

THE STRATEGIC USE OF INTELLECTUAL AND INDUSTRIAL
PROPERTY LAWS TO MAINTAIN AND EXTEND A DOMINANT
POSITION IN THE PHARMACEUTICAL INDUSTRY

by

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ABSTRACT

It is assumed at the outset of this thesis that there is a public interest in the purchase of prescribed drugs at the lowest aggregate price consistent with the maintenance of research and development in the pharmaceutical field.

The thesis investigates the operation of intellectual property law in this area and its effect on prices, investment, research and the availability of new drugs. The principal focus is on the United Kingdom but the conclusions reached may be validly applied to other jurisdictions.

Each chapter is devoted to a specific branch of the law with a view to demonstrating how its exploitation by pharmaceutical firms has operated in the detriment of the public by virtually eliminating competition and thereby increasing prices.

The unique nature of the pharmaceutical industry renders the desirability of exclusive rights in this area highly questionable and the abolition or curtailment of all forms of protection for pharmaceutical products is advocated.

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CHAPTER I

THE PHARMACEUTICAL INDUSTRY

In 1973 the Regulation of Prices (Tranquilizing Drugs) Order (No. 720) (UK) imposed a maximum selling price upon the drugs Chlordiazepoxide and Diazepam.¹ The order followed an investigation by the UK Monopolies Commission into the pricing policies of the manufacturing firm Hoffman-La Roche.²

The arguments presented by the report and the fierce reaction they prompted from Hoffman-La Roche represented the continuation of a dispute which had surrounded the question of prices in the pharmaceutical industry since the early 1950s and still continues today.

It was a committee of the US Senate which first focused world wide attention on the ethical pharmaceutical manufacturing industry.³ The Kefauver report had condemned as the root cause of high drug prices the manufacturing and distribution policies of ethical drug manufacturers in the US.⁴ A Bill was introduced into the US Senate which proposed to alter drastically the patent

system under which drugs were manufactured to make compulsory licences more readily available, to modify methods by which doctors receive information about new drugs and to impose stringent measures of protection and quality control. The patent and compulsory licensing provisions of the Bill were subjected to a barrage of criticism and were finally deleted. However, the attention focused on the report and the information contained therein prompted other jurisdictions to look into the workings of the pharmaceutical industry, in particular, the market structure under which drugs were distributed and the private monopolies under which they were manufactured.

In Canada, an investigation was conducted under the provisions of the Combines Investigation Act⁵. The Restrictive Trade Practices Commission recommended the abolition of patents in the pharmaceutical industry and the imposition of stringent regulations to control all aspects of the manufacture, promotion and introduction of drugs. In Britain, the Sainsbury Committee was appointed in 1965 to enquire into the relationship of the pharmaceutical industry to the National Health Service⁶. Leaving the question of the patentability of drugs to the subsequent Banks Committee investigation, the Sainsbury Committee

concentrated on marketing, promotional and cost issues⁷. It recommended the establishment of a "Medicines Commission" to take over functions then exercised by the Committee on Safety of Drugs and to advise the government on matters such as compulsory licensing of individual drug. It also proposed the abolition of brand names for all drugs products. New products, whether patented or not, should, the Committee suggested, be marketed under a generic name only approved by the Commission although they might also display the name or house mark of the manufacturer. The Committee also recommended the abolition of advertising for all medicines.

Owing to intense lobbying by the Association of the British Pharmaceutical Industry (ABPI) none of these proposals were put into effect. Provision was made in the Medicines Bill (1968) for the establishment of a Medicines Commission but it had nowhere near the influence recommended by the Sainsbury Committee. Provisions dealing with cost and marketing were deleted from the Bill and the abolition of brand names was rejected on the ground that it would have serious economic consequences and would put British based firms at a disadvantage in export markets.

However, the high profit margins of the large pharmaceutical firms have continued to provoke hostile criticism and there can be little doubt that intellectual property laws play a large part in maintaining these high prices. Patents give a temporary monopoly to the drug in return for disclosure of the chemical formula involved while the law of trade secrets guarantees a perpetual monopoly but requires eternal vigilance to assure that the secret is kept. Patent monopolies are reinforced by other intellectual property rights: registered trademarks are protected against imitation so long as they are employed in the trade; unregistered elements of name or design may be protected under the law of passing off; registered designs protect the novel appearance of mass produced drugs and copyright will protect artistic and literary elements of the drug or packaging.

Subsequent chapters will focus on the interaction of all these rights and the methods by which they may be employed to secure for the firm in question the maximum possible protection for the longest possible time.

Before studying these laws individually it is necessary to consider why their operation in the field of pharmaceuticals has given rise to such controversy.

The political and economic consequences of exclusive rights are significant in any industry. Most intellectual property laws reflect an attempt to balance the need to encourage innovation by rewarding the inventor with the need to maintain free competition and the free circulation of goods.⁸ Yet although this conflict occurs in every industry, pharmaceuticals are singled out for special treatment. The reason is that this industry is particularly susceptible to monopoly control. Certain factors which generally limit a manufacturer's ability to earn super-competitive profits do not exist in this field.

The structure of the U.K. economy is typical of the worldwide structure. A few large producers with international connections dominate the market in brand name drugs. On expiry of a patent a number of smaller firms manufacture so called "generic drugs" of the same composition and sell them at a fraction of the price of the brand named drug.⁹ However, where the physician prescribes a drug by its brand name the dispensing chemist must supply that drug. Only where the generic name is originally employed may the chemist supply the cheapest equivalent drug.

In almost any other industry where two products are identical their prices will be similar. It is an elementary principle of economics that, all things being equal, the product selling at the lower price is likely to capture the market. The pharmaceutical industry, however, is less price sensitive as the creation and maintenance of demand depends largely on prescribing physicians who do not themselves pay for the drug. A further characteristic of the U.K. market is that the patient does not pay either (except, at most, a small flat rate prescription charge.) Most consumers know little about medicines; they often do not know what has been prescribed and certainly do not know or care whether the prescription is the most economical from the taxpayer's viewpoint.

Thus the pharmaceutical market is "product competitive" rather than "price competitive". Producers concentrate their advertising campaigns on the prescribing physicians emphasising the brand name of their product in the hope that physicians will prescribe by that name.

Advertising consists of direct mailing of brochures and samples, visits from drug company

representatives, advertisements in medical journals and exhibits at medical meetings and conferences.

The Kefauver Committee found that, in the U.S., the largest single item of expenditure for a pharmaceutical firm, next to the cost of goods sold, was advertising. The report gives figures of 25% of total profits spent on advertising while only 6% was spent on research and development.¹⁰ Figures in the U.K. are less startling. The Monopolies Commission found in 1970 that the amount spent on advertising in England by Hoffman-La Roche was approximately 11% of profits.¹¹ Even so, this is a substantial sum and leaves a large margin for economy.

The high pressure advertising campaigns are generally embarked upon as the period of patent protection draws to an end with a view to extending the monopoly period.

While the drug is protected by the patent, provided there are no equivalents and no compulsory licences have been issued, the pharmaceutical firm is in an unassailable position. No savings can be effected by encouraging generic prescribing. The pharmaceutical

company will be free to determine price on a cool calculation of what the traffic can bear. Costs of production are irrelevant.

In any other industry, even the sole producer of a product will be restrained to some extent by the possibility of pricing himself out of the market; but for an essential commodity such as drugs this check is minimal. Demand is largely inelastic, that is, unresponsive to changes in price.¹² Even when the drug is not prescribed on a National Health Service prescription a sick person will spend (within his means) whatever is necessary to secure the desired medication. There is little likelihood of his "shopping around" for a cheaper alternative or "managing without" for a period.

In England, such price restraint which does exist comes not from market forces but from the Voluntary Price Regulation Scheme (VPRS) negotiated between ABPI and the Department of Health and Social Security (DHSS).¹³ Parties to the agreement record their common interest in securing not only that safe and effective medicines are available on reasonable terms to the National Health Service (NHS) but also that a strong and profitable

pharmaceutical industry is capable of sustained research and development expenditure leading to future new and improved medicines for the NHS and for export.

The limitation lies in the fact that the VPRS, as its name implies, is a voluntary scheme; Hoffman-La Roche was one of the major companies who refused to join the scheme.

It also objected strongly to compulsory licence provisions in the Patent Act 1949 (now repealed)¹⁴ and to what it termed the "counter promotional activities" of the DHSS. The DHSS has brought strong pressure to bear on physicians to prescribe generically although there is no compulsion to do so. This contrasts with the U.S. where many states have passed mandatory substitution laws.¹⁵

There can be no doubt that the DHSS does exercise important influence in the market for any drugs which are supplied to the NHS. As the ultimate paymaster, it is in a position to exert some pressure over prices but it cannot decide which drugs shall and shall not be prescribed. Nor can it exert its bargaining power as an independent buyer would do because it must have some regard to the effect

this would have on the general prosperity of the industry including exports and research programmes.

On each new attack the industry relies on the need to reinvest in research programmes as a justification for high prices:

"It is widely accepted that the basic risk in such research is that, no matter what is spent, a new remunerative breakthrough may not result. There should be an acceptance that either embarking on pharmaceutical research or expanding it, both of which involve heavy investments, cannot take place except out of resources which can only be previously earned and taxed profits."¹⁶

The Monopolies Commission found that large research based companies spent about 7-12% of turnover on research and development. However, where the company was foreign owned not all of this sum was spent in England. A figure of 10% was given as broadly representative.¹⁷

While no government enquiries have denied the importance of research, it is arguable that present purchasers of pharmaceutical products are paying too much towards the future expansion of the industry.

In the Hoffman-La Roche enquiry the Commission expressed the view that research expenditure had been inflated by the use of excess profits to a point at which it had ceased to be reasonable to regard the expenditure as fully recoverable from current sales. In the specific cases of Librium and Valium the success of the drugs had far exceeded the conservative estimates upon which the initial pricing policy had been based. The return was therefore abnormally high especially as Hoffman-La Roche had not subsequently reduced their prices.¹⁸

The Commission suggested that, in order to determine a reasonable limit to exploitation in a particular case, it was necessary to look at the profitability of a drug over its patent life as a whole. After a few years, when sales have increased and high rates of profit may have been achieved, exploitation should be kept within reasonable limits through adequate regular price reductions. In the instant case there had been no reduction for more than 2/3 of the patent life. Accordingly reductions were forced upon the company by the Regulation of Prices (Tranquilizing Drugs) Order 1973.¹⁹

Use of the restrictive practices legislation to restrain excessive pricing was successful in this instance and probably set a valuable example to other pharmaceutical firms. However, it is a cumbersome and expensive way of proceeding. The VPRS helps to some extent to keep prices down but it can be seen from the Hoffman-La Roche case that it is not always effective.

A simpler way to keep prices down would be to restrict the amount of protection conferred upon pharmaceutical products through the intellectual property laws. Prices in the industry are sufficiently high and barriers to entry sufficiently daunting that, even with reduced protection, it is likely that profits would remain sufficiently lucrative to encourage the development of new products.

NOTES TO CHAPTER I

- ¹ Better known by their Trade Names - Valium and Librium (respectively).
- ² The Monopolies Commission Report on the Supply of Chlordiazepoxide and Diazepam presented to Parliament in pursuance of S.9 of the Monopolies and Restrictive Practices (Inquiry and Control) Act 1948, 11th April, 1973 (Monopolies Commission Report).
- ³ Report of the Committee on the Judiciary United States Senate made by its subcommittee on Anti-Trust and Monopoly pursuant to Senate Resolution 52, 87th Congress 1st Session, Report NO. 448 (1961) ("Kefauver Report").
- ⁴ The term "ethical" denotes drugs which may only legally be sold on prescription. Drugs which are advertised to the public and usually bought without prescription are termed "proprietary drugs".
- ⁵ Restrictive Trade Practices Commission Report concerning the Manufacture Distribution and Sale of Drugs, Ottawa, 1963 ("RTPC Report").
- ⁶ Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service, 1965-70 HMSO Cmnd 3410 ("Sainsbury Report").
- ⁷ Sainsbury Report at p.46.
- ⁸ With the possible exception of trademark laws where the primary function is to provide the consumer with an indication of source.
- ⁹ For the distinction between brand name and generic name, see generally Chapter 4.
- ¹⁰ Kefauver Report Part IV, Advertising and Promotion of Drugs, at p.156.
- ¹¹ Monopolies Commission Report at p.39 para 141, p.67 para 226 and Appendix 5.
- ¹² Kefauver Report at p.3; Sainsbury Report at p.73.

¹³The first VPRS was devised in 1957 by a negotiating committee of the Association of the British Pharmaceutiucal Industry ("ABPI") and officials of the Ministry of Health. Members of the commitee were: Mr J V L Fergusson, Chairman and Managing Director of Evans Medical Supplies Ltd, Mr E D Carey, Managing Director of Allen & Hanburys Ltd, Mr T B Maxwell, Managing Director of May & Baker Ltd, Mr H W Palmer, Managing Director of Glaxo Laboratories Ltd, Mr J D Robinson, Director of the Wellcome Foundation Ltd, Mr L O Smith, European General Manager of Parke Davis & Co Ltd, Mr G F Williams, Managing Director of the British Drug Houses Ltd., Source: ABPI Annual Report 1956-7, p.15.

¹⁴Patent Act 1949, S.41.

¹⁵Under many state substitution laws, the chemist is compelled to use the cheapest generically equivalent drug, unless the physician specifically expresses an alternative wish. Dispensing chemists are provided with an approved formulary listing interchangeable products and their related prices. Between 1972 and 1979 thirty one states and the District of Columbia enacted various types of laws permitting substitution.

See Alaska Stat. 08.80.295 (Supp. 1978); Ariz. Rev. Stat. Ann. 32-1963.01 (Supp. 1978); Ark. Stat. Ann. 72-1047 to -1048 (Supp. 1977); Cal. Bus. & Prof. Code 4047.6 (West Supp. 1978); Colo. Rev. Stat. 12-22-118.5 (Supp. 1976); Del. Code Ann. tit. 24, 2589 (Supp. 1978); D.C. Code Ann. 33-832 (Supp. 1978); Fla. Stat. Ann. 465.30 (West Supp. 1978); Ga. Code Ann. 79A-408.2 (Supp. 1978); Iowa Code Ann. 155.37 (West Supp. 1978); KRS 217.822 (1977); Me. Rev. Stat. tit. 32, 2806 (Supp. 1978); Md. Ann Code art.43, 273A (Supp. 1978); Mich, Comp. Laws Ann. 338.1114a (Supp. 1978); Mo Ann. Stat. 338.056 (Vernon Supp. 1979); Mont. Rev. Codes Ann. 66-1528 to -1536 (Supp. 1977); Neb. Rev. Stat. 71-5401 to -5408 (Supp. 1978); N.J. Stat. Ann. 24:6E-7 and 8 (West Supp. 1978) N.Y. Educ. Law 6816-a (McKinney Supp. 1978); Ohio Rev. Code Ann. 4729.38 (Page Supp. 1978) Or. Rev. Stat. 689.830-.850(1977); Pa. Stat. Ann. tit. 35, 960.2 - 7 (Purdon 1977); R.I. Gen. Laws 5-19-38 (Supp. 1978); S.C. Code R99-22 (1976); S.D. Codified Laws 36-11-46.1 to -11-46.4 (Supp. 1978); Tenn. Code Ann. 52-1211 to -1226 (Supp. 1978); Utah Code Ann.

58-17-29 to -17-35 (Supp. 1977); Vt. Stat. Ann. tit. 18, 4605 (Supp. 1978); Va. Code 54-524.109:17 (1978); Wash. Rev. Code 69.41.100 - .41.180 (Supp. 1977); W. Va. Code 30-5-12b (Supp. 1978); Wis. Stat. Ann. 450.075 (West Supp. 1978).

- ¹⁶Roche Replies to Monopolies Commission.
The Pharmaceutical Journal, April 28, 1973 at p.367.
- ¹⁷Monopolies Commission Report at p.44.
- ¹⁸Monopolies Commission Report at p.69.
- ¹⁹Hoffman-La Roche initially refused to obey the order and moved to have it declared invalid but the Government obtained an interim injunction barring the seller of the drug from charging prices in excess of those specified in the order: Hoffman-La Roche A.G. v Secretary of State for Trade and Industry [1973] 3 A.E.R. 945 (C.A.), aff'd [1975] A.C. 295 (H.L.)

CHAPTER II

PATENTS

1. Introduction to Patent Law in the Pharmaceutical Industry

Patents confer upon the patentee a limited monopoly in return for the disclosure of a new invention. The ostensible aim behind the introduction of the patent system was to encourage research and to stimulate the development of both old and new industries but the monopolies thereby granted have remained subject to persistent criticism and suspicion. This suspicion stems from the seventeenth century when Elizabeth I and James I granted many patents as "favours" and as a method of raising revenue without recourse to Parliament.¹

In 1624 the Statute of Monopolies was passed in an attempt to curb these abuses. All future monopolies were declared null and void with one important exception contained in section 6:-

"Provided also...any declaration before mentioned shall not extend to any letters patent and grants

of privilege for the term of fourteen years or under hereafter to be made of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventions of such manufacturers which others at the time of making such letters patent and grants shall not use, so also they be not contrary to the law or mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient." ²

This section laid the foundations of modern patent law which now confers upon the inventor a monopoly in England of twenty years in return for full disclosure of his invention. It will be noted however that, even at that early stage, the law attempted to limit the scope of monopoly where the detriment to the public outweighed the benefits accruing through the incentives to innovate.

Since the statute was passed controversy has surrounded the question of whether the granting of patents is beneficial to the nation. Competition is generally believed to be a "good thing" and patents, by their very nature, restrict competition. The existence of a patent system represents therefore a conscious decision that the gain resulting from the promotion of inventiveness outweighs the loss resulting from the elimination of competition.

An investigation into the effectiveness of the patent system in general and the possible consequences of its abolition is beyond the scope of this paper.³ In England, the system has existed for so long that its right to continued existence is virtually unassailable. Instead, the writer echoes the words of Professor Machlup:

"If we did not have a patent system, it would be irresponsible on the basis of present knowledge of its economic consequences to recommend instituting one. But since we have had a patent system for a long time it would be irresponsible on the basis of our present knowledge to recommend abolishing it."⁴

However, while this stance may justify retention of the patent system for most industries, the writer is of the opinion that it is less valid in the specific context of the pharmaceutical industry.

The existence of even a limited monopoly which may be justifiable, or at least excusable, in many industries is questionable here in view of the unique nature of the product, viz., those qualities of relieving suffering and preserving life which place the pharmaceutical industry in a position of special responsibility towards the public.

The Kefauver Report in the US found that in 1961 most countries from which information was obtained did not allow patents on drug products although many allowed them on the processes of production. Of the seventy seven countries investigated, only twenty eight granted product patents and some of those twenty eight specifically excluded patents on "combination drugs" which are a mixture of known ingredients.⁵ The evidence collected for submission to the Canadian RTPC (The Green Book)⁶ disclosed that in many countries drug products were ineligible for patent protection.

In England, prior to 1919, the law permitted the patenting of chemical substances but a process limitation was introduced into the Patent and Designs Act, 1919. This Act also provided for compulsory licensing of processes for producing food, medicine and surgical appliances.

In 1947, the Swan Committee⁷ recommended that all chemical substances, including medicines, should be eligible for patent protection once more subject to retention of the compulsory licence procedures. These recommendations were adopted in the Patents Act 1949.⁸

The 1977 Act retained protection for drug products and repealed the compulsory licence provisions thereby placing pharmaceutical manufacturers in the same position as manufacturers of any other product (subject to the Crown Use provisions considered below).

This chapter discusses whether pharmaceuticals should enjoy patent protection at all, whether protection should be limited to the chemical process involved rather than the final product, the advantages of compulsory licences or licences of right and, finally, the value, in theory and in practice, of the Crown Use provisions in the English Patent Act.

2. The Exclusion of Pharmaceutical Products & Processes from the Patent System

Italy is the oft-quoted example of a country which, until recently, denied patent protection to both drug products and the processes of production. Few countries adopt such an unequivocal position although some, including Canada, deny protection to the product alone. In Canada, the Restrictive Trade Practices Commission (RTPC), reporting in 1963,⁹ found that even the limited

protection available in Canada had resulted in unduly high prices for drugs and thought that, while a provision for licences of right might alleviate the situation, the real solution would be the total abolition of patents on drugs:-

"As the Commission believes that close control exercised by patents has made it possible to maintain certain drugs at levels higher than would have obtained otherwise and that such patent control has produced no benefit to the public of Canada which would outweigh the disadvantages of the monopoly, the Commission recommends that patents with respect to drugs be abolished."¹⁰

In England, the Sainsbury Committee was appointed in May 1965.¹¹ Among its terms of reference was the consideration of the effects of patents. Unlike the Canadian RTPC, the Sainsbury Report did not recommend the abolition of patent protection. The Committee was far more cautious. It recommended retention of provisions dealing with Crown Use of Patented inventions (considered in detail below) but preferred to refer the question of patent protection to the Banks Committee.¹²

The Banks Committee looked first at the international scene which appeared to have been moving towards increased protection for chemical substances.

Since the reports of Kafauver and the RTPC, Germany had passed a new law providing for the protection of chemical substances whereas previously only processes were patentable. New laws in the Scandinavian countries had extended protection to chemical substances and a new French law was less restrictive towards drugs. Even Italy was moving in the direction of patent protection for drug processes.¹³ Recent moves within Europe towards harmonization of industrial property rights will lead to the patentability of drug products in all member states of the EEC.¹⁴

The Banks Committee, having found that the patent system played a significant role in encouraging individuals to invent and commercial organisations to develop inventions, considered this to be as true in the pharmaceutical field as any other and saw no reason to treat that industry differently:

"We are convinced that, as a general proposition, research and innovation in the pharmaceutical industry are capable of benefiting the community at least as much as research and innovation in other fields and that any general diminution of patent protection for drugs would work against the long term interests of the public."¹⁵

The answer to the question of whether to exclude drugs from the patent system depends on what we expect from the system and whether those expectations are being met. The reasons for the existence of the system appear to be threefold: reward for both the inventor and the entrepreneur responsible for the promotion of the invention, supply of technical information to the industry and the encouragement of research and development.

The pharmaceutical companies maintain that all three aims are being met and that the maintenance of a patent system is vital to secure those aims. It will be seen from what follows that this assertion is far from proven and, in the writer's opinion, the onus lies upon those asserting the monopoly (i.e., the pharmaceutical firms) to prove their case.

The aim of reward is clearly being satisfied. Both Kefauver and the Canadian RTPC found profit margins in the pharmaceutical industry to be higher than in any other industry and considered patents to be a significant factor in the high prices.¹⁶ In Britain, prices are generally lower despite the availability of patents owing to the existence of the VPRS.¹⁷

Even so, Kefauver found that prices in countries without patent protection were significantly lower than in Britain.¹⁸

The second aim is to provide information to the industry. The patent specification should

"disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art"¹⁹

and must contain a claim or claims which

"define the matter for which the applicant seeks protection"²⁰

This aspect of the system appears to work reasonably well in Britain. The chief defect is probably that, as a result of the firms desire to obtain patents on minor variations and derivatives of existing drugs, there are too many of them and it is difficult to extract those specifications which are worthy of detailed study. The Canadian RTPC considered that no substantial benefits flowed from disclosure but this is probably because the Canadian Pharmaceutical Industry, unlike the British, is largely foreign owned. Most discoveries are made abroad and

patented in the country of the inventor. By the time they are filed in Canada they have already been made known to the world or, at least, knowledge of them has been made available to all interested persons. Britain has a large native drug manufacturing industry which benefits from the disclosure of new inventions and to that extent the second justification for the existence of patent protection may be considered satisfied. Without such protection it is arguable that firms would rely heavily on trade secret protection to the detriment of the industry as a whole.

