figure.

Notification using Form A/B is only as good as the information given in support of it. A considerable amount of judgment and discretion is applied when compiling supporting market information and the parties necessarily play down the potential ill-effects of the agreement notified. This does carry the risk of subsequent challenge by the Commission, by a party to the agreement or a third party. When advising the purchaser of a business to which a

notified agreement is crucial, it is impossible to verify the completeness or accuracy of the notification detail without performing a repeat market analysis. Yet if the notified document was wrong when submitted, the notification is flawed and the agreement itself is fundamentally open to challenge.

The more informal comfort letter procedure however is available to the parties, following notification, instead of pursuing the notification procedure to a formal conclusion. The advantage of a comfort letter, which is merely a statement of the Commission’s view on the matter before it, is that it may protect the parties from a fine or other penalties but it has the shortcoming that it is not binding on any national court, nor even the parties. If a party relying on the agreement wishes to enforce it in a national court, proceedings are stayed until the matter is formally dealt with by the Commission by way of individual exemption based on the information given at the time of seeking the comfort letter. However it is too easy for a party challenging the validity of the agreement to claim that the information previously given is out of date and that the Commission is not entitled to grant individual exemption. Even if the circumstances have not changed and individual exemption may be granted, the delay will be considerable and may be tactically fatal to the litigation. Comfort letters need to be reviewed with scepticism with these additional points in mind.

H. ARTICLE 86

Quite apart from considerations of Article 85(1), an exclusive licence may fall foul of Article 86 if granted to a licensee which is dominant. Even if granted to a licensee which is not dominant at the date of the agreement, if the licence

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is subsequently acquired by a company that is dominant, or which owns alternative technology, this may result in infringement of Article 86\textsuperscript{208}.

I. SUMMARY

The consequences of infringement of Article 85(1), in terms of the economic value of intellectual property and far-reaching and therefore due diligence investigation to reveal the extent and effect of any such infringement is critical. The difficulties posed for any purchaser of a business involved in agreements concerning intellectual property rights are considerable. Guidance has been given by the Commission and Regulations issued in order to offer automatic exemption and in order to provide clarity on the status of such agreements. The aim of the block exemption Regulations, of reducing the Commission's caseload, is unlikely to be achieved as successfully as it might for so long as the Commission is so conservative in its approach to such Regulations and places such emphasis on market share calculations. The end result is that the guidance (such as it is) is so specific, and exemption offered by Regulation is so narrow, that it really offers little comfort to a business purchaser where the risks of infringement of Article 85(1) or 86 exist. This itself might operate as a considerable disincentive to technical progress.

CHAPTER FOUR:
HARMONISATION BY DIRECTIVE

(ILLUSTRATED BY SOFTWARE, DURATION AND BIOTECHNOLOGICAL INVENTIONS DIRECTIVES)

"If you go into the labyrinth take a clew with you"
A. INTRODUCTION

The use of Directives as a means towards harmonisation is perhaps best illustrated by the Commission's initiatives in the field of copyright, which began with the EEC Green Paper on copyright and the challenge of technology which highlighted a number of issues. Disparities were evident in the levels of copyright protection throughout the Community, as determined nationally, in spite of the Berne Convention, since minimum standard-setting in conformity with the Berne Convention did not result in uniformity of legislation above the minimum guaranteed levels of protection. These disparities were considered to pose obstacles to the Single Market. Uniformity at higher levels of protection across Member States would be the best way of ensuring a competitive position for the Community as this in turn would combat counterfeiting which was seen as a disincentive to investment. Effective copyright protection at a high standard was therefore taken to be in the economic interests of the Community and a number of Directives were proposed pursuant to Articles 100 and 100A of the Treaty of Rome. Article 100 empowers the Council to issue Directives

"for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the Common Market."210

The extent to which relations between Member States and non-EC countries can be regulated by Article 100A is unclear. In the Silhouette case, Advocate General Jacobs distinguished

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209 COM (88) 172 and follow up to the Green Paper COM (90) 584

210 Article 100A was added (by Article 18 of the Single European Act) to provide for qualified majority voting for the purpose of establishing the internal market with the opportunity for Member States to opt out (under Article 100A(4))
"measures of commercial policy on the one hand" from "provisions governing the effects of trade mark rights within the Community on the other." 211

To the extent that internal measures will inevitably affect relations with third countries, Article 100A is capable of regulating such relations, as confirmed by the ECJ in that case.

Directives then ensued on the following subjects:

1. The legal protection of computer programs212 ("the Software Directive").

2. Rental and lending rights213 ("the Rental Right Directive").

3. The duration of copyright protection214 ("the Duration Directive").


5. The legal protection of databases216

Two of these measures, the Software Directive and the Duration Directive, have been selected for the purpose of this chapter to illustrate that, although

211 Paragraph 46
effective to achieve some measure of harmonisation, these Directives are nevertheless flawed in that they fail in that aim in certain serious respects and at the same time aggravate the task of due diligence investigation. These particular measures may well have achieved significant strides beyond the Berne Convention but nevertheless fall short of the standard of harmonisation required to result in transparency throughout the Community.

Finally, the directive on the legal protection of biotechnological inventions has been chosen to highlight further some of the difficulties in adapting traditional forms of protection to take account of technological advances.

B. THE SOFTWARE DIRECTIVE

1. Overview

The Software Directive was adopted on 14th May 1991 and was one of the earliest industry-specific harmonisation measures. It was implemented in the United Kingdom on 1st January 1993 by means of the Copyright (Computer Programs) Regulations 1992.

The Software Directive focused on specific issues, namely ownership and scope of protection of computer software, addressing particularly the issues of interface and inter-operability. In the discussion that led up to the Software Directive, battle-lines were drawn between the computer software giants such as IBM, Philips, Digital, Siemens and Apple, who belonged to the Software Action Group for Europe (SAGE), to lobby against exceptions to copyright protection to allow inter-operability, and their opponents such as Amstrad, Bull, Olivetti and Fujitsu who advocated it on the basis of their dependence on interfacing their products with the software market leaders, and formed the

\[ \text{\textsuperscript{217}}\text{COM (95) 661 (1996) OJ L296/4} \]

\[ \text{\textsuperscript{218}}\text{SI No. 3233} \]
European Committee for Inter-operable Systems (ECIS). A third group, comprised mainly of independent software maintainers, formed themselves into the group, Computer Users of Europe.

The Software Directive was drafted as closely as possible to the Berne Convention and required Member States to protect computer programs as literary works. (The TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 10(1)) now also puts GATT members under obligation to protect computer programs and literary works in a similar way.) Computer programs are not defined (except to say that the term includes preparatory material), but this was deliberately done in order to offer greater flexibility in implementation. The classic distinction is maintained between the ideas underlying the program (which are not protected by copyright) and their expression in the computer program (which is).²¹⁹

Article 2 deals with the critical issue of authorship and Article 3 with ownership but largely leaves the matter to be determined by the laws of each Member State. As a simple means of arriving at consensus, this mechanism works but it does not result in harmonisation. Although national laws are broadly similar in their provisions concerning authorship and ownership, there will be important differences. For example, where the program is a commissioned work such rules are left open, because it was thought that to designate the commissioner as author in the Software Directive might interfere with the activities of the emerging self-employed sector of freelance programmers. Rules of authorship of commissioned works are therefore unharmonised. When verifying authorship and ownership, care must therefore be taken to ensure that differing rules in different countries are taken into account (since principles of national treatment apply to software as to other copyright works). It would have been better to have taken the opportunity to

²¹⁹ Article 1.2
harmonise these principles. Similar difficulties exist with computer-generated works where no attempt was made at harmonisation.

