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Chairman: H. TREVES BROWN

CHAIRMAN'S ADDRESS

PATENTS IN PHARMACY AND MEDICINE

IN accordance with its Constitution the British Pharmaceutical Conference meets annually for the discussion of matters relative to the science of Pharmacy and to further the objects of the Pharmaceutical Society. One of these objects is the advancement of Chemistry and Pharmacy. Even in these days which have seen the establishment of a Restrictive Practices Court and a Monopolies Commission it is generally accepted, perhaps more often axiomatically than after full consideration, that a patent system is an essential prerequisite of industrial research by making it possible to obtain the financial resources needed to conduct it. At no previous time in history have the benefits of chemical research as reflected in the practice of medicine been so striking, and it becomes increasingly desirable that not only those who practise the profession of pharmacy but also those who are associated in any way with its practice, whether as research chemists, administrators or users of its products, should understand something of the ways in which our patent system affects it.

A learned judge once said "It is a matter of common knowledge that . . . research scientists are 'patentwise.' If they are not, they should be[1]".

Research chemists in industry are certainly brought closely into touch with the procedure for obtaining patents but I am rather doubtful if many of those here this morning would regard themselves as "patentwise". In my limited experience, many research workers in the pharmaceutical field regard the subject of patents as something that, if possible, is best left severely alone. The explanation of the difference between the learned judge's experience and my own may lie, at least in part, in the fact that the remark was made by an American judge. Nevertheless, the second part of his observation—"If they are not, they should be"—suggests that he was not too sure of his assertion. While, therefore, there will no doubt be some research workers here this morning who know from experience what is involved in filing and prosecuting patent applications, there will be other members of the Conference, including many not engaged in research, who have no such experience. I propose, therefore, to give some account of the legal requirements and the procedure for obtaining a chemical patent in this country, to describe some of the problems involved in obtaining corresponding patent protection overseas, and then to deal with some special considerations relating to patents in the fields of pharmacy and medicine in this country. I must stress that I am speaking mainly about chemical patents, which differ in some respects from the generality of patents dealt with in the text books.

I must also emphasise that in dealing in a relatively short address with such a complex legal subject it is inevitable that I shall frequently oversimplify the position. A patent lawyer would no doubt wish to qualify with "ifs" and "buts" many of the statements I shall make.

The first patent was granted in 1449 for making coloured glass for the windows of Eton and King's Colleges[2]. Addresses on patents, however, usually start with the Statute of Monopolies, 1624, which is regarded as marking the origin of the patent system in this country and indeed throughout the world, and I am following the precedent. The reason is that the economic philosophy which led to the passing of the Act is still the basis of patent law to-day and must be kept in mind when considering what the provisions of that law should be.

The object of the Statute of Monopolies was to prevent James I from filling the royal coffers at the expense of the public by the sale of monopoly rights. Its general effect was to render void all grants of monopolies for the making or selling of anything. But by Section 6 of the quaintly worded statute an exception was made of "letters patent and grants of privilege . . . of the sole working or making of any manner of new manufactures . . . to the true and first inventor or inventors of such manufactures which others at the time of making such letters patent and grants shall not use, so as also they may 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". This exception was intended to encourage the introduction of new industries into the country and the encouragement of new manufacturing activities is still the object of a patent system. Section 6 of the Statute of Monopolies is still in force to-day, and it is of the utmost importance for a patent is granted only for an "invention", which is defined in the current Act, the Patents Act, 1949, as "any manner of new manufacture . . . within section six of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture". A method of testing was not patentable before 1949 and little use has so far been made of the provision in the pharmaceutical industry.

It follows from this definition that, apart from the new provision relating to testing, the first requirement for an invention to be patentable is that it shall be for a manner, or kind, of manufacture. Secondly, it must be a manner of *new* manufacture; in technical language, the invention must have novelty, by which is meant that it must not be known.

The third requirement is that there shall have been an inventive step—a patent must have what in technical language is called subject matter. Finally, it must have utility—it must be useful. I will deal with these in turn.