So we come to the third, and most frequently quoted, justification for the patent system - the promotion of inventiveness and the exploitation of new inventions with the minimum of delay. If this aim is achieved it is a strong argument in favour of the retention of patent protection for pharmaceuticals. It is more important to provide society with new and advanced drugs than to prevent anyone from deriving a profit through making a contribution to technology. Furthermore, the mere discovery of a drug will not cure anyone; time, energy and money must also be dedicated to the task of distribution and education. The Canadian RTPC was convinced that the patent system failed to achieve this aim and therefore recommended the abolition

of patents on drugs. It should be recalled however that the Canadian pharmaceutical industry is engaged primarily in importing the basic chemical ingredients, tableting them and packaging them in their final form. Very little innovative research is carried out in Canada in any event. Nevertheless, the RTPC said:-

"The Commission inclines to the view that the abolition of patents, while it may possibly have some effect upon future research developments, would neither eliminate the limited amount of research carried on, nor prevent further research being undertaken in the future."²¹

The RTPC did not confine its findings to the Canadian Industry. After looking at the international scene the Commission concluded that patents were not the sine qua non of invention in this area. The RTPC pointed out that the U.S., which has always enjoyed full product patent protection, has only come to the forefront in this field in the last twenty years whereas many European countries which granted process patents but not product patents had a long history of notable developments. Indeed the Kefauver Report even went so far as to suggest that the very existence of a patent system detracts from innovative research by encouraging firms instead to devote resources

to obtaining patentable derivatives of basic drugs already in existence.²² To the extent that the same may be said of other industries, this is a reflection on the patent system per se. However this paper is concerned with the pharmaceutical industry where the case against patent protection is particularly strong.

Kefauver found that drug discoveries in countries without patent protection outnumbered discoveries in countries with protection in the order of 10:1 although prices were considerably higher in countries with patent protection.²³ While these figures alone are not conclusive and may be subject to a number of variables they lend some support to the view that high prices generated by the patent system are not justified by a corresponding increase in research.

The Banks Committee, without providing detailed evidence in support of its conclusions, found however that the British Patent System did foster research and innovation in the pharmaceutical industry as much as in any other field and that any diminution in patent protection would work against the long term interests of the public. The Committee considered that the reasons for reducing

protection in Canada did not apply with equal force in England where there was a well established drug manufacturing industry with a substantial British owned component.²⁴

The anti-protection lobby argues that the unique properties of drugs in alleviating suffering and preserving life justify the abolition of patent protection in this industry. Of course, if the patent system is achieving its expressed goal of promoting investment in the research and development of new drugs the unique nature of the industry could be a strong argument in favour of strengthening patent protection. If, as the writer suspects, the system is achieving its subsidiary aim of rewarding inventors and entrepreneurs without achieving its main aim of promoting research the system is operating against the public interest and should be abolished.

Abolition would be a radical move and one is instinctively cautious:

"If one does not know whether a system is good or bad, the safest policy conclusion is to muddle through, either with it, if one has long lived with it, or without it if one has lived without it."²⁵

The Banks Committee was possibly a little overcautious, preferring to "muddle through" rather than propose a radical change in the law. The writer proposes radical change but is aware that the English legislature would have difficulty instituting such a change in national patent laws without some support from her European partners. Indeed, one of the motivating forces behind the enactment of the 1977 Patent Act was the desire to bring English Patent Law into line with the rest of the EEC.

The present position is that national laws are not yet unified and no centralised procedure for the grant of patents currently exists. However, when the Community Patent Convention comes into force, an inventor or his assignee should be able to obtain patent protection in all of the member states where he wishes to exploit his invention since patentability rules will be the same throughout Europe.²⁶ The idea of a community patent is that it will be unitary in character, that is, it can be granted, transferred, revoked or allowed to lapse only in respect of the whole of the Common Market territories and will be subject to the legal regime established by the Community Patent Convention itself. The situation where a

product is patented in some member states and unpatented in others will become increasingly rare (although it will still be possible to seek separate national patents rather than a community patent).

In the light of the Community Patent Convention, Britain would not be in a position to deny patent protection to pharmaceutical products protected by a community patent.

This practical difficulty does not however affect the writer's opinion on the question of principle. The main part of the present discussion focuses on the patentability of pharmaceuticals under the UK Patents Act yet the arguments apply with equal force to the entire EEC and it is therefore suggested that pharmaceuticals should also be excluded from the Community Patent Convention.

3. Limitation of Protection to Process only

A less drastic proposal than total abolition is the restriction of patent protection to processes of production. This used to be the position in England as well as in most European countries although the present trend is in favour of complete protection.

Process patents are a much weaker form of protection because of the comparative ease with which, by a slight change in the process, the patent can be avoided. The idea behind this limitation is that, instead of restricting access to life saving drugs, inventors will be encouraged to develop constantly better and cheaper methods of production resulting in lower prices for the products. This was explained in the Kefauver Report

"The limitation of protection for chemical products in general and pharmaceutical products in particular to process claims is essentially a continental European conception and it is tied up with social thinking in the 19th century during the industrial revolution. It became a matter of practically unassailable dogma that, if the public is to receive the benefit of new pharmaceutical products at a reasonable price and in amounts sufficient to meet the demand, this could only be accomplished by restricting the inventor to his process so that others will be encouraged to invent new and improved processes which will make the product cheaper and available in greater quantities." ²⁷

The representative of Cyanamid of Canada submitted evidence to the RTPC criticising the restriction of patent protection to processes only explaining that there is an almost insurmountable difficulty in establishing whether or not two drugs have been made by the same process. ²⁹

Arguments for or against this restriction are similar to those surrounding the question of whether to allow patent protection at all for pharmaceuticals. If the patent law achieves its stated purpose of promoting invention and research full protection should be afforded to drugs. If it serves only to reward the inventor without contributing to new developments it should be abolished. The proposal under consideration here is a halfway house solution. It does not resolve the important question of principle, that is, whether patent protection operates to the benefit or detriment of society. As there is no indisputable answer to this question the proposal to limit protection has some merit as an attempt to obtain the "best of both worlds". It is an attempt to foster the aims of the patent law by protecting and thereby encouraging research while at the same time avoiding the drawbacks of full protection - monopolies on the sale of life giving drugs and the corresponding right to charge high prices for those drugs. It may prove easier to secure acceptance of this compromise.

During the years 1919-49 process protection was the only form of protection available in Britain. When the

Swan Committee recommended that the law be changed so that all chemical substances, including medicines, should be patentable the recommendation was subject to retention of the special compulsory licence procedure for food and medicines.²⁹ The Banks Committee however recommended retention of full patent protection and the abolition of compulsory licences.³⁰ This was a strongly protectionist measure. Considering the doubtfulness of the utility of patents in this field, a compromise limiting protection to processes would have been preferable.

4. Compulsory Licences

It has been demonstrated that English law has moved decisively in the direction of greater protection for pharmaceuticals. Not only does the 1977 Patent Act allow full product protection, the special compulsory licensing procedures for food and medicine have been abolished.

The compulsory licence is a device employed in many countries to limit the exclusive rights of a patentee. The usual grounds justifying the grant of such a licence arise in situations where the patentee is abusing his patent, for example, by non-use where this is detrimental in some way to the interests of the public. In

some countries compulsory licence provisions are contained in patent legislation; in others they are found in anti-monopoly legislation; sometimes they are found in both.

In addition to situations of abuse, many countries also provide for compulsory licences in cases where national defence, public health and other public purposes are in question. In England, the concept of special compulsory licence provisions for food and medicines was introduced in the Patents and Designs Act 1919. In 1947 the Swan Committee recommended the retention of these provisions and they were consequently incorporated into s.41 of the 1949 Patents Act. The section was concerned with

1. substances capable of being used as food or medicines
2. processes for producing such substances
3. inventions capable of being used as, or as part of, a surgical or curative device.

The Comptroller was obliged to grant a licence under these powers on the application of a person interested unless it appeared to him that there were "good

reasons" for refusing the application.³¹ It was sufficient to establish interest that the applicant intended to operate the licence and there were reasonable grounds for supposing that he would. "Good reasons" for refusing a licence had to be compelling reasons and not matters subject to compensation by adjustment of royalty.

This section has been omitted from the 1977 Act on the recommendation of the Banks Committee which considered that

"the benefit which might accrue to the public through the licensing of an alternative supplier did not outweigh the discouragement to research inherent in a system which may deprive a successful researcher of a part of his expected return to the benefit of a manufacturer who may never have undertaken research of any kind."³²

The Banks Committee did not present any evidence to prove that compulsory licences were a disincentive to research.

There is no doubt however that the section was most unpopular with the pharmaceutical industry which mounted a powerful lobbying campaign while the 1977 Bill was in Parliament. This resulted in the section being repealed on the date of the Royal Assent making it the only

part of the 1949 Patent Act to be repealed with immediate effect.

One of the justifications for the repeal was that the section was rarely used. During the eighteen years from 1950-1967 inclusive only nine licences were granted.³³ The Banks Committee took this statistic as proof of the fact that section 41 had not worked in the way in which it was intended. If this was true one wonders why the Committee did not examine ways of making the section more effective instead of recommending its total abolition. In any event, the evidence indicates that, while the section was relatively unused in the early years, during the years immediately prior to the report and following the report there was a considerable increase in the number of licence applications.³⁴ All applications under the section were vigorously contested but rarely refused although some were withdrawn and some licences were never worked.³⁵ The Sainsbury Committee, when referring the question of compulsory licences to the Banks Committee, had commented that it was a section which "so far has been little used" and that there appeared to be a "great reluctance on the part of most business firms to apply for compulsory licences".³⁶ The Banks Committee appears to

have accepted these findings without conducting its own investigation to see whether the number of applications had increased since the Sainsbury Report.

Evidence adduced before the Canadian RTPC ³⁷ suggested that the very existence of compulsory licences led to voluntary licensing which would not otherwise take place. Unfortunately, as there is no requirement to register voluntary licences at the Patent Office, no precise figures are available to verify this highly plausible view.

Kafauver recommended the institution of compulsory licence provisions in the Bill which embodied the results of his subcommittee's enquiry ³⁸ but the American Pharmaceutical Association led a strong campaign representing this proposal as an attack on the patent system in general (which arguably it was). Much powerful lobbying by American industry resulted in the deletion of this provision.

Similar lobbying in England led to the abolition of compulsory licensing for food and medicines in the 1977 Patent Act, an unfortunate development in English patent law.

The Sainsbury Committee made a tentative suggestion that a shorter period for the patent followed by a right to receive royalties under licence of right might provide adequate protection while at the same time reducing the degree of monopoly in marketing. The Banks Committee did not even consider the advantages of providing for licences of right which would surely have been preferable to total abolition.

The Canadian RTPC approved in principle of licences of right but felt that the effects would be merely palliative and not truly remedial. The only true remedy in their eyes was to remove patent control from drugs.

One of the reasons for the underutilization of S.41 has undoubtedly been the need for the Comptroller of Patents to investigate whether there existed "good reasons for refusing the application". As most applications have been strongly opposed delays of several years have frequently arisen. The introduction of licences of right would eliminate the need to examine this question and licences would be obtained relatively quickly, the only question being the amount of royalty payable. The Banks

Committee however did not even consider the desirability of licences of right.

Compulsory licences to manufacture pharmaceuticals may still be obtained if the applicant shows that the patentees actions fall within the "abuse" provisions of the 1977 Patent Act,³⁹ that is; if the invention is not being worked to the fullest extent in the UK., if UK demand is not being met on reasonable terms or is being met to a substantial extent by importation, or if refusal of licences prevents an export market from being supplied by UK products. These provisions are reasonable and, in the writer's opinion, operate in the public interest. European commentators however have suggested that the provisions of S.48 constitute a "disguised restriction on trade" and will therefore be unenforceable in an EEC context as violations of Art. 30 of the Treaty of Rome.⁴⁰ The European Court of Justice has not yet been called upon to decide this issue and the authors of the Community Patent Convention have not agreed to a unified conception regarding the effect of community patents. At least during an initial period, they will be subject to compulsory licensing under the laws of the contracting states. To this extent therefore community patents will not have a uniform effect throughout the EEC.

5. Crown Use

The pharmaceutical industry did not have things all its own way in the 1977 Patent Act. The Crown Use provisions embodied in S.46 of the 1949 Act were retained in the new act.

The grant of a patent was originally a Royal Grant issued under the prerogative powers of the sovereign and for this reason for the common law did not regard the monopoly created by a patent as applying to the Crown. When, in the late nineteenth century, the administration of patents was placed on a more official basis, Parliament provided that the owner of a patent was to have the same rights against the Crown as against any other person save for certain privileges which were reserved for the benefit of the Crown. Government departments were entitled to use or authorise others to use certain patented inventions "for the services of the Crown".

It was not intended, of course, that ministerial departments should be able to compete commercially with the patent owner but only that they should be able to perform their duties in the public interest unimpeded by patent

rights. The inclusion of Crown Use provisions in the 1949 Patent Act highlighted a vital distinction between the British Health Service and those of Canada and the US; the existence of a National Health Service.

The establishment of the NHS has meant that the cost of prescription drugs is no longer the concern of the patient but has become the responsibility of the Department of Health. As the Sainsbury Committee said:

"Medicines are developed, manufactured and supplied by the pharmaceutical industry. They are prescribed by doctors, they are consumed by patients and, through the National Health Service, the taxpayer eventually pays for them. But neither the doctor who prescribes nor the patient who consumes is immediately concerned with prices." 41

Thus the state bears the responsibility for obtaining drugs at the lowest possible prices. On 17th May 1961, Enoch Powell, then Minister of Health, announced to the House of Commons that the Government intended to invoke S.46 of the Patents Act 1949 to obtain for the hospital service supplies of certain widely used drugs. S.46(1) of the 1949 Act reads as follows:-

"46(1) notwithstanding anything in this Act, any government department, and any person authorised in writing by a government department may make use and exercise any patented invention for the services of the Crown."

The decision to use this section to authorise the procurement of drugs for the hospital service was a severe blow to the pharmaceutical industry in Great Britain. The decision illustrates the limited extent to which the pharmaceutical industry was acknowledged to be a special case, that is, not subject to the constraints of a normal supplier/customer relationship. In a speech to the ABPI on 26th April, 1961, Mr Powell announced

"It is not possible to reproduce perfectly the conditions of a normal supplier/customer relationship in the circumstances created by the NHS. However, that is no reason for not doing our best to get as close to normal conditions as possible." 42

Mr Powell invoked S.46 as part of his attempt to obtain drugs for the NHS on terms on which they would be available in the conditions of a free and open market.

The ABPI reaction was predictable. It condemned use of S.46 on the grounds that it would reduce prices to

such an extent as to make prohibitive the maintenance of research and development.

S.46 provides for compensation to be assessed on a "reasonable royalty" basis, viz., at whatever rate would be reasonable between a willing patentee and a willing licensee. Such compensation would rarely equal the profits to be enjoyed by a manufacturer as the exclusive producer of a much needed drug.

The legality of this use of S.46 was tested before the courts in Pfizer v Minister of Health.⁴³

As the Crown Use provisions have been maintained in the 1977 Patents Act, the Pfizer case is still good law.

There were three main issues before the House of Lords. The plaintiffs contended (1) that the sale of drugs to patients in NHS hospitals was not a use of an invention for "services of the Crown"; (2) that the supply of drugs against a 2 shilling prescription charge was a "sale" which could not be authorised by the Minister; and (3) importation of the drug into England was not an act which could be authorised by the Minister under S.46 as it needed

no authorisation, and therefore infringement occurred when the imported drugs were sold to the public, something which the Minister could not authorise.

On the first point, the House of Lords found by a majority of 3:2 that the use of patented drugs for both in and out patients of NHS hospitals was a use of the invention for "services of the Crown". It rejected an argument that there was any distinction between services of the Crown in the sense of services related to the functions of government as such and services of the Crown in the sense of the provision of facilities commended and defined by Act of Parliament for the general public benefit.

On the second point, the House of Lords was unanimous in holding that the supply of drugs on payment of a statutory prescription charge was not a sale. There is no element of consensual bargaining. The patient has a statutory right to demand the drug on payment of the prescription fee and the hospital or dispensing chemist has a statutory obligation to supply it on such payment. The fee certainly does not represent the price of the drug.

On the third point, importation was held to be a use of the invention which could be authorised by the Minister under S.46.

Pfizer was therefore unsuccessful on all three issues. The case recognised, to a limited extent, the special position of the pharmaceutical industry. This special position arises only because the NHS comes within the definition of "services of the Crown". Were it not for the NHS the pharmaceutical companies would be in an unassailable position.

However, the industry has reason to be grateful for the inclusion of the NHS in the Crown Use provisions. Without the discretionary check on monopoly power, supposedly exercised by the Department of Health, it is unlikely that the Banks Committee would have recommended the abolition of the compulsory licensing provisions. Private firms have shown themselves more willing than the government to intrude on the patentees monopoly but those firms are no longer able to apply for compulsory licences. If the Department of Health continues its reluctance to employ the Crown Use provisions the drug companies will continue to enjoy a monopoly of production for at least

twenty years. When the Pfizer case was first decided it looked like a major incursion into the rights of pharmaceutical firms. Lord Wilberforce said in a strong dissenting judgment:-

"My Lords, such a definition of the powers of the Crown to use or authorise the use of patented inventions seems to me to be alarmingly wide and to make a formidable incursion into the supposedly valuable monopoly right which the Crown has granted to the patentee...an enormous breach is made in the rights of proprietors of patents on drugs." 44

The "enormous breach" did not in fact reduce patent protection in the pharmaceutical industry to any appreciable extent. Despite its success, the Department of Health made little use of S.46 seeming content to rely upon private enterprise to invoke the compulsory licensing provision of S.41.

Furthermore the "breach" was not as great as it might have been at that time because the Pfizer case established that only the hospital services of the NHS were services of the Crown. General medical and pharmaceutical services of the NHS were not within the definition. This was clearly anomolous and the Sainsbury Committee

recommended therefore that the NHS Acts be amended to bring the whole service within the scope of the definition.

Consequently, S.59 of the Health Services and Public Health Act provided that a government department or person authorised by a government department may "make, use, exercise and vend" an invention for the production and supply of drugs and medicines

"required for the provision of pharmaceutical services, general medical services or general dental services."

It should be noted that this provision, unlike S. 46, includes a specific power to "vend". This caused consternation among ABPI who voiced strong criticism of this further "discrimination" against the pharmaceutical industry.

"The effect is to make the pharmaceutical industry the only private sector industry which, in times of peace, has to suffer its inventions being laid open to the power actually to sell patented goods to the wholesaler, retailers and consumers being given to both government and by the government to third parties."⁴⁵

The Banks Committee, however, favoured this limited form of discrimination against the pharmaceutical industry. The Committee admitted that prices were disquietingly high but, rather than remedying the situation through stronger forms of statutory discrimination, the Committee preferred to leave the question to the discretion of the Department of Health by retaining the Crown Use provisions.

"We are certain that if the Department of Health is of the opinion that a drug patentee's prices are too high, taking all factors into account, it is in the public interest that a final sanction should be available to the Department whereby supplies of the drug can be obtained at competitive prices. However, we firmly believe that this result should be sought on a selective basis rather than weaken patent protection for drugs overall."⁴⁶

The statement acknowledges the existence of a problem but proposes no effective measure to combat it. The Crown Use provisions had been enacted in the Patent Act 1949. During the years between the enactment of that statute and the publication of the Banks Report, in 1970, the Department of Health had used those provisions only once - in the Pfizer case in 1965. It must surely have been apparent to the Banks Committee that patents were

being abused and that S.46 was not proving to be an effective sanction.

ABPI made representations to the Banks Committee opposing the continuance of Crown Use provisions and suggested that if they were to be retained at all the exercise by the Crown of its powers should not be lawful until the patentee had been given an opportunity to argue before an independent tribunal that the proposed exercise was not, on balance, in the public interest.

The Banks Committee, while expressing some sympathy for the patentee who, aggrieved by partial loss of his patent rights, wished to question the authority depriving him of those rights, rejected this proposal - in the writer's opinion rightly. The procedure would involve both parties in expense and would introduce lengthy delays in the employment of Crown Use provisions. The Committee also pointed out that the pharmaceutical industry enjoys a measure of protection against the abuse of Crown Use powers by the terms of S.59 of the Health Services and Public Health Act 1968. The powers are exercisable by Statutory Instrument only which is subject to annulment by resolution of either House of Parliament.

Crown Use provisions are contained in S.55 of the new Act and include power to sell as well as use the drug.⁴⁷ Use is not limited to hospital services of the NHS but extends to drugs which are required for pharmaceutical, general medical or dental services.

It is fortunate that Parliament acted on the recommendation of the Banks Committee and retained the Crown Use provisions. In view of their decision to allow full patent protection for pharmaceuticals and to abolish compulsory licence provisions for food and medicines it would have been a serious step if this last barrier against total monopoly had been removed.

Unfortunately this power is likely to be used sparingly particularly in the light of Britain's entry into the EEC. Crown Use provisions are viewed critically by other EEC countries which do not allow their governments so wide-ranging a weapon.

One can only hope that the mere existence of S.55 will be sufficient to deter firms from unreasonably exploiting patents.

NOTES TO CHAPTER II

- ¹See also Terrell on the Law of Patents, London, Sweet & Maxwell (12th ed.) 1971 at p.3; Fox, The Canadian Law and Practice relating to Letters Patent for Inventions, Toronto, The Carswell Co Ltd (4th ed.) 1969 at p.3-4.
- ²Statute of Monopolies 1623 (21 Jac. 1, C.3).
- ³For a general discussion of the nature and effects of patents and their economic consequences see Edmund W. Kitch, The Nature and Function of the Patent System, 20 Journal of Law and Economics 265 (1977); Donald G. McFetridge and Douglas A. Smith, Patents, Prospects and Economic Surplus: A Comment, 23 Journal of Law and Economics 197 (1980); Edmund W. Kitch, Patents, Prospects and Economic Surplus: A Reply, 23 Journal of Law and Economics 205 (1980).
- ⁴Fritz Machlup, Study 15 prepared for the O'Mahoney Sub-Committee of the Committee on the Judiciary, U.S. Senate p.79-80 (1961).
- ⁵Kefauver Report at p.105.
- ⁶The Green Book - Material collected for submission to the Restrictive Trade Practices Commission in the course of an Inquiry under Section 42 Combines Investigation Act relating to the Manufacture, Distribution and Sale of Drugs. Department of Justice, Ottawa 1961.
- ⁷Departmental Committee on the Patents & Designs Act under the chairmanship of Sir Kenneth Swan Q.C. The Committee made three reports: first Interim Report published in 1945 Cmd 6618; second Interim Report published in 1946 Cmd 6789; Final Report published in 1947 Cmd 7206.
- ⁸Patents Act 1949, S.41.
- ⁹Restrictive Trade Practices Report concerning the Manufacture, Distribution and Sale of Drugs, Ottawa 1963 (RTCP Report).
- ¹⁰ibid at p.516.