The rules of authorship are not therefore simplified and this has consequences for housekeeping and verifying intellectual property. In the case of software, they are exceedingly complicated given the fact that programs themselves comprise contributions from a great many sources such as programmers who may be employees of the target owner, employees of related companies, secondees from unrelated entities, or freelances. The position is aggravated by the risks and consequences of joint ownership between any of these individuals and entities, which is a particular hazard of software programming. The stages of software development should, in a perfect world, be monitored and recorded, and suitable contractual documentation put in place. Given the importance of know-how as well as copyright, confidentiality undertakings should be sought from all concerned in the development of software, as well as express assignments of copyright and know-how from the author (if not an employee), though at the time of executing the assignment, if done in advance of the development, it may be difficult to identify the program to be produced or even to name it. Retrospective confirmation of the property covered by an assignment is necessary to link the property to the author and to ensure that all rights created vest properly in the target owner. There is considerable risk also of the creation of equitable interests in copyright, particularly where partnerships are involved in the creation of software\textsuperscript{220}.

At the heart of the Software Directive, are Articles 4, 5 and 6 which define the restricted acts constituting infringement, and the exceptions which do not. The restricted acts include "the permanent or temporary reproduction of a computer program by any means and in any form, in part or in whole", even loading, displaying, running and transmission requiring any form of

\ \textsuperscript{220} \textit{Roban Jig} v \textit{Taylor} [1979] RPC 130
reproduction require authorisation. Translation, adaptation or any other alteration of a program (as well as the reproduction of the results of those acts) are restricted acts, as also of course is distribution to the public (including rental). Article 4(c) expressly incorporates principles of exhaustion by stating,

"the first sale in the Community of a copy of a program by the right holder or with his consent shall exhaust the distribution right within the Community of that copy, with the exception of the right to control further rental of the program or a copy thereof."

This is a straightforward reflection of Warner v Christiansen, distinguishing the reproduction right from the performance right, and is a useful confirmation of the ECJ case law in anticipation of the Rental Right Directive.

Although on its face Article 4 is reasonably clear, it will at best only partially harmonise Member States' treatment of copyright. National differences concerning principles of infringement will continue to apply even if all countries are clear about the list of restricted acts. Different national laws will result in different interpretations of what constitutes infringement by each restricted act: for example, in the United Kingdom, reproduction must be of a substantial part to amount to infringement whereas in Germany the relevant part taken alone must contain sufficient creativity to be original, before it is taken to be infringed by that restricted act.

Furthermore, the scope of restricted acts in Article 4 is so broad and general that the exceptions in Article 5 then become critical. This approach has been

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221 Article 4(a)
222 Article 4(b)

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criticised by the independent maintainer lobby as too unbalanced in favour of the large software houses. Much of the debate surrounds the scope of legitimate use of a program by the user or, on the user's behalf, by independent maintainers of software. To the extent that the restricted acts of Article 4(a) and (b) are necessary for the use of the program (by authorised users), those restricted acts are permitted under Article 5 and this expressly allows use for error correction, copying for back-up purposes and reverse engineering. For the maintainer, the only exclusion from the list of restricted acts is error correction and then presumably, only to the extent that it is done on behalf of lawful users. Error correction, however, falls far short of the full range of activities which a maintainer is required to undertake and in this respect, the error correction exclusion is far too narrow. It would not, for example, cover adaptation to new operating systems. This is a significant shortcoming, especially when taken together with the pro-competitive ambitions of the Software Directive. The Software Directive can only be properly understood in the context of the developed laws of exhaustion of rights and competition, as expressed in the principles already covered in Chapters 2 and 3. However, the Software Directive does nothing to clarify (on the contrary, it obscures) the position concerning the application of those principles.

2. Exhaustion

The restricted acts referred to in Article 4(a) and (b) are only permitted if undertaken by the lawful user "in the absence of specific contractual provisions." It therefore appears that it is possible by contract to reinstate those activities as restricted acts. The interrelation between this reservation and the free movement content of Article 4(c) is unclear. There are two limbs to the issue.

224 Article 5.1
The first concerns the status of the contractual reservation once the first sale (and exhaustion) has occurred. If the range of restricted acts is limited by contract in any licence of software when first marketed, it is possible to interpret Article 4(c) to exhaust the distribution right in its entirety and to disapply contractual limits on use in relation to all restricted acts. Support for this possibility comes from the wording of Article 4(c) itself and also from the fact that there is no privity of contract between the original licensor (on first sale) and the user (on resale) and therefore "no specific contractual provision". It is unlikely that this was the intended effect of the Software Directive but the position is unclear.

The second limb concerns the freedom of an original licensor to prevent resale. It is common to find that software licences are non-assignable and non-sub-licensable. If a first sale is to exhaust the distribution right (following Warner v Christiansen), it must in effect render unlawful the typical non-alienation undertaking by the first licensee. In short, in both cases, it is unclear on a literal interpretation of the Software Directive whether contractual restrictions on use and assignment are permitted at all following first sale. If they are not, fundamental assumptions made in the computer industry are undermined.

Article 5.2 expressly prohibits a contractual ban on making back-up copies and this suggests that if other contractual restrictions are prohibited, they would have been included at this point. It is clear from Article 9.1 that the terms of the Directive are "without prejudice to any other legal provisions such as those concerning .... unfair competition... or the law of contract". Nevertheless, the Software Directive does not explain how it intends the principles of unfair competition or the law of contract to be applied.
3. **Competition Law**

The core decompilation Articles 5 and 6 ensure that legitimate decompilation may occur, and this is guaranteed in the second sentence of Article 9.1 which specifically renders any contractual provisions to the contrary null and void. At the heart of Articles 5 and 6 is a policy of ensuring interface with protected works, to enable competition to flourish in related products that are interoperable with those works. The same principle is expressed in the "must fit" and "must match" exceptions applicable to spare part manufacturers under design right and registered design protection. However, in the case of software, unlike design right or registered design works, considerable know-how is needed beyond what is expressed in pure code. Article 9.1 preserves for the proprietor all rights in relation to "trade secrets" and "the law of contract" which together protect confidential information. The Software Directive is therefore far too limited in its effect. It applies only to written code and not know-how. Articles 5.3 and 6.1 do refer to know-how but not to confer rights of use over it. Article 5.3 permits investigation of underlying know-how ("ideas and principles that underlie any element of the program") but only while performing, "the acts of loading, displaying, running, transmitting or storing the program". Article 6.1 permits reproduction of the code if "indispensable to obtain the information necessary to achieve the interoperability of an independently created program" but only if the interoperability know-how has not previously been readily available.

Know-how is a vital commercial component of software, yet according to the Software Directive, it may be withheld. The use permitted under the Software Directive focuses only on the code itself and the use that may be made of the code that would otherwise amount to infringement. The fact that know-how rights are not to made available in support is striking even if the Recitals

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acknowledge the distinction between ideas and their expression. The issue of the treatment of know-how is an important one and should be considered due for harmonisation. In the United Kingdom, know-how is protected by basic principles of confidentiality and contract. Consistency of protection across Member States has not been considered to be a matter of harmonisation. Insofar as the Software Directive deals with copyright to the express exclusion of know-how, it is to be regarded as an omission given the crucial role of know-how in any software program. Even if the Software Directive creates a new market in programs dependent on interface and interoperability with other programs, it fails to deal adequately with the entirely separate market of the independent maintainer which, as before, remains to be dealt with only as a matter of competition law. Third party maintenance is not legitimised by the Software Directive since maintenance goes far beyond error correction. Reliance must therefore be placed by maintainers on other sources of law.

To the extent that the matter has been the subject of Community-wide consideration, it has only been incidental and accidental, by means of the decisions concerning Articles 85(1) and 86. First, the prohibition inherent in Article 85(1) against tying clauses would prevent software houses requiring the licensee of software to obtain maintenance services only from the licensor (Digital). Secondly, Article 86 and the principles established in Magill and IBM, might enable the maintainer to obtain access and a licence to use the key component of software and know-how for providing maintenance services. There is every risk that the Commission would find

225 "whereas for the avoidance of doubt, it has to be made clear that only the expression of a computer program is protected and that ideas and principles which underlie any element of the program, including those which underlie its interfaces, are not protected under this Directive"


227 (n. 184 above)

228 IBM settlement (21st Report on Competition Policy)
software houses to be dominant in the supply of maintenance services for their own software unless exceptional market power is exerted by others to dissipate any suggestion of dominance yet it is difficult to see how others would find a market toehold in the absence of express licence or a widening of the Software Directive to cover maintenance services. As a matter of due diligence, this should be investigated if acting in the purchaser of a business or shares of a software house. The pricing policy must also be scrutinised for excessive or discriminatory pricing (even discounts will be sensitive). All of these issues, however, require detailed market analysis and a prediction of the Commission’s likely view of such matters.