- ¹¹Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-7 HMSO Cmnd 3410 (Sainsbury Report).
- ¹²ibid at p.46.
- ¹³Banks Report at p.115, para 402.
- ¹⁴On the harmonization of industrial property laws within Europe, see generally Chapter VI. When the Community Patent Convention comes into effect, an application for a Europatent which designates any E.E.C. country will lead to the grant of a community patent valid in all common market countries.
- ¹⁵Banks Report at p.117.
- ¹⁶Kefauver Report at p.25. Canadian RTPC Report at p.371.
- ¹⁷See Chapter I n.13.
- ¹⁸Kefauver Report at p.107.
- ¹⁹Patent Act 1977, s.14(3).
- ²⁰ibid.
- ²¹Canadian RTPC Report at p.521.
- ²²Kefauver Report at p.115.
- ²³Kefauver Report at p.131.
- ²⁴Banks Report at p.116.
- ²⁵Evidence prepared for U.S. Senate by Fritz Machlup supra n.4 at p. 79-80.
- ²⁶For detailed discussion of the Community Patent Convention, see generally Chapter VI.
- ²⁷Kefauver Report at p.106.
- ²⁸Canadian RTPC Report at p.100.
- ²⁹Patent Act 1949, s.41.

- ³⁰Banks Report at p.119.
- ³¹Patent Act 1949, s.41(1).
- ³²Banks Report at p.118-119.
- ³³Banks Report, in Chapter 14.
- ³⁴J.R. Geigy S.A.'s Patent [1964] R.P.C. 391 (P.A.T.), Hoffman-La Roche A.G.'s Patents [1969] R.P.C. 504 (P.A.T.), [1971] R.P.C. 311 (P.A.T.) [1973] R.P.C. 130 (Q.B.). These three decisions relate to the same application for a compulsory licence concerning the drug "Librium", Hoffman-La Roche A.G.'s Patents and Berk Pharmaceuticals Ltd's Application for a Compulsory Licence [1973] R.P.C. 587 (P.A.T.); Hoffman-La Roche & Co. A.G.'s Patents [1973] R.P.C. 601 (P.A.T.) application for a compulsory licence to produce the drug Valium; Fabwerke Hoechst A.G. (Sturm and Others) Patent [1973] R.P.C. 253 (P.A.T.).
- ³⁵See Blanco White, Patents for Inventions, London, Stevens & Sons (4th ed.) 1974 at p.379.
- ³⁶Sainsbury Report at p.49.
- ³⁷The Green Book at p.400.
- ³⁸Senate Bill No. s.1552.
- ³⁹Patent Act 1977, s.48.
- ⁴⁰Demarret, Patents, Territorial Restrictions and E.E.C. Law (1978) at p.86.
- ⁴¹Sainsbury Report at p.5.
- ⁴²Pharmaceutical Society of Great Britain, "The Industry: Ministers Speech at ABPI Dinner" Pharmaceutical Journal 6th May 1961 at p.381.
- ⁴³[1965] A.C. 512 (H. of L.), [1965] R.P.C. 261.
- ⁴⁴ibid at p.567, R.P.C. p.316-7.

⁴⁵Memorandum by ABPI, Health Services and Public Health
Bill No. 552/68. 22nd May 1968 at p.3.

⁴⁶Banks Report supra n.9 at p.117-8.

⁴⁷Patent Act 1977, s.55(c).

CHAPTER III

TRADE SECRET PROTECTION

1. Introduction to the Law of Trade Secrets

A pharmaceutical firm, having discovered a new product, need not apply for a patent. Instead of disclosing the formula to the world in return for a monopoly limited to twenty years only, the firm may elect to keep the formula a secret, to enjoy a perpetual monopoly by disclosing it to no one outside a privileged circle of employees and licensees all of whom will be bound by stringent restrictive covenants. Such trade secret protection will be available for all formulae regardless of whether they satisfy the patent law requirements of novelty utility and non-obviousness. The minority report attached to the Kefauver Report stated:¹

"It is not necessary for a firm to secure a patent. On the contrary they could operate a plant and produce a product under a secret process indefinitely whereas a patent grants a limited monopoly for seventeen years² in return for complete disclosure by the inventor. In many countries where patent protection similar to our own is not available there is a tendency for more secrecy in terms of production and processes than exists here in the U.S."

In this chapter it is proposed to examine the nature of trade secrets and the degree of protection afforded to them, the relative advantage to a firm of choosing the trade secret rather than the patent route, and finally whether, given the existence of a sophisticated patent system providing a twenty year monopoly for both products and processes with no special compulsory licensing provisions for food and medicines, it is necessary or desirable to leave alongside this system an alternative method of protection which allows the producer to retain a perpetual monopoly without the corresponding obligations of disclosure.

2. Nature of Trade Secrets

The law of trade secrets dates far back into English case law. The term is not used in any legislation. The rules are found in various cases but no one case provides a generally accepted definition of the nature of the beast.

In the U.S., the Restatement of Torts provides that a trade secret may consist of

"any formula, pattern, device, or compilation of information which is used in ones business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." ³

One of the leading English texts describes a trade secret as follows:

"The subject matter capable of protection may be an industrial secret, like a secret machine, process or formula or it may be industrial knowhow (an increasingly important ancillary of patented inventions); it may be information of any sort; it may be an idea of a scientific nature or a literary nature ... it may be a slogan or suggestion for a method of advertising, lastly the subject matter may be the product of work or expenditure of money or of trial and error or the expenditure of time." ⁴

Does this mean that trade secrets are "property"?

The above definition evades the issue and the case law yields no satisfactory solution. In some cases they have been referred to as property, in others as contract and in others again they have been treated as founded upon trust or confidence.

One learned writer has said: ⁵

"The above study of cases where the plaintiffs confidence has been breached reveals great conceptual confusion. Property, contract, bailment, trust, fiduciary relationship, good faith, unjust enrichment, have all been claimed at one time or another as the basis of judicial intervention."

There is no doubt that trade secrets have some attributes of property in that they may be assigned or licensed as part of a business but they are not property in the patent law sense because one attribute - the right to exclude all others - does not accrue to the trade secret holder. One influential writer has recently reassesed the argument that, when not based upon an express or implied contractual relationship, any action for breach of confidence is based on a proven relationship of trust and that there are no property rights, legal or equitable, in information.⁶

The pharmaceutical company is more likely to frame an action as an equitable one of breach of confidence or breach of contract, express or implied.

In the U.S. Supreme Court case of Du Pont de Nemours Powder Co v Masland, Holmes J. stated:

"Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied but the confidence cannot be. Therefore the starting point for the present matter is not the property or due process of law, but that the defendant stood in confidential relations with the plaintiffs or one of them."

The courts in both England and the U.S. have seen fit to protect the confidential nature of trade secrets regardless of whether they are correctly described as "property".

3. The Degree of Protection

Chemical formulae and processes have long been considered among the highest forms of trade secret but not every pharmaceutical formula will qualify as such. The U.S. Restatement lists six criteria which have met with approval in a number of cases:-⁸

- 1) The extent to which the information is known outside the business.
- 2) The extent to which information is known by employees and others within the business.
- 3) The extent of measures taken to guard the secrecy of the information.
- 4) The value of the information to the business and to competitors.
- 5) The amount of effort and money expended in developing the information.

- 6) The ease or difficulty with which information may be acquired or duplicated by others.

If a chemical formula qualifies for trade secret status the firm responsible for the development of the formula can use it for its own purposes only and is under no obligation to disclose it. Protection will last as long as the secrecy lasts and is lost on disclosure in a patent specification or trade journal or on disclosure to third parties in circumstances which do not import an obligation of confidence.

Trade secret protection is no defence against independent creation or reverse engineering both of which are a particular danger to the pharmaceutical firm. The drug industry is highly susceptible to the "Ripeness of Time Theory". The state of medical knowledge is such that several laboratories may be working simultaneously on a cure for the same complaint and may all be on the brink of making a similar discovery. The appearance of the first drug on the market will alert competitors to the fact that a solution is available and, even if careful study and reverse engineering does not yield the secret, the very

existence of the drug will provide an additional spur to research in rival firms.

Disclosure to competitors through theft or breach of a confidential relationship in circumstances where proof of the theft or breach is hard to come by may destroy trade secret status.

Recent cases have focused attention on another limitation of trade secret protection - public interest.^{8a} The courts will not intervene to restrain disclosure of confidential information if the public interest lies in disclosure. Cases on this issue have revolved around the conflict between the public interest in promoting business confidence through the protection of trade secrets and the public interest in a free press.^{8b}

The most recent case is Shering Chemicals Ltd v Falkman Ltd.⁹ The pharmaceutical company were granted an injunction to prevent the television broadcast of certain information concerning their drug Primodos, suspected of causing deformity in children before birth.¹⁰ The principle was accepted however that in certain circumstances the obligation of confidentiality may be overborne:

"If the subject matter is something which is inimical to the public interest or threatens individual safety, a person in possession of knowledge of that subject matter cannot be obliged to conceal it although he acquired that knowledge in confidence." 11

Where a firm is interested only in protecting its chemical formulae from discovery by competitors trade secret law will provide complete protection as long as the finished product cannot be reverse engineered, no other firm has been conducting research in the same area, strict security measures minimise the chances of theft or industrial espionage, the firm has issued no licences and the formula is known by very few employees all of whom are bound by restrictive covenants - a formidable list of prerequisites.

4. Employer/Employee Relationships

The fewer people with access to the secret information the greater will be the firm's chance of preserving its monopoly over production of a drug. However, in order to exploit a discovery commercially certain employees must be allowed access to the information. The pharmaceutical firm will usually ensure

that those employees are contractually bound to secrecy, often where they fail to do so the court will imply an obligation of secrecy:

"Whether bound by express contract or not, no employee is entitled to filch his employers property in whatever form that property may be, whether in the form of a secret process or goodwill or in some other form."¹²

To avoid uncertainty on the question of what constitutes a protectable trade secret, the pharmaceutical firm will enter into specific contracts with each employee containing the appropriate restrictive covenants.

Covenants which are too wide or too vague will be void as in restraint of trade unless the firm can establish that they are reasonable, founded upon good consideration, and clear as to their scope in terms of both time and place.

The distinction between the employer's secrets and the employee's skill and knowledge places a very real, although ill defined, restriction on the extent of the protection. In United Indigo Chemical Company Ltd v Robinson,¹³ the plaintiff's former chemist could not be enjoined from using a formula learnt while in the plaintiff's employ because the court refused to consider

the information secret. The defendant had not been told when he joined the firm that he would be put in possession of secret information and he had no difficulty in discovering the exact quantities of the elements involved in the manufacture of the chemical Algaloid. By contrast, in Printers and Furnishers Ltd v Hollaway and Others¹⁴ the fact that the defendant had been able to commit a chemical formula to memory did not make it a part of the employee's skill and knowledge.

To minimise problems over what information is protectable firms will usually list in an appendix those formulae regarded as secret and the restricted fields of activity.

5. Licensor/Licensee Relationship

The use of the term "licence" in a trade secret context is something of a misnomer - no doubt a term borrowed from patent law.

"It should be remembered that it is not apt to speak of licensing a trade secret (although this is the terminology most usually used.) What the discloser is in fact doing is disclosing secret matter to the disclosee with the undertaking that he will not disclose it to anyone else except pursuant to a secrecy agreement. In return, the disclosee undertakes to pay a royalty for use

during continued secrecy and not further to disclose the matter contrary to the terms of the agreement." ¹⁵

The distinction between such a conditional disclosure and a patent licence arises from the fact that, as explained above, trade secrets, while possessing certain attributes of property, are not property in the patent sense.

"In its original and true sense, a licence is the grant by the proprietor of a right of an authority to do that which, but for that authority, would constitute an infringement of his right. This definition assumes the prior existence of a right of property protected by common law or statute. In the field of Intellectual Property the rights in question relate to letters patent, trade marks, registered designs and copyright." ¹⁶

If demand for a new drug is heavy the pharmaceutical firm may not be able to meet it and will "license" other firms to produce the drug upon payment of a royalty. Under these circumstances disclosure will not destroy the trade secret status of a formula. The courts, quite rightly, protect the confidentiality of secret information regardless of whether the arrangement is correctly termed a licence.

6. Relative Merits of Trade Secrets and Patents

The drug firm can choose to protect its new product either through the patent or trade secret law. The choice will usually depend on the nature of the drug. Trade secret law is wider and will protect many formulae which do not have the required degree of novelty for a patent.

Indeed trade secret protection extends further to such things as customer lists and advertising programmes. For such material trade secret protection is the only option and the firm relies heavily on it. There is also a grey area of formulae which the drug firm feels may be patentable but are of doubtful novelty. The firm will need to consider carefully the relative merits of the two forms of protection for such material. Trade secret protection will certainly be available, it will be perpetual, and there are no obligations of disclosure. There will be no need to expend time and money preparing detailed patent specifications, protection will be immediate on the terms and conditions specified by the trade secret holder. However, there are disadvantages; the firm choosing the trade secret route must exert strong pressure on licensees and employees to maintain confidentiality, there is a

constant danger of negligent or inadvertent disclosure in circumstances which do not indicate the trade secret nature of the information. There will be problems of enforcement as Xerox machines and advanced photographic equipment make thefts constantly harder to detect. Once a secret is out problems of tracing will practically assure the victim's inability to stop competitive use.

Furthermore, if the firm entertains genuine doubts about the novelty and consequent patentability of a formula the chances are that another firm working in the same area will independently develop a similar product. Not only will trade secret law provide no protection to the original producer, any publication of the formula by the second firm will destroy trade secrecy for both firms. In Kewanee v Bicorn¹⁷ Chief Justice Burger said of the two forms of protection:-

"Where patent law acts as a barrier, trade secret law functions relatively as a sieve."

This all seems to point in favour of patent protection but the drug firm should exercise caution before opting for this apparently attractive alternative. Not

only will the monopoly be limited to twenty years duration, the patentee will be obliged to disclose to the world full details of the formula. On publication of the specification trade secret protection is lost and can never be regained even if the patent is subsequently found to be invalid. This is a very real danger as the mere issue of a patent is not conclusive on the question of validity and standards of patentability applied by the courts are significantly higher than those applied by the Patent Office. The drug firm therefore will only choose the patent route if it is reasonably certain that the patent will be valid or, at least, has sufficient appearance of validity that no rival firm will feel confident to embark on the lengthy and expensive process of challenging the patent.

In the case of the clearly patentable invention the firm will be well advised to ignore the trade secret option and apply for a patent provided they are prepared to expend the necessary resources to "police" it. The time and expense involved in filing an application will generally be more than compensated for by enjoyment of an absolute twenty year monopoly. Furthermore enjoyment of the position of sole producer for twenty years will place

the firm in a strong position to engineer an extension of the monopoly through manipulation of other intellectual property laws.¹⁸ The drug industry is in a state of perpetual motion and many patented formulae will become absolute within twenty years in any event. There can be no doubt that the shorter stronger patent protection is preferable to trade secret protection.

7. Should both Alternatives be Available for the
Newly Discovered Drug?

Given the existence of a strong patent system available for both products and processes and the abolition of the special compulsory licencing provisions for food and medicines, it is necessary or desirable that the trade secret alternative should exist? Society regards monopolies per se as undesirable and they are only tolerated in the patent field because of the belief that society benefits from the resulting incentives to research and the disclosure of technical information. Such monopoly protection is only allowed if the firm satisfies the stringent requirements of novelty, utility and non-obviousness.

What is the justification for retaining alongside this heavily regulated system of protection a subsidiary common law method whereby the courts will enforce a perpetual monopoly while society enjoys none of the supposed advantages of disclosure and enhanced research programmes?

The main justification is a moral one expressed by the U.S. Court in E.I. du Pont de Nemours & Co. Inc. v Christopher¹⁹

"To obtain knowledge of a process without spending the time and money to discover independently is improper unless the holder voluntarily discloses it or fails to take reasonable precautions to ensure its secrecy."

Alongside the moral issue, there are economic advantages in retaining trade secret protection for processes which do not satisfy the patent criteria. One justification is that most frequently cited in support of patents - the encouragement of invention. Unless a firm can keep information about its new processes secret, regardless of their potential patentability, it will be unwilling to incur the research costs. It will also be reluctant to allow any but the most vital employees to have

access to relevant information and would be reluctant to grant licences - all factors resulting in under-utilisation of the invention. Trade secret law therefore encourages invention in areas where the patent law does not reach; competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, inventions.

The existence of trade secret protection for customer lists and advertising copy is unlikely to encourage research and development but may, nonetheless, promote business efficiency and encourage firms to initiate new and individualised plans of operation. Furthermore it is hard to see how society would benefit from forced disclosure of such material.

The availability of trade secret protection for unpatentable or doubtfully patentable formulae prevents the over-burdening of the patent office with dubious applications and the issue of many invalid patents. Even those dubious applications which are finally rejected will have been held in limbo for many months whereas they could have been made available for exploitation at an early stage through trade secret protected licences.

There is therefore no compelling reason to restrict trade secret protection for unpatentable formulae and the two systems of protection can operate side by side.

Trade secrets are harder to justify when the formula in question is clearly patentable. The firm has the option of protecting its invention through the patent law with the corresponding advantage to society of disclosure. Abolition of trade secret protection for such inventions will merely force all producers of new drugs to obtain patents and disclose their formulae to the world. The denial of protection would not result in reduced incentives for research because the patent option will always be available. Firms will not hesitate to give licensees or employees full access to all information as all will be disclosed anyway in the patent specification if that is the only option.

The solution is attractive but unfortunately clearly unworkable. If trade secrets serve a valuable function in the realm of non-patentable material the same protection must be given to all material. A patentable/non-patentable distinction would mean that no firm could be certain of the status of their trade secrets

until their patent application had been rejected. Not only would this lead to considerable uncertainty, it would also, in many cases, promote the anomalous situation whereby the party with most to gain from the failure of a patent application would be the applicant himself. So we are left with a situation where trade secret protection is available for every trade secret regardless of patentability.

The inherent weakness of trade secret protection will however encourage most firms to seek the patent alternative wherever possible. There is no compelling need to abolish or restrict trade secret protection because the chances of a pharmaceutical firm which has discovered a new patentable drug sitting back and relying on the law of trade secrets to protect their discovery are remote indeed.

NOTES TO CHAPTER III

- ¹Report of the Committee on the Judiciary United States Senate made by its sub-committee on Antitrust and Monopoly pursuant to Senate Resolution 52, 87th Congress, 1st Session, Report No. 448 (Kefauver Report) at p.263. Individual views of Senator Everett McKinley Dirksen and Senator Roman L. Hruska.
- ²The U.K. Patents Act 1977 provides for a twenty year period of protection.
- ³U.S. Restatement of Torts, 1st Ed., para 757 (1939).
- ⁴Turner, The Law of Trade Secrets. London, Sweet & Maxwell Ltd 1962 at p.4.
- ⁵Forari, A Comparative Outline of the Law of Trade Secrets in Australia and the U.S.A., 54 Journal of Pat. - Office Society, 8 August 1972. p.545-6.
- ⁶Stuckey, The Equitable Action for Breach of Confidence Is Information ever Property? 1981 Sydney Law Review 402,404.
- ⁷(1917) 244 U.S. 100, 37 Sup Ct Rep. 575.
- ⁸U.S. Restatement of Torts 1st Ed. para 757.
- ^{8a}This topical issue is likely to be considered in the Law Commission Working Paper on Breach of Confidence due for publication within the next few weeks.
- ^{8b}British Steel Corporation v Granada T.V. Ltd [1980] 3 W.L.R. 744 (H. of L.).
- ⁹[1981] 2 W.L.R. 848.
- ¹⁰Lord Denning M.R. delivered a strong dissenting judgment championing the cause of press freedom ibid at p.851.
- ¹¹supra n.9 per Lord Shaw at p.869.

¹²Triplex Safety Glass Co v Scoria [1938] Ch. 211 at p.217 (1938) 55 R.P.C. 21 at p.27 per Farwell J.

¹³(1932) 49 R.P.C. 178 (Ch).

¹⁴[1965] R.P.C. 236.

¹⁵Turner, the Law of Trade Secrets, London, Sweet & Maxwell Ltd 1962, p.463.

¹⁶Lane, English Law and Practice relating to International Licensing Agreements, The Bobs-Merrill Co., Indianapolis, New York 1965 at p.87.

¹⁷(1974) 416 U.S. 470.

¹⁸The methods by which a firm can achieve this "extended monopoly" are discussed in the succeeding chapters.

¹⁹(1970) 431 F. 2nd 1012.

CHAPTER IV

TRADE MARKS & PASSING OFF

A pharmaceutical company, having enjoyed a privileged position as the patentee of a chemical formula for nearly twenty years, will, as the expiry date approaches, look around for an alternative to patent protection.

One of the first areas to explore is the possibility of protecting the name and the appearance of the drug. With this aim in mind pharmaceutical firms have protected under the law of trade marks and passing off their brand names, the colour combinations of their capsules, the shape of their pills and capsules and their containers.

The belief is that, during the term of the patent, both physicians and patients will have come to associate the name and appearance of the drug in question with its chemical properties and therapeutic effects. The hoped for result is that physicians will continue to prescribe by the

brand name rather than turn to possibly cheaper generic equivalents and that patients will refuse to take drugs which are not identical to those which have already successfully relieved their symptoms.

This chapter explores how the pharmaceutical firms have made use of the laws of passing off and trade mark registration to extend their monopoly on production of certain popular drugs.

1. The Two Forms of Action Considered¹

The law of passing off and the law of trade mark infringement are both based on the single principle that no trader should be allowed to represent his goods or business as those of another.²

A passing off action in England is governed by the common law and equity and is a generalised form of the action to restrain infringement of trade mark. It is the right of a person or trader who uses a name or mark or distinguishing get up to present his wares to the public to prevent another person from using a similar name or get up to deceive the public.

As this is also the rationale behind trade mark law the two actions are frequently combined although the term "infringement" is employed only where the plaintiff bases his case on a registered trade mark.

The system of trade mark registration developed out of the laws of passing off. Early cases of infringement were regarded as a specialised form of passing off. It was incumbent upon the plaintiff to establish that the alleged trade mark did indeed identify his goods and success against one party was no insurance against further infringement by other traders. The need for statutory control was recognised and the Register of Trade Marks was established in 1875. Registration was prima facie evidence of the right of a registered proprietor to exclusive use of the mark.³ Today, the Register is divided into two parts, A and B, with part B conferring lower rights than registration under part A.

There are certain differences between infringement actions and passing off actions, as explained by Greene M.R. in the Saville Perfumery Case;⁴

"(1) It [the law of infringement] is concerned with only one method of passing off namely, the

use of a trade mark and (2) the statutory protection is absolute in the sense that, once a mark is shown to offend, the user of it cannot escape by showing that, by something outside the actual mark itself he has distinguished his goods from those of the registered proprietor."

Thus, when considering whether the firm "Gala Ltd of London" had infringed the trade mark "Goya", he said that, while the addition of the words "of London" may be adequate to differentiate the name in a passing off action, the addition was of no avail in an infringement action.

In Hoffman-La Roche v DDSA⁵ however, the addition of the letters DDSA to an otherwise identical capsule were too small to amount to a valid defence to a passing off action. If they had been more striking they may have exonerated the defendants from liability.