The underlying principle of Article 86 in this context is reflected in the statement of Sir Leon Brittain that,

"companies cannot unreasonably sit on their intellectual property in order to stifle enterprise and prevent emergence of new forms of competition."

In the IBM Settlement case IBM withheld its system/370 interface information to prevent the emergence of inter-operable systems made by competitors. IBM was found to be dominant in the market for hardware which implemented the system/370 instruction set and the Commission dropped its investigation only when IBM gave undertakings to release the interface information.

The extent to which similar information is to be made available (to reconcile the competing interests of SAGE and ECIS) is dealt with in the decompilation Article 6. The copyright holder’s consent is not required for reproduction of the code and translation if

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231 Commission press release 11/7/91 (IP/91/668)
"indispensable to obtain the information necessary to achieve the inter-operability of an independently created computer program with other computer programs",

provided various conditions are met, namely that it is done for the benefit of the lawful user, it does not go beyond the purpose of inter-operability and the information necessary is not readily available. The last requirement means that decompilation is only allowed if the interface information is not "readily available". If it is, decompilation is not permitted.

Article 6.2 places limits on the use of information acquired during decompilation and confines it to the goal of achieving inter-operability of the independently created program, and prevents unnecessary disclosure to others. It also prevents use for the "development, production or marketing of a computer program substantially similar in its expression", presumably where the information is used as a springboard for competing with the licensed software. Article 6.2(c) in reality only prevents substantial similarity in the code of the newly created work which must be independent if it is to avoid infringement. Article 6.2(c) does not prevent the creation of competing programs ("other programs") provided the similarity in non-inter-operability code does not amount to infringement.

Before leaving the subject of competition law, it is worth noting that, quite apart from the competition issues raised by the Software Directive as outlined above, the software industry suffers from no clear guidance from the Commission on the status of agreements concerning computer software. This

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232 Article 6.2(a)
233 Article 6.2(b)
234 Article 6.2(c)
235 Article 6.1
is in spite of what has been described as "the gigantic theoretical sweep of Article 85(1)."\textsuperscript{236}

The Commission has stated\textsuperscript{237} that it regards products protected by copyright in the same way as it regards products protected by patents. This is of little help given the peculiarities of software protection and exploitation already discussed. Even though classic software distribution may take the form of product distribution exempt under Regulation 1983/83\textsuperscript{238}, software distribution will nevertheless not be exempt because that Regulation only applies to "goods for resale"\textsuperscript{239}. In any event, the nature of software distribution is sufficiently different from that of other products that it typically requires restrictions concerning enforcement of intellectual property, confidentiality and post-term use which, though exempt under the R&D Regulation or Technology Transfer Regulation, are not even mentioned in Regulation 1983/83. Furthermore, the supplier will want to ensure that the user enters into contractual relations either with the supplier or the distributor (for the supplier’s benefit) to confine software use to particular hardware, limited users, and to prevent reverse engineering or decompilation beyond the limits prescribed by the Software Directive. All software agreements which contain any such clauses should be treated with caution.

Similarly, there is no automatic exemption for software under the Technology Transfer Regulation even though territorial exclusivity may well be a common requirement. Even if the Technology Transfer Regulation did apply to software, the appropriate duration of exclusivity is unclear given the copyright term of 70 years compared with 10 years for know-how. Use restrictions in

\textsuperscript{236} Forrester: Software and Licensing in Light of Current EC Competition Law [1992] 1 ECLR

\textsuperscript{237} 12th Report on Competition Policy, para 162


\textsuperscript{239} Article 1
the case of exploitation are frequently imposed on the licensee, taking the
matter outside the Technology Transfer Regulation. Also software
transactions of this sort will not be merely ancillary to the licensing of patents
and know-how. Reliance will therefore need to be placed on open exclusivity,
following Nungesser\(^\text{240}\), but only if justified by the investment in the product
in question (which will be difficult to discern case by case) in order to
promote technical progress.

Added to this is the uncertain status of licensee restrictions to prevent
disclosure and use by a third party, commonly needed to ensure the protection
of the software. Such restrictions though common, have been condemned in
Société du Vente de Ciments et Betons v Kerpen and Kerpen\(^\text{241}\) and Bayo-
on-ox\(^\text{242}\) as restrictions that prevent resale. The restrictions should be
justified (though are not) on the basis of the ease of copying of software and
also the lack of privity of contract between the initial supplier and ultimate
user. On the other hand, site restrictions are generally justified since they
form the basis of the charging structure and the licence fee\(^\text{243}\).

4. Due Diligence

If a core asset of a target business is software written to take advantage of the
exceptions afforded by the Software Directive, it may be extremely difficult
to verify that the software has been written in such a way as to avoid
infringement.

\(^{240}\) Case 258/78 Nungesser v Commission [1982] ECR 2015 (n. 181 above)

\(^{241}\) Case 319/82 [1983] ECR 4173

\(^{242}\) OJ (1990) L22/71 [1990] 4 CMLR 930

First, the principle of national treatment for software (as confirmed by the Software Directive) will result in differing standards of infringement across Member States. National treatment multiplies the time and expense of any due diligence investigation as it requires examination of the laws of the Member States in which the software is to be marketed. However, the rules of national treatment are to be read subject to the reciprocity principle and this itself will require the laws of all applicable territories to be examined for the presence of any disparity in protection between the countries (inside and outside the EEA) where protection is intended. To the extent that such things as the meaning of "infringement" are not harmonised, the Software Directive also fails to render harmonisation to software protection even if it defines certain activities as "restricted acts": the test for infringement (such as substantiality) remains a matter for national determination and trans-national anomalies remain across the Community. This is the case even if under the Software Directive all Member States protect software as literary works and apply to it the benefit of the same restricted acts (and exceptions to restricted acts).

Secondly, an evaluation of whether a program written to be inter-operable with an existing program and used in a business is within the terms of the Software Directive will require detailed discussion with the creator of the interface of the existing program. Whether there is an infringement depends on whether any code within Article 5.3 was examined "while performing any of the acts of loading, displaying, etc....". Any information which is obtainable by further acts will be unlawfully obtained. The extent to which permissible decompilation occurs under Article 6.1 depends on what is "indispensable" to achieve inter-operability and depends on use that is "necessary" to achieve inter-operability. Verification of these limits is a purely technical matter and the program creator is not generally the best judge of what the Software Directive permits. Even then, the resulting program must not be "substantially similar in its expression" to the original (beyond the interface elements).
5. The Correct Form of Protection?

It is to be remembered that *sui generis* protection was not given to software because the lesson learned from the US Semiconductor Chip Protection Act 1984 was that such an approach would incur many years of debate and delay. In any event, the Berne Convention was considered to provide a readily available framework of international protection for software based on copyright.

At the same time, in the United Kingdom copyright protection has also proved to be too narrow and has been extended to cover such matters as non-literary copyright to cover structure, sequence and organisation\(^244\) and look and feel.

A non-literal approach has proved necessary because if infringement is confined only to literal copying, it is easy to escape infringement. For example, in *John Richardson Computers Limited v Flanders*\(^245\), although no text of the source code or object code had been reproduced, profound similarity in the operation of the programs (look and feel) were attributable to copying a substantial part of the original program from recollection of its main routings and functions amounting to infringement. The judgment has been criticised for conferring copyright on functions, but the decision reflects the need to expand on "literal" interpretation of protection for literary works as adopted by the Software Directive. The principle established in *John Richardson* has been confirmed in *IBCOS Computers Limited v Barclays Mercantile Highland Finance Limited and others*\(^246\) which, although a case of literal copying, explained the significance of ideas as follows:

\(^{244}\) Whelan Associates v Jaslow Dental Laboratory, [1987] FSR 1

\(^{245}\) 1993 FSR 497

\(^{246}\) 1994 FSR 275
"Where an "idea" is sufficiently general, then even if an original work embodies it, the mere taking of the idea will not infringe. But if the "idea" is detailed, then there may be infringement. It is a question of degree. The same applies whether the work is functional or not and whether visual or literary".

This case nevertheless highlights the importance of know-how and ideas beyond the lines of written code, a feature not adequately recognised by the Software Directive.

6. **Summary**

The last recital of the first Proposal for the Software Directive\(^\text{247}\) gave as one aim of the Software Directive the need for common rules to avoid restrictions on circulation due to diverging intellectual property protection. Secondly, it also emphasised the need to stimulate research and investment.

The differing rules of copyright protection accorded by national treatment militate against the first aim and the lack of consistency in protection, following the Berne Convention, is not sufficiently recognised. The lack of protection for know-how by adhering inappropriately to literary copyright stifles the second aim. Research and investment is also stifled in the field of software maintenance because independent maintainers will only operate if they are prepared to run the gauntlet with the major software houses on the principles that favour them under the Magill and IBM cases but that is a risk that few would take with any comfort. The Recitals to the Software Directive confirm that it is without prejudice to the rules of competition in Articles 85(1) and 86 yet these are blunt (and expensive) instruments in the hands of the independent maintainers. Even in the case of those who write inter-operable programs (rather than maintain existing ones) the balancing rights of access to inter-operable information and the right of the proprietors to control

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this by making such interface information available in a limited way are
difficult to interpret. They are even harder to interpret in the light of Article
86. Protection for expression in the case of software is too broad and for ideas is too narrow.

It is worth observing that Jean-Francois Verstrynge who has been described
as principal promoter in the field of intellectual property within the EC, regards the Software Directive as the first successful copyright harmonisation
exercise of the Community248. Others have commented that the EC has set
the standard for WIPO discussions and this Software Directive offers a
"universal guideline" preceding other copyright Directives249. It is
submitted that it is inappropriate to regard the Software Directive as providing
such a model. Later Directives in the sphere of copyright are equally if not
more flawed, notably the Duration Directive250, which will now be
considered.

C. DURATION DIRECTIVE

1. Introduction

Discussion of due diligence would be incomplete without illustration of at least
some of the issues close to the surface which require investigation on
acquisition of intellectual property. The Duration Directive has been selected
for the purposes of this illustration for two reasons. First, it exemplifies some
of the obstacles resulting from the earliest attempts of international
harmonisation (in the loosest sense) by means of the Berne and Paris
Conventions already discussed, the principle aim of which was to provide for
certain minimum standards, reciprocity of protection and international

cooperation in enforcement. The Duration Directive therefore serves to
demonstrate some of the challenges faced by the Commission in reconciling
its ambitions of true harmonisation with the legacy of international cooperation
over the preceding century. Secondly, it highlights the sheer complexity of
due diligence verification, the conclusion being that it is in reality
impracticable in the context of copyright but made worse by the Duration
Directive.

2. Due Diligence Steps Illustrated

The purpose of due diligence investigation should be the verification of
ownership of all rights conveyed by assignment or licence by the owner of
intellectual property and determination of the scope and duration of the rights,
in particular the extent to which the restricted acts amounting to infringement
are, or are not, enforceable.

If the process is capable of being described systematically, it might be said to
involve the following steps. These steps reflect the position in the United
Kingdom with regard to copyright before the Duration Directive came into
being. (For the sake of simplicity, the illustration assumes that there are no
design right works, patents, registered designs or know-how of relevance
though in practice these obviously should themselves also be investigated
thoroughly.)

a. Products

All products for which a business is acquired must be identified.

b. Copyright Works

For each product, all constituent copyright works must be identified.
c. **Restricted Acts**

The manner of exploitation of the products must be identified to establish the extent to which restricted acts of copyright are the intended source of business revenue. For example, publishers and film producers are dependent on restricted acts of copyright as the basis for deriving their income but library and information providers are not, even though they all have in common trade based on delivery of copyright works. Clearly, those businesses dependent on copyright (which will generally be the rule) will need to establish the scope of copyright protection in terms of the particular restricted acts, the geographical coverage and duration of protection for business plan purposes.

d. **Subsistence**

For each copyright work, it must be established that copyright subsists in the case of literary, dramatic or musical works. Subsistence depends on a multiplicity of factors including the following:

i. Whether the work was "published" within the meaning of Section 175(1) of the Copyright Designs and Patents Act ("CPDA"). If the work was not published then see (iv) below.

ii. Where the work was "first published". First publication must have been in the United Kingdom or a country listed in Schedule 1 to the Copyright (Application to Other Countries) Order 1993 (subject to certain date restrictions applicable to certain countries) ("the 1993 Order"). Reliance can not be placed on whether or by whom the work was made (under (iv) below) if the work was first published outside a "qualifying
country". Simultaneous publication in a qualifying and a non-
qualifying country will suffice for protection where publication
occurs in those countries within fourteen days of each other.

iii. When the work was published. If before 1 August 1989 (when
CPDA came into force) the author (or one of them if in joint
ownership) must have been a "relevant person" then, or if
dead, at publication the author must have been a "relevant
person" on the date of death. If first published after 1
August 1989, the author must have been a "qualifying person"
then, or if dead at publication the author must have been a
"qualifying person" on the date of death (Section 155 of the
CPDA).

iv. When the work was made. The author must have been a
"qualifying person" when the work was made for copyright to
subsist.

v. The date when certain countries acceded. As countries have
accessed to the Berne Convention, copyright has arisen in works
which, until then had not been protected. Care must be taken
to examine any disposition of copyright during which there was
no copyright protection in any country in which copyright

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251 Under the 1956 and subsequent Copyright Acts, simultaneous publication of a work in different
countries may take place within thirty days of each other (Section 49(2)(d) and Schedule 7, para 33(1)
of the CPDA)

252 "relevant person" under Article 2(2) of SI 1989/1293 means a Commonwealth citizen, a British
protected citizen, a citizen or subject of any country specified in Schedule 1 to 1993 Order or a person
domicile or resident in the UK, another country to which Part I of the CPDA extends or a country
specified in Schedule 1 to the 1989 Order.

253 "Qualifying person" is defined to mean (a) a "relevant person" (as above) or (b), a British Dependent
Territories citizen, a British National (overseas), a British Overseas citizen, or (c) a body incorporated
under the law of the United Kingdom or any country to which Part I of the CPDA extends
protection is required, as copyright may not be transferred by that disposition. It would not be possible to rely on the disposition as an instrument to transfer rights that did not exist at the date of the disposition\(^{254}\).

vii. Whether the countries still exist. Further difficulties arise with countries that cease to exist such as was the case with many countries of the former Soviet Union. This has partly been cured by the 1993 Order which does recognise particular succession states but potential exists in the future where similar political changes occur, at least until appropriate Order clarifies the position.

As far as films are concerned, under the CPDA, the determination of the extent of copyright protection requires the above analysis for each component part of the film. For example, the script will be protected as a literary work, the sound track as a sound recording in turn comprising a musical work (musical score) and a literary work (lyrics)), the set perhaps as an artistic work, the treatment or synopsis also as a literary work, and the plot or scenario as a dramatic work. The film recording itself in addition will be protected as a film which also fixes performances (themselves protected by corresponding performance rights\(^{255}\)). The director and all originators of literary, dramatic, musical works and artistic works will possess moral rights\(^{256}\). All of these rights will need to be cleared in favour of the producer by assignment and disclaimer from the originator.

\(^{254}\) The position is particularly unclear with regard to certain translation rights in works of foreign origin which before 1988 had been in the public domain but which were revived on 1 August 1989 by virtue of the CPDA Schedule 1 paragraph 35, (causing the importation of translations to amount to infringement after that date but not before).

\(^{255}\) under Part II of the CPDA

\(^{256}\) under Part I of Chapter IV of the CPDA
To the extent that the film itself is made from other works, such as plays or novels, rights in those third party literary works must also be cleared.