One further case illustrates the distinction between the two actions; William Hollins & Co Ltd v Cotella Ltd⁶

"There is a clear distinction in my view between an action for infringement of trade mark and an action for passing off. In considering whether a particular device or design does constitute an infringement of trade mark, the trade mark and the offending design or device or word, whatever it may be, must be considered together for the

purpose of comparison and nothing else has to be taken into consideration. One has to look at the two marks and see whether the defendant's mark is such as to be calculated to deceive....whereas in the case of passing off the court has to take into consideration the whole of the subject matter." 6a

If the drug companies rely on passing off to protect the appearance of their capsules the onus will be on them to establish that the get up is distinctive of their capsule or pill exclusively. The next step is to establish that the defendant's use of a similar get up is likely to deceive or confuse the public. A person or company is entitled to the exclusive use of a name or mark from the time at which it can be established that the mark denotes his goods or services in the market.

If the drug companies register their colour combinations as trade marks they need not prove a reputation and can rely on their title as proprietor of the mark. The certificate of registration is prima facie proof of the validity of registration.

However, nothing in the Trade Mark Act will affect a manufacturer's rights in passing off. It is no bar to a passing off action that the name or get up which has been

imitated may have been registered as a trade mark and similarly it will be no defence to a passing off action that the defendants mark has been registered. (Such a registration would, however, provide some prima facie evidence of a right to use the mark and may prevent the court from granting interlocutory relief.)

There is a prospect of change in both areas of law with the present trend in Europe towards harmonisation of intellectual property laws. The Treaty of Rome has already overridden many of the restrictive effects of national trade marks and plans are afoot to establish an EEC wide registration system to exist alongside national schemes. No doubt many firms will continue to rely on national law because of differences in language or because their business is purely local. However national trade marks may not be used as barriers to trade within member states.

2. Protection for Names and Words

In order to qualify for protection in either a trade mark infringement action or passing off action the name of a product must be indicative of its source.⁷ Descriptive words are not registrable as trade marks nor will they be protected under the law of passing off unless

they have acquired a "secondary meaning". The case of Reddaway v Banham⁸ is illustrative of how a descriptive name may acquire a secondary meaning. The plaintiffs brought an action to restrain the defendants from selling belting known as "camel hair belting" on the basis that "camel hair belting" meant exclusively the belting which the plaintiffs had manufactured under that name for years. The defendants argued that the name was descriptive and that they were merely telling the truth when they described their product as "camel hair belting". Lord Herschell said:

"I think the fallacy lies in overlooking the fact that a word may acquire in trade a secondary specification differing from its primary one and that it is used to persons in the trade who will understand it and be known and intended to understand it in its secondary sense. It will none the less be a falsehood because in its primary sense it may be true."⁹

(The facts in this case, however, were slightly unusual in that it had been believed by most people, including the plaintiff, that the name was a "fancy name" and it only emerged during the conduct of the trial that the main component of the belting was in fact camel hair.)

The main criterion for protection is that the name or mark must be distinctive of the manufacturer. A relatively early case in the pharmaceutical field was that of A.G. & General Council of Medical Education v Barnett Proprietories Ltd.¹⁰ The publishers and owners of British Pharmacopoeia failed to prevent Barnett Proprietories Ltd, the makers and vendors of medical preparations from using the letters BP in connection with their goods. There was no evidence that the words BP were distinctive of the plaintiffs goods.

3. Protection for the Brand Names of Pharmaceutical Products

As indicated in chapter one, a drug may be designated by various names. When first identified, if derived from a natural source, a potentially useful compound receives a systematic chemical name which describes the nature of the drug in chemical terms. The name must reveal every one of the compounds concerned and no other. The end result is that the chemical name will be very long and virtually unintelligible except to the specialist in the field.

Drugs which are either single chemical compounds or natural aggregates of substances such as extracts of plant and animal origin will also have a "generic" or "non-proprietary" name. The term "non-proprietary" is more accurate and descriptive because, contrary to what one might expect, the name does not relate to a class or "genus" of drug but to one specific drug which may be manufactured by a number of different producers. The term "generic drug" is of American origin and has become part of the accepted terminology to describe an unbranded drug. In the same way the expression "generic manufacturer" has been used to designate a manufacturer specialising in the fabrication of generic drugs. When many firms manufacture the identical drug, each under a brand name of its own, the need for a generic non-proprietary name is obvious. The determination of such a name is a matter of international concern. Three bodies; The American Medical Association's Council on Drugs, The British Pharmacopoeia Commission and the World Health Organisation all publish approved generic or non-proprietary names in advance of the acceptance of monographs in their respective volumes. Firms are encouraged to use these names together with the proprietary or brand name at the time of marketing to eliminate confusion but certain firms use their brand names only thus

promoting and benefiting from the confusion. Generic names may not be appropriated by any firms as trade marks nor may the chemical name ¹¹ (although the chemical formula represented by the latter may be the subject matter of a patent). The large firms therefore register a short snappy brand name as a trade mark for the manufacture of the generic drug.

The unregistrability of generic names was illustrated in the "Shredded Wheat" case.¹² Although this case concerns the food, rather than the drug, industry the principle is the same. The mark "Shredded Wheat" was expunged from the Register on the application of the Registrar on the ground that it had become descriptive of the product itself and was not distinctive of the company's make of the product. The court was particularly influenced by the fact that the name had originally been used to describe a patented article. The question was litigated in both Canada¹³ and the US¹⁴ with the same outcome. Mr Justice Brandeis delivered the opinion of the US Supreme Court:

"The plaintiff has no exclusive right to use 'Shredded Wheat' as a trade name for that is the "generic" term of the article which describes it with a fair degree of accuracy....since the term is

generic the original maker of the product acquired no exclusive right to use it." ¹⁵

And later:

"Since during the life of the patents, shredded wheat was the general designation of the patented product there passed to the public, on the expiration of the patent, not only the right to make the article as it was made during the patent period, but also the right to apply thereto the name by which it had become known." ¹⁶

Thus, it is the brand name under which the product is marketed which is registered under the Act. The purpose, as with any other trade mark, is to distinguish one firm's preparation of a generic drug from those of other firms or, where there is no other manufacturer, to identify the product with the sole manufacturer. There is, however, one difference between the use of registered trade names in this area and any other industry: instead of using a registered mark or name to denote a line of products, the firm will select a separate trade mark for each drug it sells with the obvious aim of displacing the chemical or generic name. The concurrent existence of the generic name (for example, in the British Pharmacopoeia) will reduce the danger of expungement from the register.

The Canadian RTPC¹⁷ condemned the use of brand names, as applied to single drugs, because the name indicates nothing about the nature of the drug and may vary from country to country thereby causing confusion. Furthermore, brand names, in the opinion of the Commission, resulted in increased expenditure on advertising and promotion and a reduction in competition through the pharmacist's inability to dispense anything but the branded drug if prescribed by name.

The Commission, while not advocating the abolition of trade mark protection, recommended that labels, orders and other descriptive material be required to carry the generic name of the drug prominently and in type at least as large as that used for the brand name.¹⁸

The Sainsbury Committee went even further:-

"We therefore recommend that there should be no brand names for new pharmaceutical products licensed on the advice of the medicines commission which we propose should be set up and that all such products, whether the subject of patents or not, should be marketed only under a name approved by the Commission with or without the name or house mark of the manufacturer. The Trade Marks Act should be appropriately amended. It would then be open to any person to use the approved name so long as no patent was violated."¹⁹

Not surprisingly, this bold recommendation was not adopted. It will be recalled from chapter one that one of the main reasons given for retaining protection for brand names was the need to protect the British pharmaceutical industry. However, British firms have a good reputation abroad and there is no reason why a British medicine should be more difficult to sell because it is advertised under a single accepted name provided the reputation of the British company is clearly associated with it.

Opponents of the abolition of trade mark protection (in particular the Association of the British Pharmaceutical Industry) maintain that generic drugs are not as safe as trade marked products. They also maintain that physicians are more cost-conscious than the various reports have given them credit for, and that when they prescribe a particular brand they do so because they have faith in the company and the quality of its product.

If physicians are genuinely concerned about the source of the drug, there would, however, be nothing to prevent them from specifying a particular manufacturer's

name alongside the generic name on the prescription. This would require positive action from the physician and would avoid the situation where he prescribes a brand name simply from habit.

The generic producers maintain that fears about the quality of generic drugs are largely exaggerated. Many drugs are manufactured and sold in bulk by large producers so that the generic houses often deal only in bottling, labeling and packaging. In these cases identity of the quality of the product is guaranteed by identity of source. In other cases quality control and testing could be carried out by the Medicines Commission or a similar body to ensure that all drugs packaged under the same generic name conform to the same standard.

The cost saving advantages of generic prescribing have been accepted in the US but they have adopted a different method from that proposed by the Sainsbury Committee to achieve this aim. Instead of abolishing trade mark protection for pharmaceutical brand names, many states have passed mandatory drug substitution laws whereby, even when a brand name drug is prescribed, the pharmacist is obliged to substitute the cheapest generic equivalent unless the physician specifically states otherwise.²⁰

The British approach has been less coercive. Hospitals (by far the largest consumers) have always purchased by the generic name. As far as the independent general practitioners are concerned, the Department of Health and Social Security provides them with a list of approved proprietary medicines and a recommendation to avoid prescribing branded proprietaries for which a standard equivalent is available at a lower cost.

It seems, however, that many general practitioners continue to prescribe by brand name probably out of habit and because the names are more easily memorable. It is not too late to follow the Sainsbury Committee's proposal and abolish protection for brand names. The writer is aware that this may complicate present efforts to harmonise trade mark law in the EEC. However, the proposal is in conformity with the general trend discernable in the US and Canada and an attempt should be made to persuade member states to exclude pharmaceutical names from registration as European Trade Marks.

4. Protection of the Total Appearance of the Drug

Brand names are presently still registrable as trade marks, so, it appears, are the drugs themselves. Registration of the name will not assist the pharmaceutical manufacturer if the physician takes heed of the DHSS pressure campaign and prescribes generically. The pharmacist may dispense the cheapest equivalent and the consumer, the patient, will trust the pharmacist's choice - or will he? If the physician, when writing a repeat prescription, switches from a brand name to a generic name (probably because the patent has recently expired) the patient will still expect his next supply to look the same. If the appearance of the drug is a registered trade mark the generic manufacturer will be barred from imitating that appearance. Even without registration, the generic manufacturer may be barred, under the laws of passing off, from imitating the get up. Consequently the generic drug may be rejected by those patients who want "the same again". The busy general practitioner or pharmacist may not have time to convince the unhappy patient that the drug in question is identical to that received previously and the GP may avoid problems of rejection by simply prescribing the original branded drug.

The fundamental issue is whether the patient who demands "the same again" wants the same drug in the sense of a drug of the same chemical composition and therapeutic effect or the same drug emanating from the same source. If the latter is correct then generic manufacturers are rightly barred from imitating the get up of the brand name drug and thereby deceiving the public as to source.

In this paper, the position is taken that the patient is more concerned with the therapeutic quality of the drug than its manufacturing source. The consuming public are not recipients of the drug company's advertising material and consequently know little about the various companies. In most cases they do not know or care by whom a certain drug is manufactured but they care very much whether the drug is of the correct chemical composition.

The weakness of this position, as the writer acknowledges, is that in no English case has evidence been submitted to indicate what the public understand by the distinctive name and appearance of a drug.

In the absence of such evidence, however, the onus surely rests upon those seeking to assert an exclusive

right to justify that right and this the drug companies have so far failed to do. They rely heavily on the Yorkshire Relish Case²¹ to support their contention that the public care about the source of a product even when they do not know the identity of either the original manufacturer or its immitators:

"A person whose name is not known is just as much injured in his trade as if his name was known as well as his mark. His mark, as used by him, has given a reputation to his goods. His trade depends greatly on such reputation. His mark sells his goods."²²

The principle is now embodied in the Trade Mark Act 1938 (UK)²³ and in the context of the above case it is no doubt valid. But can a drug be equated with a relish? Many variations of taste and smell may flow from the concoction of a relish by different chefs. Each will endow it with something of his own personality and subtle distinctions will be noticeable to the purchaser. In the case of prescription drugs however, the purchaser will notice no distrinctions of taste or smell. The only distinctions will be superficial markings deliberately imposed by the pharmaceutical company with a view to fostering the minds of the public an association between the markings and the nature of the drug.

The recipe for Yorkshire Relish was a secret and no one else could manufacture it to precisely the same recipe. It is understandable therefore that the consumer should be concerned about source:

"Now the thing that is sold as Yorkshire Relish is not Yorkshire Relish in the sense of being the same chemical composition, the sense of it having the same taste, in the sense of it being so properly assimilated to the preference of the persons who take it, either in smell or in taste, as the original composition."²⁴

Generic drugs however will be of the same chemical composition as the brand named drugs and there will be no variations in smell or in taste. Admittedly, in the nineteenth century case of Massam v Thorley's Food,²⁵ the Defendants were enjoined from using the name "Thorley" without qualification to mislead the public into supposing that the article sold by them was manufactured at the original establishment of one Joseph Thorley. It was considered irrelevant that the product was made using the same ingredients and to the identical recipe because the public had faith in the name as indicative of a reputable manufacturer.

The principle of the case is not, however, applicable to the pharmaceutical industry because there is no evidence that the public are aware of, or put their faith in, the name of a particular manufacturer. Until the pharmaceutical industry can adduce positive evidence in support of its case, it should not be presumed, in its favour, that patients know or care about the source of their drugs.

The most effective way for pharmaceutical companies to secure a monopoly on the appearance of their drugs is to register their get up as a trade mark. In the writer's opinion, registration of the appearance of a drug is not only undesirable, it rests on a dubious legal foundation.

The definition of "mark" in the 1938 Act includes

"a device, brand, heading, label, ticket, name, signature, word, letter, numeral, or any combination thereof."

The definition is not exhaustive but does indicate an intention on the part of Parliament to provide for registration of marks which are capable of existing independently of the goods themselves.

In order to be registrable under part A of the register, the mark must contain one or more of the five essential particulars enumerated in s.9(1) of the Act. The last category is a "sweeping up" provision providing for registration of "any other distinctive mark". It is under this section that pharmaceutical firms have succeeded in registering the physical appearance of a drug.

"Distinctive" is defined in ss.9(2) and 9(3) of the Act.²⁸

The leading case in this area is Smith Kline & French Laboratories Ltd v Sterling Winthrop Group Ltd.²⁹ The appellants wished to register ten trade marks in respect of pharmaceutical substances sold in pellet form within coloured capsules. The respondents opposed registration on the ground that the colour combinations were not "marks" or "trade marks" within the definition contained in s.68 of the Act and were not "adapted to distinguish within s.9. Furthermore it was alleged that the colour combinations contravened s.11 in that they were likely to cause deception and confusion amongst persons taking the medicine in capsule form with the risk of serious consequences.³⁰

Lord Diplock did not find that registration of the marks would cause confusion. He had no hesitation in holding that a mark could be three-dimensional and could cover the entire surface of the goods. Furthermore, the trade mark was held to be distinctive within section 9.

The judgment requires careful scrutiny particularly in view of the fact that when a similar application was previously considered by Windeyer J. in the High Court of Australia the mark was held to be unregistrable because it could not be described and depicted as something apart from the goods to which it was applied.³¹

Lord Diplock considered the definitions of trade mark and mark in s.68 and continued:

"My Lords, I see nothing in this context that requires one to exclude from the definition of trade mark a mark which covers the whole of the visible surface of the goods to which it is applied. Such a mark is as capable of indicating a connection in the course of trade between the goods and the proprietor of the mark as it would have been if it had only covered half or three quarters of the visible surface. No one has been able to point to any business purpose that would be served by drawing a distinction between marks that cover the whole and those which cover a part of the surface."^{31a}

Lord Diplock also considered the Trade Mark Rules 1938 which require the application for registration to contain a representation of the mark which is usually a drawing but may, as in this case, be a specimen of the mark. He said:

"I see nothing in these rules to require a trade mark to be two dimensional only, or to exclude from registration a mark which covers the whole of the visible surface of the goods." ^{31b}

In the writer's opinion, there is a distinction between a mark which covers a part of the article and the entire get up of the article. The definition of mark contained in the statute, although not exhaustive, does imply something separate from the thing it is affixed to. All the examples given are capable of physical application to an article.

The Court of Appeal, grappling with the same problem of interpretation,³² referred to various dictionary definitions of "mark" but could not find one which included the entire appearance of an article without qualification.

"The definition of 'mark' in the statute is not confined to the items it is said to include and we were invited to consider a number of dictionary definitions. Chambers (1901) includes 'a visible sign, that by which anything is known, a badge' Chambers (1952) includes 'a visible indication or sign; a distinctive device; a brand; a streak; smears or other local modification of appearance' Murrays Oxford Dictionary has a main heading III 'a sign, token, indication' and thereunder numbered arabic 10 'an appearance action or event that indicates something, a sign, token, symptom' and further numbered arabic 11 'a sign affixed or impressed for distinction' and '(a) a device, stamp, seal, label, brand, inscription, written character or the like placed upon an article as an indication of ownership or origin'"³³

A consideration of the remainder of the statute throws no light on the question. Section 16 is the only one to deal specifically with colours but the section clearly does not envisage the registration of colours per se as trade marks.³⁴

Lord Diplock accepted the authority of Reddaways Application³⁵ for the proposition that a mark need not be distinct from the article. In that case Warrington J. held that three coloured lines which extended throughout the entire length of a hose were capable of registration provided the mark was limited to the colours red and blue and extended throughout the fabric.

"My Lords, I can see no sensible distinction between the mark registered in the Reddaway case and one which, in addition to the blue and red stripes, involved the application of some colour to the remaining external surface of the hose throughout its length, nor can I see any sensible distinction between such a mark and the marks sought to be registered in the instant case."³⁶

In the writer's opinion, Reddaways case may well have been decided differently if the entire external surface of the hose had been coloured. Such repetition would not have been a "mark" as it would have amounted to the appearance of the hose itself.³⁷ The clearest illustration of this was given by Buckley L.J. in the Court of Appeal:

"If a red pillar box was painted blue no one could, in my opinion, say that it bore a blue mark or that it had been marked blue. If, on the other hand, a blue band of perhaps two inches wide was painted around its waist one might very well reasonably say that it had been marked with a blue mark. In the one case it has ceased to be a red pillar box, in the other it remains a red pillar box but distinguished by a blue mark on it."³⁸

It is worth noting, however, that in a subsequent case the court allowed registration of the words "Blue Parrafin" although they were descriptive of the product in its entirety and not a several element thereof.³⁹

In Re James Trade Mark⁴⁰ the plaintiffs registered as a trade mark a design for dome shaped blocks of lead which was impressed upon all lead sold regardless of shape. The registration was allowed to stand only because the applicants were not claiming the sole right of selling lead in that shape but merely the right to use the dome shape as a trade mark on all lead sold by them. Lindley L.J. began his judgment by saying:

"We must be careful to avoid a confusion of ideas. A mark must be something distinct from the thing marked. The thing itself cannot be a mark of itself."⁴¹

The Court of Appeal in the Smith Kline & French case rejected the trade mark application on the strength of Re James but, in Lord Diplock's view, this case was irrelevant. He considered that the "thing marked" was the pharmaceutical substance and the "mark" the various colours applied to it. There appear, however, to be no other reported cases in which the total external appearance of the article in question has been registered.

In the Irish case of Parke Davis v Comptroller of Patents Designs and Trade Marks⁴², decided under similar legislation, a coloured band encircling the middle of pharmaceutical capsules was held to be a mark. The case is analagous to Buckley L.J.'s red pillar box with a blue band and is a more sound application of the statute.

It appears, however, that the Smith Kline & French case has now made it possible for the drug companies to obtain a trade mark registration on the total appearance of their capsules. The view is reinforced by the present draft of the European Trade Mark Convention which provides that not only will traditional elements such as names and prints serve as trade marks but also "shapes and articles of packing and all other signs which distinguish the goods or services of an undertaking."⁴³

If a firm neglects to register the appearance as a trade mark, or is unsuccessful in its application, the get up will still be protectable under the law of passing off. Indeed, even counsel for the defendants conceded in the Smith Kline & French case that the use of marks so nearly resembling Smith Kline and French's as to be deceptive would amount to a passing off at common law.⁴⁴ No doubt

counsel had in mind the case of Hoffman-La Roche v DDSA.⁴⁵ The plaintiffs in that case succeeded in enjoining DDSA from manufacturing green and black capsules containing the drug Chlordiazepoxide (CDP). The plaintiffs sold the drug, under the brand name Librium, in green and black capsules. "Librium" was a registered trade mark but the capsule was not. (No doubt, if the Smith Kline & French case had been decided five years earlier the capsule, as well as the name, would have been registered.) DDSA, after considerable argument, managed to secure a compulsory licence and proceeded to manufacture the drugs in similar coloured capsules, the only distinction was that, instead of the word "Roche", the capsules bore the letters "DDSA". Neither counsel nor the court paid much attention to the marking of the capsules despite the finding in Schweppes v Gibbons⁴⁶ that the placing of the defendant's name upon an allegedly copied product precluded the possibility of deception and absolved the defendants from liability in passing off. The DDSA marking was probably too small to be considered significant but more could have been made of this point particularly as one of the doctors testifying in a similar case⁴⁷ maintained that patients tend to inspect their drugs carefully and are apt to notice details of markings on the tablets and any minor differences.

It will be more difficult to win a passing off action where the capsule design or tablet is "ordinary" in appearance. Roche were unable to prevent Berk Pharmaceuticals copying their yellow or white Valium tablets.⁴⁸ Berk Pharmaceuticals, having obtained a compulsory licence to manufacture Diazepam, proceeded to employ the Roche colour scheme; white or yellow tablets according to dosage. Although they freely admitted that they had copied the Roche colour scheme with a view to securing acceptance from consumers, they were not guilty of passing off because, in the words of Russell L.J.;

"the evidence does not sufficiently establish that the very ordinary appearance of the plaintiffs white and yellow DZP tablets has led consuming patients to attribute them to one manufacturing trade source or provenance; and unless there be such an attribution the defendants substantial copying of that very ordinary appearance cannot be more than a representation that it contains the medicament DZP."

The reason that Roche failed was that the tablets were not sufficiently distinctive. The court did not question whether the public are concerned about the source of a drug rather than its therapeutic content.

5. Marks Partially Covering the Surface of the Goods
 & Functional Features

Purely functional features are open to the world apart from the protection of the patent law. The position becomes complicated when the functional feature is clothed in a distinctive guise. Can that distinctive guise be protected even though it serves a purpose?

In J.B. Williams & Co v Bronnley,⁴⁹ Fletcher Moulton L.J. said that the get up of an article means a "capricious addition" such as the colour or shape or the wrapper. He would not grant protection to anything which had a value or use as part of the get up.

However, only one year later the House of Lords modified this rule in Edge v Niccolls.⁵⁰ This case involved the imitation of the get up of the plaintiffs laundry blue. The blue was parcelled up in a porous cloth bag with a handle in the form of a stick which enabled the colour to be dissolved in water without staining the hands of the operator. The plaintiff's predecessor had initially taken out a patent on the blue but it was revoked before the plaintiffs took over the business. The Court of Appeal⁵¹ attached importance to the revoked patent and

found that the stick was useful and therefore not protectable. Cozens-Hardy said:

"I do not think that the useful part of an article, as distinct from an ornamental addition, can be regarded as part of the get up of the article. No length of exclusive use can entitle a man to a monopoly in the manufacture and sale of a useful combination not protected by a patent."⁵²

Similarly Farwell L.J. said:

"The claim is, in my opinion, founded upon a misconception of the meaning of 'get up', that word implies something extraneous to the article not the article itself."⁵³

This is consistent with the Williams v Bronnley approach, but the decision was reversed by the House of Lords.⁵⁴ Lord Gorrell paid no attention to the revoked patent and found a distinction between any stick and "the stick" as used by the plaintiffs. An injunction was granted restraining the defendants from imitating the plaintiffs' stick although they were free to manufacture the product with a stick of a different shape.

English authority therefore indicates that a feature may be protectable notwithstanding that it also

serves a function. In the pharmaceutical context, Canadian law has deviated from this principle. In Parke Davis Co Ltd v Empire Laboratories Ltd⁵⁵ a blue gelatin band encircling pharmaceutical capsules was not registrable as a trade mark because, although it was distinctive of the product, it also served a function in sealing the capsule. The gelatin bands had, at one stage, been the subject of a US patent and the trade mark registration was made on expiry of the patent. Hall J. recognised the application as a device to unlawfully extend the patent monopoly and held that their functionality alone was sufficient to preclude registration.

"the validity of the trade marks may, in my view, be disposed of on the ground that coloured bands have a functional use or characteristic and cannot therefore be the subject of a trade mark."⁵⁶

This is not consistent with the English authority of Edge v Nicolls. In the lower court, Noel J. had refused registration not on the basis of functionality alone but the "monopolistic functional features" of the band.⁵⁷

The application had denoted not just one coloured band, but ten different coloured bands which more than covered the spectrum. The plaintiff was also using various shades of those colours which, in Noel J.'s opinion, amounted to a monopoly not only in those ten colours but a multitude of different shades and hues of the ten colours. He did not suggest however that all functional features were unregistrable:

"Now a functional part per se is open to the world apart from the patent law. A trader can however obtain a valid trade mark on a distinctive form of the functional part or parts such as the Haig Case⁵⁸ provided that, by so doing, he does not hold a monopoly on all forms of the functional part or parts."⁵⁹

Hall J. in the Supreme Court did not make this distinction:

"The law appears to be well settled that, if what is sought to be registered as a trade mark has functional use or characteristic, it cannot be the subject of the trade mark."⁶⁰

In fact the law is far from well settled in either England or Canada. McClean J. said in Imperial Tobacco Company of Canada v Registrar of Trade Marks⁶¹ that a combination of elements which are primarily designed to perform a function is not a fit subject matter for a trade

mark, but other authorities indicate that, where a functional element is clothed in a distinctive style, that aspect of the style may be protected provided that competitors may copy the idea of the functional feature. Thus, in the Parke Davis case the plaintiffs could possibly have registered grey gelatin bands of a certain width. Competitors would then be able to copy the functional feature, namely the gelatin band, but could not copy the precise dimensions and colour of the band. (Registrability would, of course, also be dependant upon the plaintiff's establishing the distinctiveness of the grey band - something they failed to do in this case.)

The question of the functionality of colours in a pharmaceutical context has arisen more frequently in the US than in England. In Ives Laboratories v Darby Drug Co Inc⁶² the plaintiffs alleged that imitation of their colour schemes amounted to a "false designation of origin" pursuant to s.43a of the Lanham Act.⁶³ Under US law a colour alone may not be registered as a mark but may be protected if part of a distinctive combination or colour configuration. The colour itself may acquire protection similar to that of a trade mark if it is non-functional and has acquired a secondary meaning. The claim of false

designation of origin closely resembles an infringement action although the plaintiff is denied the presumptive source association of a registered trade mark and must therefore establish secondary meaning. The court found the colours to be functional in several respects:

"first, many elderly patients associate the appearance of their medication with its therapeutic effect....when patients associate the appearance of a drug with its therapeutic effect in this manner, to insist that the defendants use a different colour would put them at a competitive disadvantage....second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctor's instructions.....some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times.....third, to some extent, colour is also useful to doctors and hospital emergency rooms in identifying overdose of drugs."

Another US case on the same point is Norwich Pharmacal Company v Sterling Drug Inc.⁶⁴ The plaintiffs marketed a pink liquid called "Pepto Bismal" to remedy minor stomach disorders. Although non-functional in the therapeutic sense it was apparently soothing and pleasing to the eye of the sufferer and therefore more acceptable to the stomach. The functionality lay in the get up of the entire article, not in some specific aspect of the get up

(as in the gelatin band in the Park Davis case). It was impossible to separate the distinctive aspect of the alleged trade mark from its functional aspect and protection was therefore refused. In the opinion of the court, imitation of certain successful features of another's product was not unlawful and to that extent a "free ride" was permitted.

The present draft of the proposed European Trade Mark Convention indicates that, within the EEC, features which are purely functional will not be registrable. Article 8 provides that elements of design which are dictated solely by the goods themselves or effect their essential value or result in technical effect may not be registered - presumably however, where a functional element is clothed in a distinctive guise it will continue to be registrable.

The English cases dealing with protection of the get up of pharmaceutical products have generally been decided on the basis of distinctiveness not functionality. For example, in Hoffman-La Roche v Berk Pharmaceuticals⁶⁶ the functional nature of the tablets was clear. Yellow tablets indicated a 10mg dose and white tablets a 2mg

dose. The plaintiffs lost, however, not because of the function of the colour code but because, in the words of Whitford J. in the lower court;

"Anything less likely to strike one as out of the way than either the white pill or yellow pill I can scarcely imagine."⁶⁷

Thus the question of whether functional features are protectable under English law has not been conclusively answered. The reasoning in Edge v Niccolls⁶⁸ suggests that the utilitarian feature must be presented in a novel and distinctive manner. Yet the facts of the case refute this, the plaintiffs had made no attempt to dress the stick in a distinctive manner.

6. Product Simulation

Present trends allowing protection for the total appearance of an article or functional features of an article are steps on the way to a situation whereby the laws of trade marks and passing off may be used to protect a manufacturer against product simulation. However, trade mark law developed as a means of protecting the identifying features affixed to a product not the product itself. Similarly, a passing off action is intended to protect the

"get up" only, a term which implies something extraneous to the article. The Court of Appeal in Edge v Niccolls⁶⁹ followed the Williams v Bronnley approach because the protection sought would amount to be protection of the product itself, but in the House of Lords⁷⁰ no real distinction was drawn between the get up and the product:

"The real question is whether the defendant's goods so resemble the plaintiffs as to deceive the persons who buy."⁷¹

The House of Lords did not distinguish between a functional feature which is also part of the get up and a functional feature of the product itself in a situation where imitation of either feature will cause the public to be deceived as to the origin of the goods.

Anything which fulfils a function must be part of the product and not merely get up. If it is clothed in a distinctive guise it may be impossible to separate the guise from the functional feature. Protection of the former will therefore inevitably result in protection of the latter, but Edge v Niccolls goes further than this. The stick was not adorned in a distinctive guise it was merely the cheapest effective method of achieving the

desired result. It was purely functional but, because it had become associated in the minds of the public with the goods of the plaintiff, the defendants could not copy it notwithstanding that adoption of any other stick would involve additional expenditure.

It appears therefore that a manufacturer will now be able to withdraw from the public domain any feature of his product which motivates the public to buy provided he can prove its distinctiveness. Such protection is available without the costly and time consuming process of obtaining a patent and represents a considerable extension of the law of passing off.

7. Policy Considerations

A reduction or curtailment of protection for the get up of pharmaceuticals will no doubt be vigorously opposed by ABPI as a measure discriminatory of the pharmaceutical industry but such measures are justified in view of the unique nature of the industry.

Promotional advertising and other measures used to generate source identification in other spheres are, in the pharmaceutical industry, aimed at the physician not the ultimate purchaser.

Harman L.J. acknowledged this unique marketing situation in the DDSA case but, in his opinion, this only reinforced the view that imitation of the black and green capsules would amount to passing off.

"If this were an article sold to the public over the counter, there could hardly be a doubt that the green and black capsules sold in millions would long ago have been associated with the plaintiffs who would have been entitled to restrain their rivals from its use notwithstanding that the plaintiffs name was not advertised or known to the public." ⁷³

The same capsules were the subject of a passing off action in the Canadian Courts but there the court was prepared to look at the effect of the marketing situation in the pharmaceutical industry and consequently refused to find that the colour of the capsules was indicative of origin.⁷⁴ The action was brought under section 7(c) of the Canadian Trade Marks and Unfair Competition Act.⁷⁵ The court distinguished between the pharmaceutical and other trades by quoting from the affidavit of the president of the defendant company:

"Ces deux produits sont des produits qui contiennent du Chlordiazepoxide et partent ne peuvent etre vendus que sur prescription de

médecin, prescription que tout pharmacien est obligé de remplir fidèlement sous peine de perdre sa licence de pharmacien."76

The court held therefore that form and get up were of no relevance since the would-be users had no choice over type of drug purchased.

The US Court in the Ives case⁷⁷ accepted that patients associate the colour of their drugs with their therapeutic effect rather than their manufacturing source:

"Doctors who testified believed that patients do not associate the appearance of a drug with the manufacturer or other source but with the drug's effect on the patient's disability. Patients tend to identify capsules with their ailments, for example, 'my red heart pill'. Ives made no showing to indicate that any patient took the colours to mean that the drug came from a particular source."78

It would admittedly be impractical to expect the drug companies to produce a random selection of patients to testify on their behalf. Possibly evidence could be adduced by means of a survey. Ives Laboratories did present survey evidence, but in such an unsatisfactory manner that it was deemed to be of little evidential value.

In Smith Kline & French v Sterling Winthrop⁷⁹

Lord Diplock considered that no other trader could possibly have a legitimate reason for using the plaintiff's colour scheme.⁸⁰ There are, however, many legitimate reasons for copying a familiar colour scheme. If, as suspected, patients wrongly associate colour schemes with the therapeutic qualities of a drug imitation will merely reduce the risk of mistaken rejection. If all generic drugs of the same composition looked alike patients would be able to identify the drug they were taking particularly if their symptoms recur some years later when the name of the drug (if it was ever known) will have been forgotten. The advantages of uniform colour codes will also be apparent in cases of overdose. They would allow for quick an easy identification of drugs.

In the writer's opinion therefore, not only should trade mark and passing off protection be denied to pharmaceutical products, manufacturers should be actively encouraged to employ uniform colour codes for all drugs of the same chemical composition provided they correspond with stringent quality control requirements.

The fear of English Courts is that, by allowing such imitation the generic manufacturers will be "free riding" on the reputation of large pharmaceutical firms. In Hoffman-La Roche v DDA⁸¹ Harman L.J. said:

"Now I myself never received from the defendants a satisfactory answer to the plain question 'why to they want to manufacture their drugs in green and black?' I can only answer that they wish to do so in order to attract to themselves some part of the plaintiff's goodwill and trade on their reputation. In fact, to represent to the public that their goods are the goods of the plaintiffs. That, in my judgment is exactly the classic case of passing off."⁸²

This argument begs the question of whether the feature imitated is eligible for protection. If patients associate colours of a drug with their therapeutic effect it will of course be to the defendant's advantage to imitate those features but if the patients are not concerned about the manufacturing source and are therefore not deceived as to the origin of goods, commercial advantage should not, without more, give rise to a passing action.

In the Ives case⁸³ the fact that colour was an important ingredient in the success of a product led the

court to allow imitation simply because to do otherwise would place the defendants at a commercial disadvantage. The judge quoted from the judgment of Judge Brandeis in Kellogg Co v National Biscuit Co.:

"Sharing in the goodwill of an article unprotected by patent or trade mark is the exercise of a right possessed by all and in the free exercise of which the consuming public is deeply interested."⁸⁴

A further case illustrating the difference of approach between American and English Courts is Norwich Pharmacal Co v Sterling Drug Inc.⁸⁵ The court differentiated between a deliberate attempt to deceive and a deliberate attempt to compete saying:

"Imitation of certain successful features in another's product is not unlawful and to that extent a 'free ride' is permitted."⁸⁶

Thus, the colour pink could not be appropriated by the defendants for their upset stomach remedy.

The US Courts appear therefore to have adopted a more laissezfaire attitude to competition than the English Courts and are inclined to allow the defendants a limited

"free ride". It is an example the English Courts should follow. Indeed, the English Courts have hinted several times that they are aware of the policy reasons for allowing and even encouraging the use of universal colour codes. In the DDSA case, Russell L.J. said:

"I am fully prepared to assume that there are many good reasons why it would be desirable that CDP 10mg capsules should, from whatever source, have the same colour code and that, in part, the defendants are motivated in their intention to use black and green by these reasons.⁸⁷

So far however, the courts' dislike of "free riding" has been strong enough to overcome the desire to see universally applied colour combinations.

NOTES TO CHAPTER IV

- ¹For a detailed account of the development of passing off actions and actions of trade mark infringement see Blanco White, T.A. and Jacob, Robin: Kerly's Law of Trade Marks & Trade Names (10th ed) 1972
- ²Reddaway v Banham [1896] A.C. 199 (H. of L.) 13 R.P.C. 218 at p.224
- ³Trade Mark Registration Act 1875, s.3
- ⁴Saville Perfumary Ltd v June Perfect Ltd & F.W. Woolworth & Co Ltd (1941) 58 R.P.C. 147 (H. of L.)
- ⁵Hoffman-La Roche & Company A.G. and Others v DDSA Pharmaceuticals Ltd [1972] R.P.C. 1 (C.A.)
- ⁶(1937) 54 R.P.C. 81 (Ch.D.)
- ^{6a}*ibid*, per Farwell J. at p.90.
- ⁷*supra* n.1
- ⁸*supra* n.2
- ⁹*supra* n.2 at p.229
- ¹⁰(1933) 50 R.P.C. 45 (Ch. D.)
- ¹¹Trade Mark Act 1938. s. 15(3): "No word which is the commonly used and accepted name of any single chemical element or single chemical compound, as distinguished from a mixture, shall be registered as a trade mark in respect of a chemical substance or preparation....provided that the foregoing provisions of this subsection shall not have effect in relation to a word which is used to denote only a brand or make of the element or compound as made by the proprietor or registered user of the trade mark as distinguished from the element or compound as made by others and in association with a suitable name or description open to public use."
- ¹²The Shredded Wheat Co Ltd v Kellogg Co of Great Britian Ltd (1940) 57 R.P.C. 37 (H. of L.)

- ¹³The Canadian Shredded Wheat Company Ltd v Kellogg Co of Great Britian Ltd (1938) 55 R.P.C. 125 (P.C.)
- ¹⁴Kellogg Co v National Biscuit Co 305 US 111 (Sup. Ct.)
- ¹⁵ibid at p.116
- ¹⁶ibid at p.118
- ¹⁷Restrictive Trade Practices Commission Report concerning the Manufacture, Distribution and Sale of Drugs. Department of Justice, Ottawa 1963 (RTPC Report)
- ¹⁸ibid at p.496
- ¹⁹Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-67. HMSO Cmnd 3410 (1967) (The Sainsbury Report) at p.79 para 279
- ²⁰For a detailed discussion of US drug substitution laws see:
Warner, Jillian A, Consumer Protection and Generic Drugs: The Generic Drug Substitution Laws, (1978-79) 67 Kentucky Law Journal 384; Haddad, William P, Generic Drugs - Tomorrows Market, 1978 Food Drug and Cosmetic Law Journal 488; Knapp, Gene, The Issues of Generic Substitution, 1979 Food Drug and Cosmetic Law Journal 98; McCarey, Michael C, Generic Substitution Policy, 1979 Food Drug and Cosmetic Law Journal 103; Ruggieri, Nicholas L, Manufacturers View of Generic Substitution Legislation, 1979 Food Drug and Cosmetic Law Journal 108
- ²¹The Birmingham Vinegar Brewery Company Ltd v Powell [1877] A.C. 710 (H. of L.)
- ²²ibid at p.714
- ²³"Trade Mark" is defined in s.68(1) of the Act as "a mark used or proposed to be used in relation to goods for the purpose of indicating or so as to indicate a connection in the course of trade between the goods and some person having the right, either as proprietor, or as registered user, to use the mark whether with or without any indication of the identity of the person."

²⁴supra n.21 at p.713

²⁵(1880) 14 Ch. D. 748

²⁸Trade Mark Act 1938, s.9

"(2) for the purposes of this section "distinctive" means adapted, in relation to the goods in respect of which a trade mark is registered or proposed to be registered, to distinguish goods with which the proprietor of the trade mark is or may be connected in the course of trade from goods in the case of which no such connection subsists, either generally, or, where the trade mark is registered or proposed to be registered subject to limitations, in relation to use within the extent of the registration

(3) In determining whether a trade mark is adapted to distinguish as aforesaid the tribunal may have regard to the extent to which -

- (a) the trade mark, is inherently adapted to distinguish as aforesaid; and
- (b) by reason of the use of the trade mark or of any other circumstances the trade mark is in fact distinguished as aforesaid"

²⁹[1975] 1 W.L.R. 914 (H. of L.)

³⁰Trade Mark Act 1938, s.11 " "It shall not be lawful to register as a Trade Mark or part of a Trade Mark any matter, the use of which would, by reason of its being likely to deceive or cause confusion or otherwise, be disentitled to protection in a court of justice or would be contrary to law or morality or any scandalous design."

³¹Smith Kline & French Laboratories (Australia) Ltd v Register of Trade Marks [1972] R.P.C. 519 (H.C. Australia)

^{31a}supra n.29 at p.918

^{31b}supra n.29 at p.919

³²Smith Kline & French Laboratories Ltd's Applications [1974] 1 W.L.R. 861

- ³³ *ibid* per Russell L.J. at p.866
- ³⁴ Trade Mark Act 1938, S.16 "A trade mark may be limited in whole or in part to one or more specified colours and in any such case the fact that it is so limited shall be taken into consideration by any tribunal having to decide on the distinctive character of the trade mark. If and so far as a trade mark is registered without limitation of colour it shall be deemed to be registered for all colours."
- ³⁵ In Re Application of F. Reddaway & Co Ltd [1914] 1 Ch 856
- ³⁶ *supra* n.29 per Lord Diplock at p.920
- ³⁷ This was the opinion of Lawton L.J. in the Court of Appeal *supra* n.32 at p.876
- ³⁸ *supra* n.32 at p.874
- ³⁹ Blue Parrafin Trade Mark [1976] F.S.R. 29 (C.A.)
- ⁴⁰ In Re James Trade Mark James v Soulby (1886) 33 Ch D 392
- ⁴¹ *ibid* at p.395
- ⁴² 1971 - Unreported case, referred to by Russell L.J. in Smith Kline & French Laboratories Ltd's Applications *supra* n.32 at p.868
- ⁴³ European Trade Mark Convention Art. 8 see also Chapter VI
- ⁴⁴ *supra* n.29 per Lord Diplock at p.922
- ⁴⁵ E. Hoffman-La Roche & Company A.G. and Another v DDSA Pharmaceuticals Ltd [1972] R.P.C. 1 (C.A.)
- ⁴⁶ (1905) 22 R.P.C. 113 (Ch. D.)
- ⁴⁷ Roche Products Ltd and Another v Berk Pharmaceuticals Ltd [1973] R.P.C. 473
- ⁴⁸ *ibid*
- ⁴⁹ (1909) 26 R.P.C. 481 (Ch. D.)

⁵⁰1911 [A.C.] 693 (H. of L.)

⁵¹[1911] 1 Ch. D. 5 (C.A.)

⁵²ibid at p.10

⁵³ibid at p.14

⁵⁴supra n.50

⁵⁵Parke Davis & Co Ltd v Empire Laboratories Ltd (1964)
45 D.L.R. (2nd) 97 (Supreme Court of Canada)

⁵⁶ibid at p.100

⁵⁷Parke Davis & Co Ltd v Empire Laboratories Ltd (1963)
24 Fox. Pat. C. 88 (Ex Ct of Canada)

⁵⁸John Haig & Co Ltd v Forth Blending Co Ltd (1953) 70
R.P.C. 259 (C. of Sess. Scotland)

⁵⁹ibid at p.106

⁶⁰ibid n.55 at p.100

⁶¹[1939] 2 D.L.R. 65 at p.67

⁶²(1980) 206 USPQ 238 (District Court E.D. New York)

⁶³Lanham Act, 15 U.S.C. para 1125(a)

⁶⁴(1959) 271 F. 2nd 573 (US Court of Appeals, second
circuit)

⁶⁶supra n.48

⁶⁷[1973] R.P.C. 461 at p. 470 (Ch. D.)

⁶⁸supra n.50

⁶⁹supra n.51

⁷⁰supra n.50

⁷¹supra n.50 per Lord Gorrell at p.701

⁷³supra n.45 at p.8

⁷⁴Hoffman-La Roche Ltd v Roche-William Cie Ltee (1970)
62 C.P.R. 233 (Ex. Ct. of Canada)

⁷⁵1952-53 (Can) c.49 "7 No person shall.....
(c) pass off other wares or
services as and for those
ordered or requested."

⁷⁶supra n.74 at p.235

⁷⁷supra n.62

⁷⁸ibid at p.242

⁷⁹supra n.29

⁸⁰ibid at p.922

⁸¹supra n.5

⁸²ibid at p.10

⁸³supra n.62

⁸⁴(1938) 305 US 111 at p.122

⁸⁵(1959) 271 F. 2nd 567

⁸⁶ibid at p.572

⁸⁷supra n.5 p.11

CHAPTER V

COPYRIGHT AND INDUSTRIAL DESIGNS

1. Introduction

There are two remaining areas of Intellectual Property Law which, while not protecting the formula of a drug or medicine, may confer protection upon the physical appearance of the product thereby indirectly prolonging the monopoly over the product itself. These two areas are copyright and industrial designs.

Industrial design legislation exists primarily to protect the novel appearance of mass produced goods. The protection conferred is a full monopoly against both copying and independent creation. The law of copyright confers longer lasting rights and was originally intended to protect only literary, artistic, musical or dramatic creations. Although longer lasting the protection is limited to copying. The two areas overlap to a considerable extent and are therefore considered together in this chapter. In addition, features of the product which are protected by artistic copyright or industrial

design registration may be the subject of a valid trade mark registration. The second area of overlap is considered separately at the end of the chapter.

2. Histrocial Background¹

The law of copyright started with the protection of books and moved from that to encompass all forms of literary, artistic and musical endeavour. It has more recently been extended into the field of industrial design. The earliest form of copyright protection was in the literary field and took the form of printers licences. The first Copyright Act, enacted in 1709² gave authors of books the sole right of printing for fourteen years. The law developed from that in a piecemeal manner to cover various aspects of the fine arts but industrial designs were outside the scope of copyright protection.

With the advent of mass production came a desire to prevent plagiarism of manufactured goods. The hazard was first appreciated in the textile trade and as early as 1787 an Act was passed granting protection to novel designs. This statute adopted a "copyright approach" rather than a "patent approach" in that it conferred power to prevent others from copying an original pattern without

authority.³ However, between 1833 and 1949 design protection was given through successive Patents and Designs Acts, a system of registration was established and the protection conferred was a full monopoly - a "patents approach". In 1949 designs and patents were each given protection under separate statutes. The Registered Designs Act 1949 is still the governing statute in the realm of industrial designs conferring protection upon "features of shape configuration pattern or ornament" applied to any article. The Act speaks of "design copyright" but the form of protection conferred is still more akin to patent protection. It is full monopoly protection based upon novelty in the patent sense rather than copyright protection which is based on originality in the sense of originating from the author and protects only against copying.