All clearances of any constituent work must be in sufficiently broad terms to contemplate all intended exploitation, not merely as films but as multi-media products if appropriate, on different media and by different means of transmission (such as electronic or satellite transmission). All clearances of any integral work by disclaimer or assignment must be checked for the extent to which they contemplate all new media according to established rules of contract construction\textsuperscript{257}.

The purchaser or licensee of film rights must also take account of the different rules applicable under the 1911 Copyright Act (which regarded cinematography as photography and as such the creation of artistic works in each frame, and the capture of dramatic works\textsuperscript{258}) and the 1956 Copyright Act (which combined into the film both the visual images and soundtrack). Each Act gave different treatment to the meaning of film, the sounds that were taken to be part of it, the dramatic content, the position of the producer, the expiry of copyright and the meaning of infringement. Matters are further complicated by the transitional provisions between the Acts of 1911, 1956 and 1988 (particularly as the 1956 Act has numerous commencement dates).

Space does not permit further elaboration of the rules of subsistence also for publications, sound recordings, broadcasts, and cable programmes which themselves contain different constituent copyright

\textsuperscript{257} Hospital for Sick Children v Walt Disney Productions Inc [1966] 2AER 321

\textsuperscript{258} Section 35(1)
works for which copyright subsistence will need to be determined in a similar way but according to different rules.

e. **Establish Ownership of All Works**

For each work, the owner must obviously be established, as determined by Section 11 of the CPDA. The first owner will be the author unless the work was created in the course of employment, in which case the employer will be the first owner (but only if the employer is a qualifying person\(^{259}\)). If created during the course of employment, the terms of employment must not be inconsistent with Section 11.

In the case of computer-generated works, ownership must be ascertained and will accrue to the creator or the person who made the necessary arrangements for the creation of the work\(^{260}\).

As far as works of joint authorship are concerned, all joint owners must have assigned or licensed their rights, otherwise the exploitation of the work and subsequent infringement proceedings will be hampered by the need of consent of all joint owners\(^{261}\).

f. **Formalities**

The first owner (assuming it is not the vendor or licensor) must have assigned copyright and waived all moral rights in favour of any predecessor in title from the vendor or licensor, and the chain of documentation must be complete (with stamp duty duly paid, and in

\(^{259}\) Sections 11 and 154 of the CPDA

\(^{260}\) Section 9(3) of the CPDA

\(^{261}\) Section 10 of the CPDA
compliance with all formalities laid down in Section 90 of the CPDA or any predecessor Act). The original assignment should contain warranties concerning authorship, subsistence, ownership and qualification.

An assignment must be in writing but a licence need not be. However an exclusive licence obviously should be in writing as a means of evidencing locus standi for the licensee as plaintiff in infringement proceedings. An assignment may be of future copyright and when it arises it may take effect so as to vest automatically in the assignee, although this is likely to be ineffective unless a retrospective confirmation is made to identify the works with that assignment.

g. Other Miscellaneous Matter Must Be Established Including:

i. the scope of any application to the Copyright Tribunal under Chapter VII of Part I of the CPDA (Licensing Schemes)

ii. whether the vendor of licensor has been subject to any Monopolies and Mergers Commission references.

iii. whether the Crown might claim Crown copyright under Chapter X of Part I of the CPDA.

iv. whether any works were published in any patent application (if so an implied licence will be granted)

v. whether any licences granted by the vendor or any predecessor in title are inconsistent with any assignment or licence under examination.

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262 Catnic Components v Hill & Smith 1978 FSR 405

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vi. whether the principles of "national treatment" and "reciprocity" limit use in any overseas territory.

vii. whether protection is reduced by reason of concurrent design right protection. (Section 51(1) of the CPDA that

"it is not an infringement of any copyright in a design document or model recording or in embodying a design for anything other than an artistic work or typeface to make an article to the design or to copy an article made to the design").

viii. whether the Software Directive erodes the range the restricted acts\textsuperscript{263}

This is a gross oversimplification of some of the issues out of a myriad that require verification. As a summary it does not do justice even to basic principles. However, the items listed do at least help to illustrate that the level of protection given to copyright works in one sense has less to do with affording protection to the creator, as a reward for the creative effort in making the work, than the international political scene. The inadvertent consequence is that verification of copyright subsistence, ownership, scope and duration is extremely difficult and dependent on innumerable factors. Incomplete knowledge may well produce the wrong result. For example, a pre-1956 work known to be of British authorship cannot be assumed to be protected by copyright in the United Kingdom unless its date and place of first publication are known. The result of an extraordinary matrix of differing regimes and transitional provisions is that exhaustive due diligence is not

\textsuperscript{263} Increasingly, with multi-media products, other areas of law are relevant to the due diligence exercise, for example, the Software Directive will have a direct bearing. Software written with the express purpose of providing the interface between products in different media will be particularly at risk of being unprotected as a result of the Software Directive, since much of the software in interactive products is written specifically to provide interoperability function.
feasible. The purchaser or licensee cannot easily know what is conveyed and the vendor or licensee cannot easily warrant the scope of protection.

In fairness, this level of complexity results not so much from EC legislation as the basic harmonisation measures expressed in the Conventions (Berne and Paris) that preceded the Single Market. The law in 1988 merely reflects the United Kingdom’s response to its obligations under those Conventions without specific adjustment for the purposes of the Single Market\textsuperscript{264}. Nevertheless, it is with good reason that with the advent of the Duration Directive, the law of copyright is said to be so complicated that to understand it properly would take a lifetime, plus seventy years.

3. Effect of the Directive

The Duration Directive was issued on 29 October 1993 among other things “to establish a legal environment conducive to the harmonious development of literary and artistic creation in the Community”\textsuperscript{265} and for the “development of creativity in the interests of authors, cultural industries, consumers and society as a whole”\textsuperscript{266}. It is noteworthy that the Directive was issued without public consultation. The effect of the Directive, in short, was to extend the copyright term in the case of all specified works which were still in copyright in at least one EEA country on 1 July 1995, so that they all expire at the same date, namely seventy years after the death of the author. The result is that in those countries in which the copyright had already expired it had to be revived. The United Kingdom is a notable example as it generally offered fifty years protection to works where elsewhere, such as Germany, corresponding works were protected for seventy years. To ascertain whether

\begin{itemize}
  \item[\textsuperscript{264}] except, for example, the scope protection given to semi-conductor topographies following Council Directive 87/54/EEC (1987) OJ L24/36
  \item[\textsuperscript{265}] Recital 11
  \item[\textsuperscript{266}] Recital 10
\end{itemize}
Copyright and Related Right Regulations 1996 SI 1996/2967

267
For film producers, matters are made considerably more complicated also by the fact that, for United Kingdom law, the Duration Directive introduced fundamental changes to the rules of authorship of films. Under the CPDA, the producer was author and first owner (assuming the producer made the necessary arrangements). According to the Duration Directive\(^{268}\), the principal film director is author or at least a co-author although Member States are free to designate others. The range of authors whose works require clearance widens. For component works, the complexities of clearance to take account of revived copyright and the extension of the copyright term to seventy years are multiplied. Article 22 of the Duration Directive extends the term of protection to

"seventy years after the death of the last of the following persons to survive, whether or not those persons are designated as authors; the principal director, the author of the screenplay, the author of the dialogue and the composer of music specifically created for use in the cinematographic...work."

For anyone acquiring film rights a great deal is required to be known (\textit{inter alia}) about the detailed personal circumstances of the contributors' nationality and death. If the Duration Directive is said to be in the interests of the rights holder, this cannot be said of film producers who will have to pay royalties for a greater term than before. The cost of verification will also increase as the complexity of the task increases.

The cost and uncertainty to film producers is also aggravated by Council Directive 92/100/EEC\(^{269}\) which confers on authors and performers (as well as producers) the exclusive right to authorise or prohibit rental and lending of

\(^{268}\) Article 2(1)

\(^{269}\) on rental right and lending right and on certain rights relating to copyright in the field of intellectual property (1992) OJ L 346/61
originals and copies of copyright works. These rights may be the subject of licences (as they must or they would have no economic value) but the additional right to “equitable remuneration” provided for in Article 4 is unwaivable by the author or performer who is the beneficiary of that right in relation to rental of films and sound recordings. No guidance is given concerning the level of remuneration that is “equitable”. The only certainty is that the producer must bear the cost of paying it even if distribution is carried out by a distributor rather than the producer.