Copyright law was developing contemporaneously along slightly different lines. The first comprehensive Copyright Act was passed in 1911. Until that time the law had been contained in a number of statutes dealing with different aspects of the arts. The primary right conferred by the Act of 1911 was

"the sole right to produce or reproduce the work or any substantial part thereof in any material form whatsoever."

This was held to include reproduction of a two dimensional work in a three dimensional form.⁴ Clearly, many designs applied, or to be applied, to manufactured articles could conceivably come within the scope of both the Copyright Act and the Registered Designs Act. Therefore S.22 of the Copyright Act provided that if, when a work was first made, it was "intended" that it should form the basis of a design to be used industrially the right of complaint by way of alleged infringement of copyright was forfeited.⁵

The test was the intention of the designer and the House of Lords held in King Features Syndicate v O. & M. Kleeman Ltd⁶ that it was the original intention of the artist at the time of first making this drawing which prevailed. Thus, copyright protection was gained or lost at the time of creation. This is still the position with regard to works which were made before June 1st, 1957.⁷

The Gregory Committee on Copyright⁸ was concerned by the disparity between the period of registered design protection (15 years) and that of copyright

protection which lasted for the life of the author plus fifty years. It was felt that those designers who did not initially intend industrial exploitation received undue favour from the law. Furthermore, the difference encouraged subterfuge on the part of artists as to their original intention. Consequently, when the Copyright Act 1956 became law section 10 provided that, as soon as a registrable design was applied industrially or a design was registered, the copyright became ineffective immediately in the field of the design and, not later than fifteen years after marketing, in the field of all associated designs. Section 10 was substantially altered by the Design Copyright Act 1968 so that the loss of copyright in the industrial sphere is now delayed for fifteen years from the first marketing of the products. Thereafter it will not infringe copyright to do any act within the scope of a notional set of registered designs. Neither this section or its predecessor have been interpreted according to the original intention of the legislature as will be demonstrated below.

3. Artistic Copyright and Industrial Design

The design of a pharmaceutical product, the product dispenser or the packaging may all be protected by artistic copyright or an industrial design registration.

The Johnstone Committee report contains a list of the types of goods for which designs have been registered. That list includes, under the heading "containers" bottles, flasks, capsules, cartons.⁹ Registration of such items may be of considerable value to the pharmaceutical firm.

Where the pharmaceutical company seeks to register the design of a new product novelty, in the patent sense, is required. Originality, in the copyright sense of originating from the author, is not sufficient. Section 1(2) of the Registered Designs Act 1949 states:

"a design shall not be registrable unless it is new or original."

Graham J. held in a recent pharmaceutical application¹⁰ that the section meant "new and original".

"The word original does not to my mind in this context carry the matter much further than new but it does import something more than mere novelty *stricto sensu*. It is directing the mind and eye to the fact that there is a difference of form or character which is a departure from previous designs and which is therefore of some significance or substance."¹¹

The novelty requirement will involve the applicant in a search of previous registered designs. Functional features are not registrable. A design is defined in section 1(3) of the Registered Designs Act 1949:-

"In this Act, the expression "design" means features of shape, configuration, pattern or ornament applied to an article by any industrial process or means, being features which, in the finished article appeal to and are judged solely by the eye but does not include a method or principle of construction or features of shape or configuration which are dictated solely by the function which the article to be made in that shape or configuration has to perform."

The advantage to a pharmaceutical company of obtaining registration under this Act is that it will enjoy a complete monopoly over the registered design for fifteen years enforceable against all other drug manufacturers without proof of copying. However, the standard sized two tone capsule discussed in the previous chapter is probably not eligible for registration. Smith Kline & French Laboratories recently applied to register two designs to be applied to pharmaceutical products.¹² They were both for drug capsules characterised by a speckled effect and three different coloured bands. The statement of novelty in the case of each application was in the following terms:

"The feature of the design for which novelty is claimed is the ornament created by the combination of colours of the pellets as seen through the various portions of the transparent capsule."

Registration was refused and Smith Kline & French appealed to the Registered Designs Appeal Tribunal. Mr Justice Graham found, upholding the Registrars refusal, that the capsules in question did not possess sufficient novelty and originality to merit registration. The decision, however, does not necessarily mean that all future applications from pharmaceutical firms are doomed to failure. Much argument centred around whether colour should be taken into account in determining registrability. The Act contains no reference to colour but words such as "pattern" or "ornamentation" suggest that colour may be relevant. Graham J. conceded that in certain circumstances colour may be an essential feature of a design and gave as an example the Ishihara Cards, often used in diagnosing colour blindness.¹³ In this case he followed what he termed the "common sense approach" of Farwell J. in Calder Vale Manufacturing Co v Lappet Manufacturing Co

"While I am very far from suggesting that there may not be cases where differences in colour may be of importance, and indeed, sufficient to differentiate the designs, prima facie in my view colour is not a matter of any great importance in considering a question of this kind."¹⁴

It is unlikely that any of the coloured or banded capsules discussed in previous chapters would demonstrate sufficient novelty to be registrable as an industrial design, but it is not beyond the writer's imagination to envisage future design registrations for diamond shaped capsules with numerous multicoloured stripes extending in various directions over their exterior. Indeed, the courts have in one instance allowed registration of a design which consisted primarily of coloured striping applied to an article of conventional shape. Cook & Hurst's Application¹⁶ concerned a football shirt worn by the English Team. It was of a standard design but distinguished by contiguous red and blue banding (the team colours). Whitford J. considered the stripes to be of particular significance in a sporting context because of their purpose in distinguishing one team from another. He considered that, having regard to both the particular colours involved and their location on the shirt, "it would not be appropriate at this stage to refuse the application."¹⁷

While the pharmaceutical firms may derive some encouragement from this case, its value is limited, partly because the judgment is framed in such cautious terms and partly because, as Whitford J. admitted, the colours in question were functional, serving to identify the team. Functional features of a design are not proper subjects for registration. If the pharmaceutical companies attempted, on the basis of this case, to employ coloured bandings to identify certain drugs they may find their applications refused on the grounds of their functionality.

Since the success of the Smith Kline & French trade mark action the pharmaceutical firms will no doubt choose instead to register their distinctive capsules as trade marks. However, if, as suggested above, trade mark protection is abolished for pharmaceuticals the firms will no doubt turn to industrial design legislation for protection.

The most convenient method to register a capsule design would be to file a specimen of the capsule in support of the Application. The Designs Registry have indicated a willingness to accept such applications:-

"In a relatively small number of cases applicants file coloured representations or specimens in support of an application together with a statement of novelty worded to the effect that 'the feature of the design for which novelty is claimed is the pattern or ornament created by the tonal contrast of the colours applied to the article as shown in the representations'. Whilst the office is in some doubt as to the validity of such a claim the application is accepted for registration provided that the design possesses the necessary substantial novelty." ¹⁸

Aspro Nicholas attempted to register as a capsule design,¹⁹ a column of conventional tablets contained within a transparent two part capsule. This application was refused but Graham J. began his judgment by saying:

"There seems prima facie to be no a priori reason why a design for a transparent container and the article or articles it contains should not be registrable provided the conditions of novelty and originality called for in the Act are fulfilled by the combination of container and article as a whole."

The applicant's main problem was that their design consisted of a combination of two shapes both of which were so well known as to be common knowledge (although the idea of combining the two was admittedly novel). If the shape of the pills to be inserted in the capsule had been novel -

heart shaped or animal shaped tablets, for example - the outcome may well have been different.

An interesting question, however, is whether the applicants actually wanted the outcome to be different. Once it has been ascertained that a certain design is unregistrable the position seems to be that copyright in the original drawings of the unregistrable design will be unaffected by S.10 of the 1956 Act and will remain valid for the lifetime of the draughtsmen plus fifty years. Copyright will not prevent independent invention by a rival manufacturer but is, none the less, a useful "nuisance weapon" in the armoury of the pharmaceutical firms.

The copyright Act 1956 protects drawings as artistic works "irrespective of artistic quality".²⁰ Protection extends to the making of three dimensional objects resembling the drawings²¹ subject to the defence contained in section 9(8) that the article must be recognisable by someone not expert in such articles as a reproduction of the copyright drawings.

Copyright in any drawings belongs, as a general rule, to the author.²² However, Section 4(4) of the 1956

Act provides that where a work is made in the course of the author's employment by another person under a "contract of service" that other person shall be entitled to any copyright subsisting in the work. The meaning of the expression "contract of service" has been the subject of much judicial comment and various criteria have been selected as determining the existence of a contract of service.²³ The most important criterion appears to be the degree of control exercised by the master over his servant.

"The greater the amount of direct control exercised over the person rendering services by the person contracting for them the stronger the ground for holding it to be a contract of service and similarly the greater the degree of independence of such control, the greater the probability that the services rendered are of the nature of professional services and that the contract is not one of service."²⁴

In order that copyright may vest in the employer it is also important that the work be made by the servant "in the course of his employment". If the work is made while the servant is doing something which is ancillary to his employment copyright will remain with the employee.²⁵

A draughtsman who designs a new capsule for a pharmaceutical firm will almost invariably be employed by the firm under a contract of service. Furthermore, the contract itself will usually stipulate that copyright in all designs made during the course of employment will belong to the pharmaceutical company.

Returning to a consideration of the Aspro case in the context of artistic copyright protection, the first question to consider is whether there are in existence any drawings in which the applicants may claim copyright. The report contains three simple diagrams depicting the article in question. The diagrams, which did not portray anything "new" or "original" in the context of the Registered Design Act, are original in the copyright sense that they originated from the draughtsman who drew them. The diagrams certainly demonstrate no artistic merit but the courts have interpreted the words "irrespective of artistic quality" as absolving them from the responsibility of making aesthetic judgments. One judge, when considering whether "point patterns" were artistic works concluded that they were, being "lines drawn on paper".²⁶ Furthermore, they were infringed by a three dimensional reproduction when the defendants made them up into finished fabrics.

Similarly, in Merchant Adventurers v M. Grew & Co Ltd²⁷ the courts accepted the plaintiff's claim that artistic copyright subsisted in simple line drawings of an electric light fitting and this copyright was infringed by the defendants subsequent production and sale of similar light fittings.

These cases indicate that the words "diagram map chart and plan" contained in the definition of drawing in the Copyright Act 1956,²⁸ include any simple product drawing which will therefore be eligible for protection as an artistic work for the life of the employee draughtsman plus fifty years. The problem is knowing how far this principle extends. By protecting simple line drawings as artistic works the courts are coming dangerously close to protecting the idea itself rather than the expression of the idea.

In British Nothorp and Others v Texteam Blackburn Ltd and Another Megamy J. said:

"Prima facie if there is anything which can fairly be called a diagram it is a drawing and may be the subject of a copyright. It may be indeed that something may be a drawing which cannot fairly be called a diagram or a drawing of any kind. A single straight line drawn with the aid

of a ruler would not seem to me to be a very promising subject for copyright." ²⁹

If every drawing which is slightly more sophisticated than a single straight line drawn with a ruler is entitled to copyright protection what is to prevent a firm manufacturing, for example, oval shaped pills from making a simple drawing of an oval shape and claiming copyright protection for the shape. In such a situation the drawing lends nothing in portrayal to the actual idea. The drawing is the idea and protection of the drawing is tantamount to protection of the idea. The fundamental distinction in copyright law between form and expression was explained by Wills J. in the case of Kenrick & Co v Lawrence & Co. ³⁰ A diagram of a hand holding a pencil in the process of marking a cross in a box (aimed at providing instruction for illiterate voters) was not copyrightable.

"A square can only be drawn as a square, a cross can only be drawn as a cross, and for such purposes as the plaintiff's drawing was intended to fulfil there are scarcely more ways than one of drawing a pencil or the hand that holds it. If the particular arrangement of square cross hand or pencil is relied upon it is nothing more than a claim of copyright for the subject which, in my opinion, cannot possibly be supported." ³¹

Wills J. was reluctant to grant copyright protection because the kind of moral claim which such a drawing had to protection "was far more of the nature which attached to a trade design than to that which belongs to a work of art". The courts in recent years have been more willing to grant protection to trade designs. In L.B. (Plastics) Ltd v Swish Products Ltd³² Lord Hailsham was aware that, by granting protection to the plaintiff's design drawings, the court was in danger of protecting the idea but considered that if specific details of the plaintiff's design which were "substantial" were copied this amounted to more than copying of the idea:

"of course, it is trite law that there is no copyright in ideas....But....as the late Professor Joad used to observe, it all depends on what you mean by ideas. What the respondents in fact copied from the appellants was no mere general idea, it was, to quote the respondents own language to 'follow the pattern' or principle 'in part or in whole' with 'minor changes' to the design, with the same choice of principle members interfitting in the same way to the same critical dimensions."³³⁻

Thus, in the Aspro case a claim for copyright infringement could be brought provided the defendants copied more than the idea of putting tablets inside a

capsule. If the defendants capsule was of similar dimensions containing the same number of tablets a case for infringement might succeed. Furthermore, Graham J. held in Merchant Adventurers v Grew³⁴ that several drawings may be taken in composite in considering the question of infringement. Aspro therefore could rely on all three of the designs depicted in the reports to bring an infringement action.

Arguments surrounding the idea/expression dichotomy are generally submerged beneath a related, but more tangible problem - that of actually proving copying of the expression. Any manufacturer may independently conceive the same design. In the case of a very simple design (such as the oval shaped tablet) any presumption of copying arising from a striking similarity between the drawing and the allegedly infringing product may be rebutted by an assertion of independent creation. The more simple the sign the more difficult it will be to establish copying.

The Aspro drawings are slightly more complicated than an oval shaped pill. Thus a strong resemblance between the Aspro drawings and a rival manufacturer's

capsule together with an opportunity to copy and a motive will raise a prima facie inference of copying which it will then be for the defendants to rebut. If the defendant does not enter the witness box or appears to be a less than honest witness the presumption becomes virtually irrebuttable. Expert evidence may be adduced if necessary to establish whether the similarities are sufficiently detailed to raise an inference of copying. (Although the Aspro drawings are so simple that expert evidence would not be necessary.) Aspro would need to establish that a "substantial" part of their drawings had been copied. The concept of "substantiality" refers to the quality rather than the quantity of the material copied.

"Substantiality for the purposes of the Copyright Act is to be judged by quality rather than quantity and the critical dimensions can hardly be judged to be less than substantial just because they are measured in centimeters." 35

If Aspro can establish that their drawings represent an original, artistic, copyrightable work; if they can also establish that a subsequent manufacturer has copied a substantial part of the design of their capsules, thereby infringing copyright in their drawings, they will still have one further hurdle to overcome. This is the defence

provided by S.9(8) of the 1956 Act. The making of an object in three dimensions shall not be taken to infringe copyright in an artistic work of two dimensions if the object would not appear to persons who are not experts to be a reproduction of the artistic work. Section 9(8) has been the subject of much judicial criticism. Dankwerts L.J. has referred to it as "an extraordinary provision".³⁶ The problem lies in establishing the standard of the notional non expert. Parties to the various actions have avoided the problems of adducing non expert evidence and have left it to the judges to decide the issue. Lord Wilberforce recently endorsed this approach in the L.B. Plastics case. He considered that the judge should decide the matter in the context of his role as a "non expert". He should not consider the expert evidence which would already have been adduced in deciding the question of copying. This will involve the judge in some tricky mental gymnastics as, having decided the issue of copying on the basis of expert evidence, he will, by this stage of the trial, have become something of an expert himself.

The judge, in his role as "non expert", should, according to Lord Wilberforce, be credited with "some

ability to interpret design drawings". In the case of the Aspro drawings however no "ability to interpret" is necessary. The drawings are so simple that the issue may be decided on the basis of a simple comparison.

Having established that Aspro have copyright in their design drawings, what will be the consequences of putting the design into mass production? Under S.10 of the 1956 Act as originally drafted, copyright was lost as soon as a design was registered under the Registered Designs Act or "applied industrially".³⁷ After the 1968 amendment the loss of copyright was delayed until fifteen years after first marketing.

However, the Act was not clear on the copyrightable status of the unregistrable design and the courts have interpreted the provisions of S.10 as applying only to registrable designs. The case of Dorling v Honnor Marine³⁸ was decided before the 1968 amendment. It was an action for infringement of copyright in plans of a boat. No design registration had been obtained for the shape of the boat and the defendants relied upon S.10 for a defence. The court found however that the plans were purely functional and therefore unregistrable. The

plaintiffs copyright was held to remain unimpaired and unaffected by any provisions of the Registered Designs Act and S.10 was accordingly irrelevant. Harman L.J. stated the reasons behind this approach:

"To hold otherwise would, I think, amount to saying that no artistic copyright existed in the plans which could therefore be freely taken and copied and which at the same time could not be protected as a design either. I do not think the legislature intended any such result." ^{38a}

There would seem to be no harm, however, in allowing the copying of designs which are applied industrially if they do not possess the necessary criteria for design registration. It is clear from the Johnstone Committee Report³⁹ that, when they proposed a new system of design copyright to operate alongside design monopoly, they believed that the system would protect non registrable designs which otherwise went unprotected. There is no indication that the Committee believed it would be cutting down an existing copyright period of the author's life plus fifty years.

When S.10 was amended in 1968 no distinction was drawn between designs actually registered and those not,

nor was anything specific said about designs which were incapable of registration. However, in Sifam v Sangamo⁴⁰ Graham J. assumed that the principle of Dorling v Honnor Marine continued to apply to the section in its post 1968 form. The somewhat bizarre result is that a registered design monopoly and industrial copyright last for roughly the same period (15 years) but an unregistrable design will retain full artistic copyright for the life of the author plus fifty years.

If we return to the Aspro drawing and apply the above principles it seems that Aspro are now in a position to claim artistic copyright in the capsule drawings for the life of the draughtsman plus fifty years, whereas if they had been successful in their application their copyright protection would only have lasted for fifteen years, the same period as the design registration.

It is therefore abundantly obvious which route the pharmaceutical firms should take when seeking protection for new products. They should attempt to register their product as an industrial design. If successful, they will obtain a valuable fifteen year period of monopoly protection. If they are unsuccessful, then, provided they

have an original set of design drawings, they will enjoy copyright in the drawings for the life of the draughtsman plus fifty years. This will admittedly be a weaker form of protection than that conferred by a registered design but will be of considerable and long lasting "nuisance value".

This thesis is concerned primarily with the operation of intellectual property laws as they apply to pharmaceutical products. In this area however, the law is operating in an unsatisfactory manner with regard to all mass produced articles. Protection for such articles belongs properly in the realm of registered designs and patent law. It is surely anomalous that a drawing such as the Aspro capsule diagram which is so utilitarian and so lacking in artistry that it is not eligible for registration under the Registered Design Act should qualify as an "artistic work" and thus for the full term of copyright protection.

Not only does this result in an undesirably long period of copyright protection for industrial items, it also causes severe problems for manufacturers who wish to copy a mass produced article. A search of the existing patents and designs registries will inform them whether the

article is covered by a valid patent or industrial design but, if the search is clear, they will have no way of knowing whether the article began its life as a design drawing in which case they will be in danger of infringing artistic copyright.

Various writers and one government committee have suggested ways to remedy this anomalous situation but it is beyond the scope of this paper to review the potential reforms.⁴¹ In the writer's opinion artistic copyright is an inappropriate vehicle for protection of the design of pharmaceutical substances. Such products should be protected, if at all, by registration under the Registered Design Act 1949. If they fail to satisfy the requirements for registration the design should be freely available.

4. Works of Artistic Craftsmanship

Section 3(1)(c) of the 1956 Act includes in the definition of "artistic work" "works of artistic craftsmanship". If the pharmaceutical firm is unable to produce even the crudest set of working drawings in order to take advantage of S.3(1)(a) can the firm assert that their capsule is a "work of artistic craftsmanship"? In the writer's opinion such a claim is doomed to failure.

Unlike Section 3(1)(a) subsection (c) does not include the broadening phrase "irrespective of artistic quality", on the contrary, it specifies that the work of craftsmanship must be artistic.

In the recent case of George Hensher Ltd v Restawile Upholstery⁴² the House of Lords held that the word "artistic" should be given its "ordinary and natural meaning". The article in question - a prototype chair - was held not to be a work of artistic craftsmanship because any points of originality in design were aimed at appealing to the eye as commercial selling points. In the light of this decision it is inconceivable that a capsule or pill will ever be afforded protection under S.3(1)(c) of the 1956 Act.

5. Literary Copyright

The pharmaceutical industry does not spring instantly to mind as an example of an area where copyright is required to protect original literary endeavour. However, given the fact that copyright law has conferred protection upon mathematical tables and street directories as literary works it is reasonable to ask whether such protection might also be conferred upon dosage information sheets and other instructional leaflets.

Section 2 of the 1956 Act confers copyright protection upon every literary work, defined in Section 48 as including "any written table or compilation". Writing is defined to include any form of notation, whether by hand or printing, typewriting or any similar process.

Thus copyright has been used to protect virtually all printed matter irrespective of quality or style. Any requirement of skill judgment or labour is minimal.

In University of London Press Ltd v University Tutorial Press Ltd⁴³ Peterson J. said:

"It may be difficult to define literary work as used in this act but it seems plain that it is not confined to literary work in the sense in which that phrase is applied for instance to Merediths novels or the writings of Robert Louis Stevenson. In speaking of such writings as literary works one thinks of the quality, the style and the literary finish which they exhibit. Under the Act of 1842 which protected books many things which had no pretension to literary style acquired copyright. For example, a list of foxhounds and hunting dogs and trade catalogues and I see no ground for coming to the conclusion that the present act was intended to curtail the rights of authors. In my view the words "literary work" cover work which is expressed in print or writing irrespective of the question of whether the quality or style is high."

Is it possible for pharmaceutical firms to benefit from this broad interpretation?

There is little authority to indicate whether pharmaceutical firms may protect any of the instructional sheets or other literature accompanying their products although there is some authority to indicate that advertising material may be protected if sufficiently detailed and original. In Sinanide v La Maison Kosmeo⁴⁴ Scrutton L.J. admitted that there may be copyright in an advertisement although the simple slogan "Beauty is a social necessity" was too insubstantial to attract copyright. Similarly in Kirk v Flemming⁴⁵ an advertisement consisting of four common place sentences was denied copyright. Thus simple advertising claims such as "relieves cold symptoms" would enjoy no copyright but a more detailed advertisement or highly memorable slogan may be copyrightable. In the New Zealand case of Cotton v Frost⁴⁶ an advertisement for the manufacture or sale of dental plates was held to be an "original literary work" under the New Zealand Copyright Act 1913 (based upon the English Act of 1911). Although the claims amounted to no more than that certain standards to which every manufacturer of dental plates may work had been reached

they were presented in a novel way and were the result of a combination of skill, labour and expenditure contributed by the author and copyright owner.

On the question of dosage instruction sheets and other instructional material, the case of A.J. Caley & Sons v G. Garnett & Sons Ltd⁴⁷ indicates the probable attitude of the courts. The case involved rules for playing a simple game. Although the rules in question were held to be copyrightable the idea of the game was not so there would be nothing to stop anyone from describing in his own words the object of the game and the rules to be observed in playing it.

It would seem therefore that, even if the pharmaceutical firm can successfully claim copyright in their instruction sheets, such copyright will not help them to prolong their monopoly. Any other manufacturer who has overcome patent problems and the other hurdles discussed above in order to market a similar product must be free to instruct the public on how to administer the drug. If the drug itself is similar to the original product the instructions for use must, of necessity, be couched in similar terms. Mere similarity without proof of copying

will not amount to an infringement of copyright and the similarity is excuseable as there are only a limited number of ways in which to explain accurately how a certain drug is to be administered.