Rental and lending rights are also conferred on the principal director even though under United Kingdom law, directors would already have the benefit of moral rights.

It is noteworthy that the Duration Directive clarified

“That the harmonisation brought about by this Directive does not apply to moral rights.”

Waivers of moral rights will therefore need to be sought from any author or contributor found in any country to be entitled to moral rights, and the Duration Directive provides no consistency across different countries.

Other anomalies include the fact that no mention is made of computer-generated works. Their term of protection is unharmonised, presumably kept in line with the level of protection given to software.

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270 Article 2(4)
271 Recital 21
4. **Summary**

In summary, three main criticisms might be levelled against the Duration Directive. First, it might usefully be judged by the Regulations that were necessary under United Kingdom law to give effect of the Duration Directive. Those Regulations have resulted in one of the most complicated enactments known to the statute books.

Secondly, the Duration Directive has paid insufficient regard to the fact that copyright works, even well before the time for formulating the Duration Directive, were becoming increasingly “dematerialised” by electronic and digital exploitation. It has therefore become inappropriate to preserve the distinctions between different works carried in different media and yet this striking global transition has been ignored in the Duration Directive. Harmonisation has at best been achieved only for works falling in the same category where the categories are still defined by the medium in which works are carried or by their method of creation. For example, computer-generated have a harmonised term but it is different from the harmonised term for films, an approach that is manifestly inappropriate when the medium is increasingly irrelevant in a digital era.

Thirdly, if the Duration Directive is thought to offer greater economic gain to authors by extending the copyright term, it is to be remembered that generally very few works still have an economic life between fifty and seventy years following the author’s death.

Fourthly, the Duration Directive might have ignored other sources of law. It has been suggested by Weyer Verloren Van Themaat and Wolter Weffers Bettink\(^\text{272}\) that Article 234 of the Treaty requires precedence to be given to earlier Treaty obligations towards non-EU countries than the Treaty of Rome.

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\(^{272}\) "Another Side of the Story" — Weyer Verloren Van Themaat and Wolter Weffers Bettink (1995) 6 EIPR 307

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itself dated 25 March 1957. The principles of reciprocity in the Berne convention Articles 2(7) (for applied art), 6(1) (protection of works of contracting country nationals), and 7(8) (the copyright period) might render open to challenge the entire Duration Directive273. It is still possible therefore that the old principles of reciprocity apply under the Berne convention in spite of the Duration Directive. The uncertainties for due diligence will then be insuperable.

D. THE DIRECTIVE FOR PROTECTION OF BIOTECHNOLOGICAL MATERIALS

1. Introduction

Biotechnology is the cornerstone of development of pharmaceutical products and healthcare systems, heavily dependant upon the patent system for the reward of high risk investment. The patent system stands to suffer erosion from the developing case law of the ECJ, most recently reflected in Merck v Primecrown in circumstances of lack of uniformity of patent protection across Member States. This section examines some of the content of the Biotech Directive and considers its ability to achieve its aims in the light of these limitations. In particular, the adverse consequences to pharmaceutical manufacturers of the decision in Merck v Primecrown are likely to be perpetuated, rather than cured, in particular due to lack of consistency in patent protection permitted on such crucial developments determined by the issue of morality. The pharmaceutical industry is dependant on biotechnological advances based on long term reward from investment.

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"Every Member State shall admit to the protection under its law of copyright a design protected by a Community Design which fulfils the conditions required by such law, even if in another member state which is the country of origin of the design, the latter does not fulfil the conditions of protection under the law of that State".
The Commission's second Proposal for a directive on the legal protection of biotechnological inventions\textsuperscript{274} successfully completed its first reading in the European Parliament on 16 July 1997. A revised Proposal was submitted on 19th November 1997. It was approved by the European Parliament following its second reading without amendment and adopted on 30 July 1998\textsuperscript{275} ("the Biotech Directive"). It is submitted that the European patent system is an inadequate starting point for the purpose of regulating national laws on the subject of the legal protection of biotechnological inventions and this third Directive is chosen to illustrate the importance of the inter-relation of different sources of law when devising measures of harmonisation of intellectual property law.

The aim of the Biotech Directive is to harmonize certain divergences in Member States' protection of biotechnological inventions, which might result in the fragmentation of the Single Market. Member States have achieved partial harmonisation through alignment with the European Patent Convention ("EPC"). However the EPC is limited in its ability to achieve harmonisation. Dating back more than thirty years it only touches on a few of the ethical and conceptual issues raised by recent scientific advances in molecular biology involving the manipulation of self-reproducible biological materials within human, animal and plant cell systems. The EPC is also limited by virtue of Article 2(2) which states:

"The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State."

Furthermore, case law decided by the European Patent Office ("EPO") is not firmly established (as acknowledged by the Commission). The President of the EPO frequently resorts to the Enlarged Board of Appeal to attempt uniform


\textsuperscript{275} OJ (1998) L213/98
application of the law. This results in delays, compounded by the tendency of national courts to defer judgment pending EPO final decisions even if those decisions are not binding on them.

2. Content of the Biotech Directive

Much of the content of the Biotech Directive is directed at the distinction between what is patentable and what is not. The EPC criteria of patentability are, not surprisingly, preserved. Excluded under Article 53 of the EPC are inventions contrary to morality\(^ {276} \), plant and animal varieties, and biological processes for the production of plants or animals\(^ {277} \). However, microbiological processes and the products of microbiological processes are not excluded from patentability\(^ {278} \). All of these principles are restated in the Biotech Directive but are intended to be clarified in the context of the legal protection for living matter.

The Biotech Directive focuses on the issue of patentability aside from the issue of morality. It is clear from Article 5 that the human body at its various stages of formation and development and the simple discovery of one of its elements, including the sequences or partial sequence of a gene, cannot be patentable. There are many human genes that code for pharmaceutically active products such as insulin, human growth hormones, or interferons. Patentable inventions may, for example, now cover processes for the production of a hormone only if "isolated from its natural environment or produced by means of a technical process"\(^ {279} \). However, no patent may be granted on the hormone (or other element) in situ.

Articles 3 confirms the patentability of biological material, microbiological processes and their products within prescribed limits that indicate the deliberate

\(^{276}\) EPC Article 53(a)
\(^{277}\) EPC Article 53(b)
\(^{278}\) EPC Article 53(b)
\(^{279}\) Article 3.2
positioning of the Biotech Directive in the context of other intellectual property rights, in particular, plant breeder's rights. "Biological material" is defined as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system". Plant (and animal) varieties as such are excluded from patentability under Article 4.1(a) even if they would otherwise fall within the definition of "biological material." Article 4.1(b) excludes from patentability, "essentially biological processes for the production of plants or animals" being processes consisting entirely of natural phenomena such as crossing or selection.

Protection afforded by the Biotech Directive therefore expressly excludes plant breeder's rights. This is to be expected since the Directive aims to maintain, as much as possible, the existing order of the EPC which in Article 53(b) of the EPC excludes the patentability of plant varieties. It should nevertheless be questioned whether a regime of protection other than the patent system is appropriate for the protection of biological materials and processes.

3. Morality

The issue of morality is one of political controversy and its treatment under the Directive exposes significant shortcomings in its harmonisation aims. Article 6(1) of the Directive is superficially similar to Article 53(a) of the EPC although it uses the new term, "public policy", when stating, "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to public policy or morality." The familiar EPC Article 53(a), by contrast, excludes, "inventions the publication or exploitation of which would be contrary to ordre public or morality." Even though Article 53 has proved notoriously difficult to interpret, the departure from the language of Article 53 will result in the loss of useful EPO case law and will raise doubts concerning the intention behind the new reference to public policy in the English text. The French text refers to "ordre public".

280 Article 2.1(a)
which only serves to obscure the Commission's intention. It has been suggested (by Ford\textsuperscript{281}) that differences in the wording of Article 53 of the EPC and Article 6 of the Directive are sufficient to result in confusion as to the obligations of States which are members of both the EU and the EPC, even though the Directive has no immediate impact on the EPC. Guidance is given in Article 6.2(a) to (d) of the Directive in relation to isolated examples of unpatentable inventions "on the basis of paragraph 1", i.e. excluded by reason of Article 6.1, and these are processes for cloning human beings, processes for modifying the germ-line or genetic identity of human beings, uses of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals which are likely to cause suffering without substantial benefit to man or animal and also animals resulting from such processes. Clearly the onset of oncological suffering in animals in the pursuit of a cure for cancer might be justified but not a similar level of suffering in the pursuit of a cure for pattern baldness. The exclusions illustrated non-exhaustively in Article 6(2) will no doubt undergo revision by the addition of new microbiological techniques not foreseeable today and possibly might subsequently permit techniques which are in future refined in such a way as to satisfy concerns of morality; for example, germ line gene therapy targeted to prevent the inheritance of selected defective genes. The uncertain and subjective nature of the issue of morality, at the heart of so many current pharmaceutical developments, may yet result in inconsistent practices when granting patents, the very thing that the Directive aimed to prevent.

4. The Biotech Directive's Interface with other systems of Protection

The application of the Biotech Directive is likely to prove difficult in view of the interface between existing systems of protection; in particular that between patent and plant breeder's protection.

\textsuperscript{281} Ford: The Morality of Biotech Patents: Differing Legal Obligations in Europe? (1997) 6 EIPR 315
It has been suggested by Llewelyn\textsuperscript{282} that the protection of plant variety rights under the Community Plant Variety Rights Regulation (CPVR)\textsuperscript{283} might provide a better avenue for setting minimum standards among Member States for the protection of biological matter. The CPVR is aimed at protecting living matter of a botanical genus or species outside the patent system, principally to reward plant breeders for their investment in creating new varieties. Plant varieties were not originally considered appropriate for patent protection because the creation of plant material for propagation is said to lack the essential patent requirements of novelty and inventive step. Also, a level of protection falling far short of a patent monopoly was considered appropriate in order to encourage free transmission of plant material amongst plant breeders, for the public good.

As a result, plant breeders protection and patent protection exist quite separately under their own mutually exclusive systems of administration according to different rules and criteria, offering different levels of protection to the rights holder. This separation of systems has given rise to practical difficulties as illustrated by the case of Plant Genetic Systems/Glutamine Synthetase Inhibitors\textsuperscript{284}. Article 53(b) of the EPC deals with various exclusions from patent protection, including plant varieties. The Board of Appeal in that case interpreted plant varieties in such a way as to exclude plant material from patent protection and disallowed a claim (which was held to encompass unpatentable subject matter) under Article 53(b). The significance of this case in the context of a rapidly emerging science based on the manipulation of genetic material in animals, humans and plants is that the established boundaries between the existing systems of protection and that set out in the Biotech Directive are difficult to fix conceptually and harder still to apply in reality. The case turned to a large extent on whether the insertion of a single gene into plant material constituted a plant variety under

\begin{footnotesize}
\textsuperscript{282} Llewelyn: The Legal Protection of Biotechnological Inventions (1997) 3EIPR 115

\textsuperscript{283} Council Regulation (EC) No. 2100/94 on Community plant variety rights (1994) OJ L227/1

\textsuperscript{284} EPO Decision T 356/93 [1995] EPOR 357
\end{footnotesize}
the UPOV Convention\textsuperscript{285} (implemented in the form of the CPVR) and accordingly whether it should be excluded from patent protection under Article 53(b) of the EPC. A plant variety is defined in Article 1 of the UPOV Convention as a "single botanical taxon of the lowest known rank...irrespective of whether the conditions for the grant of a breeders right can be met...[suitable] for being propagated unchanged".

Until clarified by the Biotech Directive, the result of this case has, it is submitted, wrongly been that the potential that exists for genetically modified seeds and plants to become plant varieties excludes them from patent protection. This case demonstrates that the inter-relation between patent and plant breeder protection needs to be redefined as a matter of policy especially given the increasing practice of gene manipulation using plant material to devise therapeutic products for human use.

Even if that decision is corrected and clarified by the Biotech Directive, it nevertheless forewarns of difficulties in the application of the Directive. It is submitted that adherence to Article 53(b) of the EPC as a means of avoiding dual protection with plant breeder's rights is no longer appropriate. Plant breeder's rights emerged at a time when the UPOV Convention in 1961 addressed only the limited scientific uses of reproductive vegetative material as a means of plant propagation. If a given technology uses plant propagation as a production system for healthcare, environmental or other applications, there appears to be no compelling reason why those aspects traditionally given to plant breeder's rights should be excluded from patent protection. Take, for example, a plant variety which possesses pharmaceutical properties created as a means for achieving micro-processes which result in pharmaceutical products.

It is recognised that dual protection is undesirable. Rather than follow the pattern of Article 53 of the EPC to exclude plant breeder's rights from patent protection,
Llewelyn argues that excluding from plant variety protection any variety which is the subject of a patent for that variety would result in greater consistency. This would avoid complications of determining the scope of plant variety rights when excluding them from patent law. More importantly, it would provide uniformity of protection to biotechnological materials which are not intended to be used by plant breeders. It may also do away with some of the difficulties that are anticipated in interpreting the patentability exclusion in Article 4 of the Directive of "essentially biological processes for the production of plants".

5. The Biotech Directive's Interface with other sources of Law

Departure from Article 53 would be a useful first step in discouraging resort to the EPC as a tool for harmonisation when (as noted above) the EPC is an inadequate instrument to achieve that purpose. It is to be regretted that the Commission's focus in the Biotech Directive is to clarify the application of the EPC rather than address the shortcomings of the EPC or indeed the conflict between the EPC and other instruments. For example, Article 27.2 of the TRIPS Agreement states that Members may exclude from patentability certain inventions which should be prevented from exploitation to protect public order or morality including the protection of human, animal or plant life or health or to avoid serious prejudice to the environment. By contrast, Article 53(a) of the EPC states that patents shall not be granted to inventions which, when exploited, would be contrary to morality. Article 27.2 of TRIPS and Article 53 of the EPC do not correspond, yet Article 6 of the Biotech Directive attempts only to clarify Article 53. Issues of morality have proved notoriously difficult to determine as part of the patent system (especially Article 53) and there is much to be said for detaching public policy issues of morality from the regime of intellectual property (as contemplated in Article 27(3) of TRIPS) especially when it is no longer appropriate to confine the protection of rapidly advancing technologies only to patent rights.

286 Adopted as part of the "Final Agreement" of the GATT Uruguay Round
A watching eye needs to be maintained on other fronts. Ford suggests that there may be scope for those wishing to object to the grant of biotechnology patents on moral grounds (such as the Oncomouse patent) to appeal to the European Convention on Human Rights (ECHR) on the basis that the Contracting States to the EPC were already bound to the terms of the ECHR, and that the latter should prevail in determining whether an EPC patent should be granted, whether or not the ECHR had been incorporated. It is argued that questions of morality under the EPC, the Biotech Directive, even under TRIPS (Article 27.2) at least in the confines of Europe, should all be interpreted to give ascendancy to the ECHR according to the rules of interpretation of Articles 30, 31 and 32 of the Vienna Convention if only to prevent the contravention of rights derived from the ECHR. Whatever the scope of this principle, it serves to illustrate that in the Biotech Directive the Commission has failed to take adequate account of other sources of law (even its own) in order to achieve its goal of harmonisation.

6. Summary

In conclusion, lack of consistency with existing law is likely to spawn as many difficulties as the Commission attempts to resolve in its proposed treatment of biotechnological inventions. This is in spite of recognising that

"Harmonised protection throughout Member States is essential to maintain and encourage investment in the field of biotechnology."

More importantly however, it is recognised that

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287 The Convention on the Protection of Human Rights and Fundamental Freedoms
288 The Vienna Convention on the Law of Treaties 1969
289 Recital 3
290 Recital 7
"Uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the single market."