In the writer's opinion, therefore, literary copyright is not a highly potent weapon for the pharmaceutical manufacturer. Of far more potential value are the provisions dealing with artistic copyright in drawings.

6. Industrial Designs and Trade Marks

Smith Kline & French were unsuccessful in their attempt to register their two tone colour banded capsule as an industrial design but it will be recalled that they succeeded in registering the appearance of ten two tone coloured capsules as trade marks.⁴⁸

Their claim to industrial design protection failed for lack of novelty. This will not hurt the pharmaceutical company. Not only can they now enjoy copyright protection for the full "life plus fifty years" term, they can still obtain trade mark protection which may be renewed indefinitely. This trade mark protection, unlike copyright

will protect the manufacturers against independent invention within the same field as well as direct copying.

One view of the relationship between a registrable design and a registrable trade mark is contained in the following extract from the judgment of Sargant L.J. in Charles Goodall & Son Ltd v John Waddington Ltd.⁴⁹

"A design forms part of the goods themselves. A trade mark is something which is extra, which is added to the goods for the purpose of denoting the origin of the goods, and, speaking generally of trade mark and design, the same thing is not a trade mark and a design."

Lord Diplock criticised this passage in the Smith Kline & French trade mark action⁵⁰ saying:

"if it is to be understood that what is capable of being registered as a design is ipso facto incapable of being registered as a trade mark it does not correctly state the law."

Many of the criteria for registration as an industrial design are similar to the requirements for trade mark registration.

To recap briefly, a registered design is defined as:

"features of shape configuration pattern or ornament applied to an article by an industrial process or means being features which, in the finished article, appeal to and are judged solely by the eye, but does not include a principle or method of construction or features of shape or configuration which are dictated by the function which the article to be made in that shape or configuration has to perform."⁵¹

A trade mark is an ornamental feature applied to an article and must be something distinct from the article itself.⁵² It appeals to and is judged solely by the eye. Its purpose is to visually distinguish the applicants product from those of rival producers and it may not be a solely functional element of the article.

From a comparison of the above requirements it is clear that a certain feature may qualify as both a registered design and a trade mark. A novel design applied to an article is likely to be distinctive of its maker and therefore, in the light of the Smith Kline & French judgement, may be registered as a trade mark.

It does not follow however that every registered trade mark will also be registrable as a design. In the pharmaceutical field at least, the requirement of novelty in the Registered Designs Act is a more stringent requirement than that of distinctiveness in the trade mark context.

It should be remembered, however, that even a design which is neither a registered trade mark nor eligible for registration under the Designs Act is not open to the world. It may be protected under the the law of passing off discussed in Chapter IV.

NOTES TO CHAPTER V

- ¹For detailed background information to the law of copyright and the law of industrial designs see Coppinger & Skone James on Copyright, London, Sweet Maxwell (11th ed) 1971.
- ²Copyright Act 1709 (8 Anne c.19).
- ³For a fuller explanation of these terms see Wallace, William, Protection for Designs in the UK (1975) 5 1 PCL 421.
- ⁴King Features Syndicate v O & M Kleeman Ltd [1940] Ch. 806 [1941] A.C. 417 (H. of L.).
- ⁵Copyright Act 1911 (UK) "S.22(1). This Act shall not apply to designs capable of being registered under the Patents and Designs Act 1907, except designs which, though capable of being so registered, are not used or intended to be used as models or patterns to be multiplied by any industrial process."
- ⁶supra n.3.
- ⁷It is also the present position in Canada since the Canadian Copyright Act still contains a provision modelled on the old section 22. The artist's intention at the time of creation is still of paramount importance.
- ⁸Report of the Committee on the Law of Copyright, 1952, London, HMSO Cmd 8662 (the Gregory Report).
- ⁹Report of the Designs Committee 1962, London HMSO 1808 (Johnstone Report) Appendix C.
- ¹⁰Aspro Nicholas Ltd's Designs Application [1974] R.P.C. 645 (Regis. Designs App. Trib.).
- ¹¹ibid at p.652.
- ¹²Smith Kline & French Ltd's Design Application [1974] R.P.C. 253 (Regis. Designs App. Trib.).

- ¹³ The Ishihara Test consists of the use of a series of cards on which a pattern of coloured dots is printed to form a picture of one colour outlined against a background of a different colour. A normal observer will easily pick out the picture whilst a colour blind observer may fail to see the picture at all or will see a different picture from that seen by the normal observer.
- ¹⁴ (1935) 52 R.P.C. 117 (Ch. D) at p.124-5.
- ¹⁶ [1979] R.P.C. 197 (Regis Designs App. Trib.).
- ¹⁷ *ibid* at p.212.
- ¹⁸ Summary of Designs Registry Office Practice [1974] R.P.C. 262 para 3.
- ¹⁹ *supra* n.10.
- ²⁰ Copyright Act 1956, s.3(1)(a).
- ²¹ Copyright Act 1956, s.48(1).
- ²² Copyright Act 1956, s.4(1).
- ²³ Short v J.W.Henderson Ltd (1946) 39 B.W.C.S. 62 (H of L) Lord Thankerton reaffirmed the four criteria given by the Lord Justice-Clerk in the Court of Session in Parke v Wilsons & Clyde Coal Co Ltd [1928] Sess. Cas. 121 at p.133:
- (1) the master's power of selection of his servant
 - (2) payment of wages or other remuneration
 - (3) master's right to control the method of doing the work
 - (4) master's right of suspension or dismissal.
- ²⁴ Simmons v Heath Laundry Co [1910] 1 K.B. 543 (C.A.) per Fletcher Moulton L.J. at p.550.
- ²⁵ Stevenson Jordan & Harrison Ltd v MacDonald & Evans [1952] 1 T.L.R. 101 (C.A.). An accountant who also prepared and wrote lectures for delivery to Universities and professional societies was held not to have prepared lectures in the course of his employment and copyright in the lectures remained with the accountant.

- ²⁶ Le Rose Ltd and Another v Hawick Jersey International Limited [1974] R.P.C. 42 (Ch. D.).
- ²⁷ [1972] 1 Ch. 242.
- ²⁸ Copyright Act 1956, s.48(1).
- ²⁹ [1974] R.P.C. 57 at p.68.
- ³⁰ (1890) 25 Q.B.D 99.
- ³¹ *ibid* at p.104.
- ³² [1979] R.P.C. 551 (H. of L.).
- ³³ *ibid* at p.629.
- ³⁴ *supra* n.27.
- ³⁵ per Lord Hailsham in L.B. (Plastics) Limited v Swish Products Limited *supra* n.31 at p.628.
- ³⁶ Dorling v Honnor Marine Ltd [1965] Ch. 1 at p.21.
- ³⁷ A design is applied industrially if it is applied to more than 50 articles which do not constitute a single set of articles within the Registered Designs Act 1949, s.44(1) or to non hand-made goods manufactured in lengths or pieces. Copyright Act 1956, s.10(5). Copyright (Industrial Design) Rules 1957, r.1.
- ³⁸ *supra* n.36.
- ^{38a} *ibid* at p.16.
- ³⁹ *supra* n.9.
- ⁴⁰ [1973] R.P.C. 75.
- ⁴¹ Gratwick, Stephen, UK Designs Copyright - A Gilbertian Situation [1980] EIPR 243; Drysdale, John, The Application of UK Copyright Law to Manufactured Articles [1980] EIPR 75; Cornish W.R., Cumulative Protection for Industrial Designs [1973] UBC Law Rev. 219.
- ⁴² [1976] A.C. 64 (H. of L.).

⁴³ [1916] 2 Ch. 601 at p.608.

⁴⁴ (1928) 139 L.T. 365 (C.A.).

⁴⁵ [1928-1935] Mac. G. Cop. Cas. 44.

⁴⁶ [1936] N.Z.L.R. 627 (Sup. Ct).

⁴⁷ [1936-45] Mac. G. Cop. Cas. 99 (1937) (Ch. D).

⁴⁸ Smith Kline & French Laboratories Ltd v Sterling Winthrop Group Ltd [1975] 1 W.L.R. 914 (H. of L.) *supra* Chapter IV.

⁴⁹ (1924) 41 R.P.C. 658 (C.A.) at p.688.

⁵⁰ *supra* n.48 at p.921.

⁵¹ Registered Designs Act 1949, s.1(3).

⁵² Re James's Trade Mark (1886) 33 Ch. D. 392 at p.395.

CHAPTER VI

TERRITORIALITY AND THE PROBLEM OF PARALLEL IMPORTATION

One of the purposes of the intellectual property laws discussed above is to give the pharmaceutical firms protection against rival enterprises which would otherwise be providing similar drugs in direct competition. The companies, by taking maximum advantage of these rights, are able to secure considerable protection in the territory within which the right is conferred. However, these exclusive rights do not generally entitle the owner to control the resale of an article marketed by himself or with his consent. Where a product falling within the scope of the right has been put lawfully on the market most national legislatures (with the exception of Britain¹) allow it to circulate freely within the national territory. Thus, the first authorised sale "exhausts" the protection granted by law.

Protection will not reach beyond the scope of the national boundaries of the state within which the right has

been registered (with the possible exception of protection under the laws of passing off²). This is the principle of territoriality.

Pharmaceutical firms however are generally multinational corporations operating on an international scale. If the firm wishes to market a patented or trade marked drug in different countries it must secure the required protection in each country according to their respective laws. This task is facilitated by a number of international conventions the main one being the Paris Convention for the Protection of Industrial Property. By virtue of this convention a person who has filed an application for a patent, or for registration of a trade mark in one of the countries of the union shall enjoy, for the purpose of filing in other countries, a right of priority. As a result there will be a strong connection between applications made in several countries in respect of the same invention. The convention provides, however, that the "parallel" rights so obtained shall be independent of each other. Invalidation of an exclusive right in one country will not affect the validity of parallel rights in other countries. Such parallel rights may belong to different enterprises but, frequently, they are owned by

the same companies or associated companies within the same multinational group.

The multinational pharmaceutical corporations have attempted to use the intellectual property laws to prevent drugs produced by related companies from moving from one territory to another. The reason for this is the existence in certain countries of compulsory licensing schemes or voluntary price restriction schemes which lead to a considerable variation in drug prices. The pharmaceutical companies wish to prevent a third party buying their goods in a country where drug prices are cheap (e.g. Britain) and transporting them to a country where prices are higher for resale at a profit - usually in competition with the original right holder or a related enterprise. This practice is known as parallel importation.

The ability of pharmaceutical firms to prevent parallel importation is hindered by the theory of exhaustion of rights (discussed above) which is an attempt to reconcile the interests of the owner with the demands of free trade. Most states have accepted the principle of national exhaustion and the European Court of Justice has interpreted the Treaty of Rome as giving rise to a

principle of community-wide exhaustion. In international trade however the position is still uncertain. Some legislatures have applied the principle of international exhaustion and have refused patentees the right to bar imports from abroad when they have been manufactured and/or first sold by the patentee or his licensee under the protection of a parallel patent. The principle of international exhaustion however has not been accepted in all industrialised nations and in many cases intellectual property rights have been instrumental in protecting the pharmaceutical company from the parallel importer. In the writer's opinion, there is no reason why the pharmaceutical firm should be allowed to exclude goods from a national market which were manufactured abroad by the patentee or with his consent.

Presumably the patentee, by marketing abroad or granting licences abroad, has already been rewarded for his patent by the price or royalty paid. There is no reason why the intellectual property laws should assist the patentee in his efforts to practice international price discrimination. Nevertheless, national courts have in several instances allowed a national patent owner to use his right to erect a barrier to entry of patented goods emanating from the same undertaking.³

Within Europe discussions are in progress for the harmonisation of intellectual property laws in all member states. Meanwhile the European Court of Justice derives justification for the principle of community wide exhaustion from the Treaty of Rome provisions dealing with competition and the free movement of goods.⁴ The creation of the European Economic Community has had a major impact on the international operation of intellectual property rights. It is therefore necessary to consider the principle of exhaustion in two sections - the first will deal with protection against imports from non-member states and the second with the free movement of goods within the EEC.

1. International Exhaustion of Patent Rights

The pharmaceutical company will want to prevent parallel imports in order to maximise returns on their inventions through the maintenance of territorial price discrimination. It is arguable that an additional incentive to invent is created by the higher rewards earned by the patentees under a system of price discrimination. To deprive pharmaceutical firms of this additional incentive may result in a reduction in the amount a firm is

willing to expend on research and development. In the writer's opinion the profits accruing to pharmaceutical firms are sufficiently high⁵ that a denial of the opportunity to practice territorial price discrimination will not lead to a significant decrease in research programmes. Admittedly, patentees will no longer be able to maximise profits on the basis of demand in each national market but they will still be in a position to set prices and maximise profits on the basis of the elasticity of the aggregate national demands. If parallel importation between territories becomes feasible the patentee will be unable to quote different prices for drugs in different countries (assuming that national barriers to the movement of goods are minimal) and the result will be a universal reduction in drug prices.

In Britain, the principle of exhaustion has found favour in neither the domestic nor the international context. As long ago as 1871 it was held that where a British firm itself markets patented goods abroad it will be able to prevent importation of the goods into Britain - but only if the patentee attached a clear and express embargo on the original sale.

The case of Betts v Wilmott⁶ involved a patent for making metallic capsules of tin and lead compressed together for covering the corks and necks of bottles. The owner of the English patent was not permitted in this instance to restrain the sale in England of the same product emanating from his French factory. However, if he had some clear indication on first sale in France to the effect that no licence to import into England was conferred the restriction would have been enforceable in English Courts.

If the sale abroad is by a licensee under the foreign patent⁷ the court will be less willing to find an implied licence to import in violation of the licensor's national patent right. The national patentee can prevent parallel importation unless the patent licence expressly states otherwise. In Sterling Drug Co Inc Ltd v C.M. Beck Ltd and Another⁸ the pharmaceutical firm was able to enforce a condition against export on the sale of patented goods. The only issue was whether the defendants were aware of the restriction. The court did not question its validity. The case was decided on 24th June 1972 and was not complicated by E.E.C. considerations. If a similar case was heard today the condition would be unenforceable

to the extent that it applied to exports to E.E.C. countries. So far as trade with non E.E.C. countries is concerned, the case is still good authority for the principle that restrictions preventing exports to those countries are valid. Similarly, restrictions on sale in a non E.E.C. country prohibiting import of goods into the U.K. will be valid.

The right of a patentee to impose post sale restraints upon use of his patented product extends beyond the initial sale or licence and affects all subsequent dealings with the patented product. In Beecham Group Ltd v International Products Ltd and Another, heard in the High Court of Kenya⁹, Beechams had invented a novel penicillin which they marketed throughout the world. They granted to Bristol Meyers Co a licence to manufacture and sell the drug in many countries in which they owned patent rights, excluding Kenya. Beechams therefore sold the penicillin to International Products Ltd in the U.S. (where they were licensed to sell) and International Products Ltd proceeded to sell the drug in Kenya. In the ensuing infringement action the defence was raised that Bristol were licensed to sell the goods in the U.S. and goods on which a royalty had once been paid were thereafter free in the hands of the

purchaser to be sold anywhere in the world. It was held however that as a Bristol Meyer's licence conferred no right to sell the product in infringement of the Kenya patent, the sale in the U.S. to International would confer no greater right upon the purchasers who were accordingly enjoined from further selling in Kenya.

If the transaction between Beechams and Bristol Meyers had been a sale, rather than a licence, the sale would have conferred an implied licence to resell anywhere in the world in the absence of an express restriction.¹⁰ As it was a licence arrangement the extent to which the article was released from the patentees rights depended on the extent of the authority conferred upon the licensee by the agreement.¹¹

Thus, ignoring temporarily the impact of the E.E.C., the extent to which a British pharmaceutical firm can prevent parallel importation is as follows: Where the British company or its subsidiary markets a drug abroad under a foreign patent it can prevent the importation of the drug into Britain only if it attaches a clear and express embargo on the sale. If, however, the firm grants a licence under the foreign patent and the licensee sells

goods abroad, the ultimate purchaser may not import the patented drug into Britain unless the licence expressly confers the right to do so.

The principle of exhaustion appears to have no place in British patent law outside the context of the E.E.C. It is time that the law was amended to conform with the position taken by other industrialised nations. The Community Patent Convention, when it is in force, will establish the principle of exhaustion within the E.E.C. and, until then, the European Court of Justice is applying the principle under existing provisions of the Treaty of Rome. Furthermore, the theory of exhaustion has long prevailed in U.S. domestic law:

"The first vending of an article manufactured under the patent puts the article beyond the right of monopoly which the patent confers."¹²

Exhaustion of patent rights liberates trade (domestic or international) in patented products from artificial barriers. The products can then enter national markets freely and competition is enhanced both qualitatively and quantitatively with obvious resulting benefits to the consumer.

2. Trade Marks in International Law

Trade mark law confers upon the proprietor an exclusive right to use a trade mark to distinguish his goods from competing products. This exclusivity warrants to the owner that no other person may bring into circulation goods of a similar nature bearing that trade mark. However, the object of the trade mark is not to shield the owner from the impact of competition (although this may be an incidental result) but to provide a connection between the article manufactured and the trade mark owner sufficient to enable the public to identify the origin of the product. The owner of a trade mark should not be able to use the mark to repel the importation of goods which he himself has marketed elsewhere for the simple reason that a mark does not cease to accurately identify the manufacturer just because the goods cross a national frontier.

Trade mark law, like patent law, is governed by the territoriality principle, that is, the protection conferred by the trade mark law cannot extend beyond the territorial boundaries inside which this law is enforceable. The so called "universality principle" whereby

trade marks were considered to be an outgrowth of a right of personality, like a family name, and therefore entitled to universal protection beyond the frontiers of the country of origin was abandoned long ago.¹³

The territoriality principle implies that owners of identical trade marks, each having an exclusive right in the home country, can exist side by side in two countries each with its own trade mark law. This territorial sovereignty of each state in matters of trade mark law is recognised in the Convention of the Union of Paris and the Trade Mark Convention of Madrid. The territoriality principle also implies that domestic trade mark rights cannot be infringed by acts abroad and conversely acts at home may not violate foreign trade mark rights.¹⁴ It is a result of the territoriality principle that when the goods of a trade mark owner are imported into another country where an identical trade mark is held by another unconnected enterprise, the latter's claim for trade mark infringement is generally upheld.¹⁵ However, the principle has been abandoned in favour of the exhaustion principle when a special relationship exists between the two enterprises. In such a case the public are not misled about the origin of the goods and there is no reason to prevent importation.

Opponents of this trend maintain that the responsibility of the pharmaceutical firms does not end once the trade marked goods have been put into circulation. The original manufacturer should retain control throughout the sales channels until the goods reach their ultimate consumers. It is possible that drugs manufactured by the same concern for distribution in different markets may be made to a slightly different formula. In the sensitive area of public health this could have potentially serious consequences. Proponents of the right of control stress the "guarantee function" of a trade mark. The validity of the guarantee function has been the subject of considerable controversy.¹⁶

It is the writer's opinion that, although the pharmaceutical company may have a justified interest in banning imports of their own branded goods which may be manufactured for a different market to a slightly different formula, the solution lies with the pharmaceutical companies themselves. They can use different marks to distinguish products intended for different markets if there is a real difference in quality. It is not part of the trade mark function to indicate quality. Once a trade

mark owner has obtained an exclusive right for a certain category of goods he is at liberty to change the quality of his product at any time without the risk of losing his trade mark. He may or may not choose to inform the public of the change and there rests upon him no legal obligation to do so. A consistent standard quality is not an essential feature of the identification function of a trade mark, therefore the trade mark owner can have no legal claim to a guarantee function in the sense of an unchanged quality.

The right of a UK trade mark holder to prevent the parallel importation of trade marked products marketed abroad by a related company was considered by the courts quite recently in the Revlon case.¹⁷ The Revlon group operated in Europe through two subsidiaries one of which was the owner and the other the registered user of the British mark "Revlon Flex". The parent company distributed in the US a range of goods bearing the Revlon Flex mark which were not available in the UK. The two subsidiaries were unable to prevent a parallel importer importing the US range into England for resale. The vital section of the UK Trade Mark Act to be interpreted by the courts was section 4, Subsection 1 which gives to the proprietor of the trade

mark "the exclusive right to use the trade mark in relation to those goods". Subsection 3 provides however that the right shall not be deemed to be infringed

"if the proprietor or registered user has applied the mark and has not subsequently removed or obliterated it or has at any time expressly or impliedly consented to use of the trade mark."

The mark in this case had been applied by the parent company but the court was of the opinion that the subsidiaries must be taken to have consented to the use - The company structure of the Revlon Group was such that Revlon Inc. (the parent company) could at any moment impose its will on any company in the group. Thus every company must be taken to have consented to the acts of others within the group or, as Templeman L.J. put it;

"In more homely language s.4(3)(a) cannot be evaded by substituting the monkey for the organ grinder."¹⁸

This case represents a considerable step forward for the English Courts. Previously, the position in England appeared to be that although the proprietor of a trade mark could not object to the importation of branded goods marketed by him abroad¹⁹ he could object if those goods had been marketed by an associate company.²⁰

The Revlon case appears to subject English trade mark law to the principle of international exhaustion. However, it leaves certain questions unanswered. In particular; how close should the association between the companies be in order for the parallel importer to rely on the group nature of the mark? The court stressed the fact that the public associated the mark with the group and were unaware of, and uncaring about, which member of the group actually produced the goods. If the pharmaceutical manufacturing group can successfully instil in the public mind awareness of the independent nature of each company within the group it may be able to evade the consequences of the Revlon decision. In this manner the Swiss Supreme Court held that Sunlight A.G., the Swiss subsidiary of Unilver which owned registration of the trade mark "Lux" in Switzerland, could enjoin importation and sale of American made Lux soap in Switzerland despite the close relationship between Sunlight A.G. and the American Lever Bros Co.²¹ The court stressed that Sunlight A.G. had, since 1939, been entitled to register the trade mark in the name of the companies related to it. The finding by the court that the Swiss company had built up independent goodwill in Switzerland over a period of 30 years was held to be

decisive. The Italian courts applied a similar principle in the Palmolive cases.²²

Another question unanswered by the Revlon case involves the situation where the producing company appoints an independent exclusive distributor to market its goods in one country and the trade mark is registered in the name of the distributor. In fact such a situation is unlikely to occur often. The assignment of a trade mark to an independent third party for distribution purposes constitutes a somewhat hazardous venture for the owner. There is always a risk that the independent dealer will use the mark against the interests of the original owner. He may affix the mark to drugs emanating from a different manufacturer and thereby discredit the standing of the trade mark owner. Also, practical difficulties are inevitable when the relationship is severed and the mark must be reassigned. However, if such a situation was to arise the independent distributor would presumably be entitled to prevent parallel importation of his manufacturer's goods only if he has consistently built the mark up as associated entirely with him. If he acts in such a way as to convey the impression that his is only a branch office of the manufacturer and all advertising and

servicing is carried out by the manufacturer he should not be allowed to assert any independent rights against importation of the manufacturer's product.