The risks of erosion of the economic value of biotechnology patents seem to be well acknowledged in the rhetoric of the Biotech Directive and yet in such cases as Merck v Primecrown, it is submitted that the ECJ is prepared to squander the fruits of biotechnological invention even though it spans decades in development and requires enormous investment and risk to the intellectual property owner before being translated into pharmaceutical products.
CONCLUSION

"It is ill, sitting at Rome and striving against the Pope"
CONCLUSION

The over-arching principles and aims of the Community, as established in the Treaty of Rome are not criticised. However, their implementation in the field of intellectual property is.

As was noted in Chapter Two, Articles 30 and 36 of the Treaty have been interpreted by the ECJ with rigid adherence to Single Market principles, to the cost of the intellectual property proprietor, and in particular, its expectation of economic return through exploitation.

The ECJ judgment in the Silhouette\textsuperscript{291} case has done much to highlight fundamental issues concerning the scope of the principle of international exhaustion even though that case only directly concerned trade marks. Clarification of the position of other intellectual property rights is still needed. Future development could usefully be directed at achieving uniform treatment of different intellectual property rights on such fundamental matters as the interpretation of Articles 30 to 36. Adherence to notions of "specific subject matter" which vary across different intellectual property rights has been necessary in the interpretation of Articles 30 and 36 but general principles applicable to all rights are of far greater value.

In the case of patents, there is no equivalent to the Trade Marks Directive unless the patent across a single European territory is introduced. In the meantime the disparities in relation to patent protection across Member States are set to continue, exacerbated by price differentials caused by government control in particular industry sectors. It is submitted that the most successful harmonisation measures are those such as the Trade Mark Directive, aimed at achieving the "unitary character" of a particular right and "designed to be substituted for the diverse national laws across the whole range of its provisions"\textsuperscript{292}. The level of resulting homogeneity will truly

\textsuperscript{291} Case C-356/96 (n. 38 above)

\textsuperscript{292} Paragraph 39 of the Opinion of Advocate General Jacobs in Silhouette
assist the due diligence process and limit the need for investigation of national laws to matters of procedure and enforcement. The success of this approach should be noted for the purpose of future measures.

Likewise, copyright, as discussed, has not yet undergone Community-wide systematic harmonisation comparable to that of trade marks. The Commission has expressed concern in its Green Paper on the Legal Protection of Industrial Design 1991 at the disparity between national design laws (made worse by a significantly lower period of protection given in the United Kingdom to design right). At present the Commission has adopted a draft Regulation\(^ {293}\) and a draft Directive\(^ {294}\) both of which are likely to give rise to contentious debate. The draft Directive only aims at harmonisation of registered design (rather than unregistered design) law in Member States in line with the draft Regulation. However, Article 18(1) of the draft Directive states that

"The extent to which and the conditions under which [unregistered design] protection is conferred, including the level of originality required, shall be determined by each Member State."

Accordingly, harmonisation will be extremely limited and due diligence made even more complicated by further tiers of legislation. It appears that for so long as there are disparities within the Community in the level of substantive protection available for any given intellectual property right, the principles of Articles 30 to 36 will be interpreted by the ECJ at the expense of the intellectual property proprietor (Merck v Primecrown)\(^ {295}\).

The focus of Chapter Three was the effect of competition law upon intellectual property in view of the far-reaching consequences for parties to agreements caught

\(^ {293}\) COM (93) 342 (1994) OJ C 37/20

\(^ {294}\) COM (93) 344 (1993) OJ C 345/14

\(^ {295}\) Joined cases C-267/95 and C-268/95 [1996] ECR I-6285 (n. 51 above)

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by the prohibition in Article 85(1) if they are not notified under Article 85(3) or do not fall squarely within the ambit of automatic block exemption conferred by Commission regulation. For the intellectual property proprietor, the consequences include the loss of the economic value of intellectual property, because no purchaser of a company or business or other owner of intellectual property would lightly accept the risk of assuming intellectual property agreements that infringe Article 85(1). The expected commercial return under such agreements may be in jeopardy if crucial restrictions (particularly those designed to guarantee that return) are unenforceable. The agreement in its entirety might be void. The consequences of infringing Article 85(1) also extend to loss of intellectual property value that inevitably stems from the grant of a licence with unenforceable territorial restrictions where this amounts to consent to the marketing of products, to which the principles of free movement and exhaustion (discussed in Chapter Two) apply. Clarification of the scope of Article 85(3) has been offered by the Commission by publishing block exemption regulations but analysis shows that their scope is narrow and they are subject to extensive pre-conditions for exemption that cannot be verified on due diligence examination. They offer little certainty to the parties that their agreement meets those terms or pre-conditions.

Suggestions for the future development of block exemption regulations would be to offer clearer and bolder guidance on intellectual property agreements. Further, block exemptions should be made available for copyright and trade mark licences to reflect the Commission's approach to licences of those intellectual property rights. Less adherence to market criteria would be a considerable advantage as well as the narrowing of the other pre-conditions to exemption which are not easily verifiable.

As to harmonisation of national laws of competition, in the United Kingdom the Competition Bill will do a great deal to conform the competition law of the United Kingdom with the regime of Article 85(1), by adopting the text of Article 85(1) (with only essential adjustments necessary to relate it to the United Kingdom only) and in the interpretation Clause 60, provision is made for consistency with the treatment of corresponding questions arising in Community law. The harmonisation of the
competition laws of other countries would be an advantage. It must be recognised that for so long as the competition laws, and related laws of unfair competition and passing off of different countries remain unharmonised, they also could represent barriers to trade. For example, the position of sub-standard goods exported by the intellectual property owner to markets where they are not considered to cause a loss of reputation may still be subject to national law on "marketing usages considered fair and proper" to prevent reimportation.  

Chapter Four focused on the effectiveness of Directives. The measures so far taken in the field of copyright have left untouched previous international cooperation, such as the Berne Convention, and aimed to achieve only a degree of harmonisation within the Community. Discrepancies continue to apply between national systems concerning substantive issues which the Software Directive did not event attempt to correct. In fact the harmonisation effected by the Software Directive introduced uncertainties that never before existed (concerning those dealings with software interfaces that are no longer to be treated as infringing acts) and failed to deal with industry concerns, for example, of the independent maintenance lobby that sought to instigate change in the Directive to permit maintenance. At the same time, the Software Directive did not adequately deal with such fundamental matters as the question of exhaustion or competition as existing areas of developed law.

The result of harmonisation with regard to copyright duration (by means of the Duration Directive) has been complexity that defies due diligence examination of the true position of the copyright owner, aggravated by the continued national disparities and application of the principles of national treatment and reciprocity.

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297 Council Directive 91/250 (n. 3 above)

298 Council Directive 93/98 (n. 4 above)
The need to take adequate account of sources of existing law was taken further, in the discussion concerning the Biotech Directive\textsuperscript{299}, especially given the likelihood that the failure will give rise to uncertainty in the future. The possibility remains of national discrepancies in patent protection with all the consequences for the patent proprietor that are apparent from \textit{Merck v Primecrown}.

It is therefore submitted that the consequences of all these harmonisation measures for the proprietor who wishes to maximise the potential return from intellectual property are twofold: the erosion of the commercial value of the intellectual property and the obfuscation of the scope of protection conferred. Nevertheless, the economic consequences of all of these measures must be examined by due diligence enquiry no matter how complicated the task, as suggested by Dworkin and J A L Sterling\textsuperscript{300}:

"The entire thrust of the harmonising Directives and Regulations and the jurisprudence of the European Court is to ensure that intellectual property operates in accordance with the principles of the [European] Union rather than stands apart from them. Short term difficulties will eventually be forgotten. Nevertheless, the short-term difficulties must be identified and their economic consequences assessed."

\textsuperscript{299} COM (95) 661 (n. 5 above)

\textsuperscript{300} G Dworkin and J A L Sterling "Phil Collins and the Term Directive" (1994) 5 EIPR 187
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<td>ECR</td>
<td>Court of Justice of the European Communities: Reports of Cases before the Court of Justice and the Court of First instance.</td>
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<td>EIPR</td>
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