Occasionally it may happen that the same trade mark is used and registered in different parts of the world by entirely separate concerns. If there is no present legal or economic link between the two concerns each should be allowed to prevent parallel importation of the other's product. Thus, the world famous trade mark "His Masters Voice" was registered in Switzerland by the British concern EMI and in the US by RCA Victor - a concern which had no connection with EMI. Sales of the US made records bearing the trade mark HMV were held to be a violation of the trade mark rights of the Swiss trade mark owner regardless of the fact that the records offered for sale by the defendant were genuine Victor records.²³

Such a situation has not so far arisen in a pharmaceutical context. Despite its defects, the Revlon decision is to be welcomed for its acceptance of the principle of international exhaustion. It is a further step towards freedom of competition which is desirable in the pharmaceutical field.

3. Passing Off in International Law

Trade mark law confers, through registration, the exclusive right to use a trade mark for the purpose of distinguishing the proprietor's goods within the territory covered by the registration. Although the trade mark owner may not have the right to prevent the importation of goods emanating from a related company he will always have a right of action against the producer or importer of spurious or counter goods bearing his trade mark. Protection may be obtained in any number of countries through registration but most countries will require as a condition of registration that the trade mark owner use the mark within the jurisdiction. Modern methods of communication and the ease of travel have led to a situation where a company's reputation may spread beyond the national frontiers of the country of registration into an area where the company is not trading and has no registered mark.

Thus, a pharmaceutical company may market a drug abroad using marketing and advertising techniques which are so successful that the mark or get up becomes well known in England even though the drug is not marketed here. Can the

company prevent a third party taking advantage of that reputation to manufacture a drug in England bearing the same mark, name or get up?

In Alain Bernadin et Compagnie v Pavilion Props Ltd²⁴ it was held that, for protection to be granted in England, there must be a reputation based upon user in England. The proprietor of the internationally known Crazy Horse Saloon in Paris was unable to enjoin an imitator from cashing in on the reputation of the name and get up. However the principle was not followed in the similar case of Maxims Ltd and Another v Dye.²⁵ The English company which owned the world famous Maxims restaurant in Paris had not, and never had had, any business in England yet it had sufficient reputation in England by virtue of the restaurant in Paris to justify the grant of relief for passing off against a defendant setting up in England under a similar name. Graham J. relied, in his decision, on a statement from the Baskins Robins case²⁶

"Some businesses are however, to a greater or lesser extent truly international in character and the reputation and goodwill attaching to them cannot in fact help being international also."^{26a}

Maxim's case is of doubtful authority in view of the recent case of Athletes Foot Marketing Associates Inc. v Cobra Sports Ltd and Another.^{26b} Walton J. discussed the relationship between the Maxim's case and the Crazy Horse case:

"What connection with this country is required before a plaintiff can successfully maintain an action for passing off? There appear, on the cases to be two schools of thought about this. There is what was described in argument as a "hard line" school of thought, which maintains that it is essential for the plaintiff to have carried on a trade in this country (best, perhaps, exemplified by the Crazy Horse case) and a much less demanding approach which suggests that something less than that will do (well exemplified by [the Maxims case])"^{26c}

After reviewing all the authorities Walton J. conceded that it did not matter whether the plaintiffs were actually carrying on business in the country provided they had customers there but where they could disclose not one solitary transaction by way of trade with anybody in the country they could have no protectable goodwill in the country notwithstanding their general reputation.

It seems therefore that the pharmaceutical firm may not rely upon its international reputation to bring a

passing off action in a country where it has no customers and has no intention of selling its product merely to prevent the defendant company taking advantage of its reputation. To that limited extent it seems that a "free ride" is permissible.

4. Impact of the EEC

The Treaty of Rome has had a considerable impact on the operation of the intellectual property rights of member states. The aim of the Treaty is to establish a single economic territory by providing for the free movement of goods and free interaction of competitive forces. The principle of territoriality ceases to apply on a national basis and will apply instead to the entire EEC. Steps are being taken to harmonise the intellectual property laws of member states in order to provide a single, unified system.

The European Patent Convention already in existence establishes within Europe as a whole (not just EEC countries) a supranational system by providing for a European Patent Office to grant Europatents in as many countries as the applicant desires. The Europatent consists of a "bundle of national patents" and each state

party to the Convention is obliged to treat the Europatent as having the same effect, and being subject to the same conditions, as a national patent. Within the EEC alone negotiations are in progress for the establishment of a Community Patent Convention. The general principle is that where an application for a Europatent designates any EEC country a community patent will be granted instead of a national patent for that country in the bundle.

The community patent will be unitary in that it may be granted, transferred, revoked or allowed to lapse only in respect of the entire EEC.

Similar negotiations are in progress for the establishment of a European Trademark.²⁷ Again, the community mark is conceived as a unity effective throughout the EEC or not at all. One contentious aspect of the present proposals for the EEC mark concerns the exhaustion of rights in legitimate goods. International companies hoping to use trade marks to divide markets are hostile to EEC Court of Justice decisions on trade marks in the national market (discussed below)²⁸ and to national decisions such as the Revlon case (discussed above)²⁹ which adopt the principle of international exhaustion.

There has been strong opposition to proposals within the EEC which would enshrine the principles on which these decisions were based in legislation.

At present neither the CPC nor the CTM is operative. The absence of any political union in the EEC has made movement towards a unified, harmonised law a complex business. However, in view of the manner in which intellectual property rights have been used to prevent the movement of goods from one part of the EEC to another, the European Court of Justice has relied upon provisions of the Treaty of Rome itself to limit the scope of those rights.

5. Exhaustion of Patent Rights in the EEC

The proposed draft of the Community Patent Convention makes specific provision for the exhaustion of patent rights.³⁰

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

A similar article³¹ applies the principle behind the article 32 prohibition to cases where the right of protection arises not from a community patent but from one or several national patents that belong to one owner or to persons who are tied to him economically.

A study of recent case law suggests that these proposed articles have become merely a restatement of the exhaustion doctrine evolved by the court under the Treaty of Rome. The Convention will be useful, however, not only in securing the free movement of goods but also in establishing uniform conditions throughout the EEC for the exploitation of inventions.

The proviso contained at the end of Article 32 may be employed to relieve firms from compliance with the Article where the product has been marketed by a third party in a country where no patent is available. The case of Parke Davis & Co v Probel and Others³² does not involve a British pharmaceutical firm and was decided before Britain entered the EEC. Nevertheless, it did involve the interpretation of national industrial property rights in the light of the Treaty of Rome. Parke Davis, an American pharmaceutical firm, owned certain Dutch patents

on which it attempted to rely in order to prevent the importation into Holland of drugs manufactured and sold freely in Italy where, it will be recalled, no patents were available for pharmaceuticals. The court held, in the writer's opinion wrongly, that to allow the plaintiffs to restrain importation from Italy would not contravene the Treaty of Rome. When a drug has been marketed anywhere by the patentee or a subsidiary or licensee there is no reason why the patentee should be able to subsequently restrict the free movement of those goods. The patentee had power to control where the goods were marketed and chose to sell them in a country where no patent rights were available. The position should be the same whether no patents are available at all or patents are available but the manufacturer has neglected or failed to obtain one.

It is arguable that this approach unfairly penalises a patentee who does not take out a patent in every EEC country where the product is patentable. It may be that despite his interest and willingness to have his invention patented in every member state protection is refused in some states. It should be remembered however that this situation will, hopefully, not last long. Once the C.P.C. is in force an inventor or his assignee should

be able to obtain patent protection in all of the member states where he wants to exploit his invention since patentability rules will be the same throughout Europe.

There is a stronger argument for allowing a patentee to prevent parallel importation of the patented product from a state without patent protection when the product is marketed by a third party. In such a case the patentee has derived no benefit from the marketing and had no choice in the matter. This is perhaps the only situation where an exception to the principle of free movement of goods may be justified. The European Court expressed approval for this approach in the Centrafarm case discussed below.

The great variation in drug prices within Europe has led one firm in particular to engage in parallel importation on a large scale which has resulted in extensive litigation. The firm is the Dutch pharmaceutical company, Centrafarm. The first action involving the company was decided on October 31st 1974.³³ The Hoge Raad held that under Dutch law the patentee had the untrammelled right to prevent importation from abroad even if the drug in question had been manufactured with consent

of the patentee under a parallel patent. However, upon referral to the European Court of Justice, the Court laid down the principle that, while the Treaty of Rome does not affect the existence of rights recognised by the legislature of a member state in industrial property, the exercise of those rights may be affected by prohibitions in the Treaty. Thus, enforcement of the patentee's right was, in this instance, incompatible with the Treaty of Rome.

6. Exhaustion of Trade Marks in the E.E.C.

The trade mark counterpart of the Centrafarm v Sterling Drug case was Centrafarm v Winthrop.³⁴ The holder of a mark in one member state was deemed to be unable to prevent the importation of goods from another member state if marketed there by him or with his consent. In that case the trade mark Negram was owned by different marketing subsidiaries of the same concern in the countries of export and import and consent was implied through the legal and economic links between the two companies.

The court has not placed undue emphasis on the requirement of consent. In Van Zuylen Bros v Hag,³⁵ the mark "Hag" was owned by two unrelated enterprises in Germany and Belgium both of which had exclusive trade mark

rights in their respective countries. The companies had at one time been related and although, as a result of government sequestration of German assets after the war, there was no longer any connection between the firms the court still maintained that it would contravene the free movement of goods doctrine to allow the owner of the Belgian mark to prohibit importation of the German company's goods.

While the writer applauds measures designed to encourage the free movement of goods it is possible that this case extends the principle too far. The court has repeated on numerous occasions that the specific purpose of a trade mark is as a guarantee of origin for the benefit of the consumer. This case sacrifices the consumer's benefit under trade mark law to the principle of free movement of goods. The court considered that the two companies could rely on other means to differentiate their products but this presupposes that the consumer notices the other distinctions and does not purchase by mark alone. The consequences of extending the Hag principle to the pharmaceutical field are potentially serious. Two totally separate enterprises manufacturing different drugs under the same trade mark could constitute a danger to public health.

Fortunately the Hag situation is unlikely to occur frequently and the court has not applied the same principle in a situation where the marks were at all times owned and developed by entirely separate enterprises.³⁶

The Centrafarm company, presumably encouraged by its success in the Sterling Winthrop action, continued their practice of parallel importation and became embroiled in two further legal battles with major drug manufacturers.³⁷ However, they were less successful as the court imposed certain limitations on the doctrine of exhaustion espoused in Centrafarm v Sterling Winthrop. The principle was held not to apply where the marked product is marketed in other member states after it has been repackaged in new packaging to which the trade mark has been affixed by a third party. The drug involved in the Hoffman-La Roche case was the tranquilizer Valium. The British subsidiary of Hoffman-La Roche supplied the drug to English chemists in large packs which the dispenser then distributed according to quantities prescribed by the physician. In Germany, on the other hand, drugs were sold to patients in small sealed packages containing a regulation number of tablets - a practice which made the large sized British packs virtually unsaleable in Germany.

Even in this case, however, the exemption to the exhaustion principle was narrowly defined. The court must examine whether the use of different package sizes was a result of marketing conditions in the two countries or was a device intended to act as a disguised restriction on trade between member states. The court laid down four criteria upon the basis of which such intent would be presumed. That is where:-

"-it is established that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between member states
-it is shown that repackaging cannot adversely affect the original condition of the product
-the proprietor of the mark receives prior notice of the marketing and repackaging of the product and
-it is stated on the new packaging by whom the product has been repackaged."

The last three elements will be relatively easy for the parallel importer to comply with. It will be harder to establish whether the use of the trade mark will contribute to the artificial partitioning of the markets. This appears to be an objective test for the court to decide.

The next Centrafarm battle was against American Home Products Corporation (AHPC)³⁸. The company marketed what was essentially the same drug as "Serenid D" in Britain and as "Seresta" in the Netherlands. Centrafarm repackaged the British drug and sold it as Seresta in the Netherlands. This was held to infringe the Dutch patent notwithstanding that the trade mark was affixed to "genuine" goods. Again however, the exception to the exhaustion principle was qualified by the court:

"Nevertheless, such prevention may constitute a disguised restriction on trade between member states if it is established that the proprietor of different marks has followed the practice of using such marks for the purpose of artificially partitioning the market."

In this case no objective criteria were laid down. The court made the issue turn on the intention of the mark owner.

These last two Centrafarm decisions represent a disappointing reversal of the trend towards community wide exhaustion of rights. There can be no harm to the consumer in permitting such repackaging and relabelling provided it

is performed under controlled conditions by qualified personnel and there is no alteration of the original product. The court should not concern itself with the subjective intent of the drug manufacturer. If his marketing techniques have the effect, albeit coincidental, of partitioning the market the producer should not be permitted to use his trade mark to prevent parallel importation.

7. Passing Off Actions in the E.E.C.

During the course of negotiations on the ETM, a conflict has arisen between those who feel that industry and commerce should be free of all restrictions except those arising out of registration, and those who wish to protect the expectations of businesses that they will have rights in passing off accruing from their growing reputation even if they do not register them.

The present draft defines a mark in very wide terms to cover not only traditional elements such as names, prints and seals, but also

"shapes, articles of packing and all other signs which distinguish the goods or services of an undertaking."

This definition seems virtually as wide as that adopted in the Smith Kline & French case discussed above.³⁹ The coloured capsules which, in the writer's opinion, were wrongly held to be registrable as trade marks will apparently be eligible for registration as community trade marks.

Even so, it is not now proposed that registration will be the only way of protecting such subject matter. Rights in national law against passing off or unfair competition may also be used. Article 16 of the 1978 Draft Regulation which restricted the proprietor of a CTM from proceeding otherwise than for infringement under Article 10 has been deleted so that there is now no prejudice against bringing concurrent actions for trade mark infringement and passing off where the circumstances warrant it.

Firms with a trade mark already registered in a member state may oppose applications or seek cancellation of marks on the register provided they also satisfy the criteria for use. Thus, the position of businesses in countries with a "registration only" background is clear. What is less clear is the extent to which prior rights

acquired by use will also form the basis of an objection. This is particularly relevant for British pharmaceutical firms which may rely on unregistered marks to bring a passing off action.

The current proposal is to allow those with a mark "well known in another member state" to oppose an application or secure cancellation but the prior right must be of more than local or regional importance. This requirement could bear hard on small businesses whose success entitles them gradually to expand but one feels it will not bear hard on the multinational pharmaceutical corporations.

Copyright in the E.E.C.

It will be recalled that the pharmaceutical companies have not so far relied heavily on copyright to protect their products so case law in the area is practically non-existent. On the question of copyright enforcement in the E.E.C. generally the leading case is Deutsche Grammophon v Metro⁴⁰ where the court restricted the use of copyright to prevent parallel imports of records into Germany. It seems from this case that the court treats copyright laws in the same way as those relating to

patents and trade marks when judging their relationship with the rules of the Treaty of Rome and, in particular, rules providing for the free movement of goods. So far as goods marketed in the E.E.C. with the consent of the copyright proprietor are concerned the doctrine of the free flow of ideas should prevail over nationally granted intellectual property rights.

9. Industrial Designs

A brief word remains to be said about industrial designs. The Paris text of the Berne Copyright Convention refers specifically to industrial designs, the principle being that works protected in one country solely as designs or models shall be entitled in any other country to only such special protection as is granted in that country to designs and models. Thus, if registration is a prerequisite to protection in the home country the applicant must also register abroad. If designs are protected simply through copyright protection similar protection may be obtained abroad.

Within the E.E.C., a European Design Convention has been proposed but no work has yet been done on this. The Commission is under pressure to act because, at

present, the degree of protection afforded in the different member states varies and this is a potential hindrance to intra community trade. The Commission is studying the Benelux Convention as a possible model. The Benelux Law, operative from 1975, provides for the new appearance of a product having a utility function to be protected as a design throughout the Benelux countries.

10. Future Developments

The European Court of Justice is working towards a uniform interpretation of national industrial property laws but there remains an urgent need for a single European Intellectual Property Law under which any marketing by the holder of a product protected by an intellectual property right will exhaust that right. There is no need to restrict this principle to marketing in the E.E.C. Marketing anywhere in the world should exhaust the right provided it is done by the right holder or with his consent.

Whenever the court finds that a protected product is subject to a substantial price differential between two territories, or a patented product is being sold for a price which is abnormally high in the light of comparable

products there is reason to suspect that intellectual property rights are being abused. It is of course arguable that a price substantially in excess of that necessary to remunerate conventional factors of production is a logical consequence of a legal monopoly. This depends on the philosophy adopted by the country conferring the right - whether to confer on the rightholder the ability to maximise his returns or to limit him to a "reasonable reward". The British view has tended toward the concept of "reasonable reward" particularly in the pharmaceutical field and, in the writer's opinion, this is the view which should prevail throughout the E.E.C.

NOTES TO CHAPTER VI

¹In Britain, the rule of domestic law has always been that the purchaser of patented goods needs the patentees licence before using or vending the marketed product, although the effects of this approach are mitigated to the extent that, where goods are sold without adequately notified restrictions the vendor confers on the purchaser an implied licence for all future dealings and uses

²See generally Chapter IV

³For detailed discussion of parallel rights, see Alexander, "The Establishment of the Common Market and the Problem of Parallel Patents" (1969) 14 Anti-Trust Bulletin 181-220, 185-193

⁴Treaty of Rome, Arts 85, 86 - Competition; Arts 30 - 36 - free movement of goods

⁵See generally Chapters I and II

⁶(1871) L.R. 6 Ch. App. 239

⁷Glaces v Tilghman (1883) 25 Ch. D. 1 (C.A.)

⁸[1973] R.P.C. 915 (Ch. D.)

⁹[1968] R.P.C. 129 (High Ct of Kenya)

¹⁰Betts v Wilmott supra n.6

¹¹Glaces v Tilghman supra n.7

¹²U.S. v Universal Lens Co. (1942) 316 U.S. 241 (Sup. Ct)

¹³Kohler, Joseph; Warenzeichenrecht 2nd Ed. 1910

¹⁴See The Maja Case in the German Supreme Court January 24 1964 (1964) G.R.U.R. Int. 202

¹⁵The Persil Cases: (C.A.) Dec. 20 1963 and January 17 1964 (1964-5) 2 CML Rev. 349 [1964] G.R.U.R. Int. 636 [1964] WuW 535

- ¹⁶Werheimer, The Principle of Territoriality in Trade Mark Law of the Common Market Countries (1967) 16 ICLQ 630; Bier [1964] G.R.U.R. Int. 205; Lutz [1965] G.R.U.R. Inst. 601; Herfermel [1964] G.R.U.R. Int. 376; Rottger [1964] G.R.U.R. Int. 128
- ¹⁷Revlon Inc and Others v Cripps Lee and Others [1980] F.R.S. 85
See also Kitchen, David, The Revlon Case. Trade Marks and Parallel Imports (UK) [1980] EIPR 86
- ¹⁸ibid at p.116
- ¹⁹Champagne Heidsieck et cie Monopole Societie Anonyme v Buxton (1930) 47 R.P.C. 28 (Ch. D.)
- ²⁰Dunlop Rubber Co Ltd v A.A. Booth and Co Ltd (1926) 43 R.P.C. 139 (Ch. D.)
- ²¹The Lux Case; Federal Tribunal, February 12, 1952 Arrets du Tribunal Federal Vol. 78, 11, p.164, Lux [1953] G.R.U.R. Int 42
- ²²Cassaz; October 20, 1956, No. 3781; Firo Italiano, 1957 I Col. 1021; Palmolive [1957] Rev. Dir Ind II 358
- ²³Electrical and Musical Inds Ltd v Delachaux, March 13, 1959 (1959) 85 (iv) B.G.E. 53
- ²⁴[1967] R.P.C. 581 (Ch. D.)
- ²⁵[1977] 1 W.L.R. 1155 (Ch. D.)
- ²⁶[1976] 2 F.S.R. 545 at p.548 (Ch. D.)
- ^{26a}See also C & A Modes v C & A (Waterford) Ltd [1976] I.R. 198 (Sup Ct of Ireland) where it was insisted that "goodwill does not necessarily stop at a frontier."
- ^{26b}[1980] R.P.C. 343 (Ch. D.)
- ^{26c}ibid at p.349
- ²⁷Draft Regulation on Community Trade Marks Document III/D/753/78; Draft Directive to approximate the Trade Mark Laws of Member States Document III/D/1293/79; Latest Draft Regulation C.O.M. (80) 635

for a full discussion on the CTM Regulation and Directives see Armitage, Edward, The CTM: Comments on the latest drafts of the proposed EEC Regulation and Directive [1981] 3 EIPR 72

²⁸infra p.143

²⁹supra p.131

³⁰C.P.C. Art. 32

³¹C.P.C. Art. 81

³²Case 24/67 [1968] 7 C.M.L.R. 47

³³Centrafarm B.V. and Adriaan de Peijper v Sterling Drug Inc case 15/74 [1974] E.C.R. 1147 (preliminary ruling requested by the Hoge Raad)

³⁴Centrafarm B.V. and Adriaan de Peijper v Winthrop B.V. case 16/74 [1974] E.C.R. 1183 (preliminary ruling requested by the Hoge Raad)

³⁵Van Zuylen Freres v Hag A.G. case 192/73 [1974] E.C.R. 731 (preliminary ruling requested by the Tribunal d'Arrondissement of Luxemborg)

³⁶Terrapin (Overseas) Ltd v Terranova Industrie C.A. Kapferer & Co. (preliminary ruling requested by the Bundesgerichtshof) case 119/75 [1976] E.C.R. 1039

³⁷Hoffman-La Roche & Co A.G. v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse Mbh (preliminary ruling requested by the Landgericht Freiburg) Case 102/77 [1978] E.C.R. 1139 Centrafarm B.V. v American Home Products Corporation (preliminary ruling requested by the Arrondissementsrecht Bank Rotterdam) Case 3/78 [1978] E.C.R. 1823 see also Rottger, Martin, AHPC and Centrafarm, the Courts Decision in the Light of its Earlier Rulings [1980] E.I.P.R. 322 Case 78/70 [1971] E.C.R. 1147

³⁸ibid

³⁹Chapter IV n.19

⁴⁰Case 78/70 [1971] E.C.R. 487(499)

CONCLUSION

It will be apparent by this stage that the tenor of this paper is strongly anti protectionist. The writer has advocated the abolition of patent protection for pharmaceutical products or, failing that, a limitation of protection to processes only. Recent trends however, in England and Europe, are firmly in favour of stronger patent protection for pharmaceuticals and the likelihood of a reversal of this trend is small.

Failing that, however, steps should be taken to prevent the extension of the twenty year monopoly through promotion of an exclusive get up. The scheme of universal capsule coloration advocated in Chapter IV would allow large firms such as Hoffman-La Roche and Smith Kline & French to superimpose their name or mark upon the coloured capsule thereby continuing enjoyment of their high reputation and any resulting benefits dependent upon doctors' prescribing habits. At the same time, the scheme would eliminate the suspicion that such firms are using the laws of trade mark and passing off as shields behind which to reap profits free from the rigours of all but oligopolistic competition.

In a territorial context, English courts should be persuaded to accept the principle of international exhaustion. The sale of a protected product anywhere in the world (not just within the E.E.C.) should exhaust all exclusive rights attached to the product provided the sale takes place by, or with the consent of, the right owner.

It is the writer's belief that incentives in the pharmaceutical industry are sufficiently high that implementation of the above measures would not lead to a significant reduction in the amount of research and development presently undertaken. Furthermore, there is a strong possibility that the measures will lead to a universal reduction in the prices of pharmaceutical products with resulting benefits for consumers and society.

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