Requirements for Validity

Although at the time of the Statute of Monopolies the kinds of new manufacture that were contemplated were new industries, the term now includes a manufacturing process and also the product of a process. It must be emphasised that not every discovery, even when it is useful, is

patentable, and a great deal of discussion has taken place in the Courts and elsewhere to determine what is "a manner of manufacture". The discovery must relate to something tangible—in one case[3] it was said that the invention must be concerned with a "vendible product", and although this is not the whole truth and has been modified by later decisions, it is probably as near as one can get in a simple explanation. For example, a method of pruning clove trees to stop the spread of a fungus disease was held not to be a manner of manufacture[4]. Another example of a patent application which failed for the same reason is a method of fumigating a building by means of an insecticidal aerosol[5]. Last year a method of increasing the yield of wool by administering thyroxine to sheep was held not to be a manner of manufacture[6].

The second requirement for patentability, that the invention shall have "novelty", means that, at the date when the patent application, which includes a description of the invention, is filed at the Patent Office, it must not be known, nor must it have been used, in this country. A problem arising from this requirement of the law is the need to restrain research workers from publishing their results before the appropriate patent application has been filed. Prior publication is a complete bar to obtaining a valid patent—but it must be publication in this country, including publication in a foreign journal available in the country at the priority date. Availability at the Patent Office Library is the standard method of proving publication, but of course any other form of publication is sufficient to destroy validity. And it must always be remembered that a communication does not cease to be a publication merely because it is marked "confidential". Disclosure to a colleague who is bound to treat his employer's affairs as confidential is however permissible.

So far as prior use is concerned, public working of the invention during the year preceding the priority date is permissible for the purpose of reasonable trial if the invention is of a kind which can only be tried in public. Presumably this would cover clinical trials of a new drug, although usually the pharmacological testing stage provides sufficient evidence to enable a decision to be made as to whether the filing of a patent application is warranted. It is not usual to shelter under this limited permission of public working because it relates only to British patents—and if it resulted in publication of the invention in another country before the British patent application was filed, a valid patent would not be obtainable in that country.

Apart from this special provision for public working prior use is a ground on which a patent application can be opposed by an interested party[7] or a patent revoked by the Court after it has been granted[8].

In most countries the Patent Office conducts a search of the literature to see if the invention has been described previously, but the thoroughness of this search for "anticipation" varies considerably in different countries. The British search is less extensive than some and a curious provision of our law[9] is that a disclosure in a patent specification whether British or foreign which is more than 50 years old does not destroy novelty although it might serve as supporting evidence of prior use.

The U.S. Patent Office is experimenting with electronic means of recording and searching the literature. At present this "Mechanised Division" is concerned only with steroids, and it seems to be handling what must be a difficult field with speed and efficiency. From the applicant's point of view it has the advantage that, so far at least, the machine is unable to think, and thus office objections based on taking ideas from several sources, combining them together and concluding therefrom that "no invention is seen in the application" are virtually eliminated—and such objections, based on opinion as to obviousness, are often extremely difficult to content. The British Comptroller-General of Patents has expressed the view that the means of searching that are available to examiners in the Patent Office are so highly developed that any mechanical or electronic alternative "will have to present considerable advantages in speed and cost to make its adoption worth-while[10]". I refer later to the possibility in our industry that serious loss may result when the grant of a patent is delayed and I suspect that many firms would prefer the speediest procedure even if the cost were somewhat higher.

Before leaving this subject, it should be mentioned that disclosure by word of mouth is just as fatal as disclosure in writing—but I hope this warning will not prevent research workers from enjoying all the amenities provided by those who entertain the British Pharmaceutical Conference.

The third requirement for patentability is that there shall be subject matter, or an "inventive step". The invention must not be obvious. The degree of inventiveness required to support a patent is very small; a mere "scintilla" of invention is sufficient[11]. The question as to whether an alleged invention is obvious is often one of great difficulty, for many admirable inventions seem obvious when once they have been made. Commercial success and supplying a long-felt want are among the criteria to be taken into consideration. Although just as essential for validity as any other of the requirements this question of subject matter does not present a serious hurdle to obtaining a patent in this country. The reason for this is that the British Patent Office does not concern itself with subject matter and the grant of a patent can be opposed by an interested party only if the invention "clearly does not involve any inventive step[12]". Yet when the patent is granted one of the grounds on which a Court can revoke it is that the invention "is obvious and does not involve any inventive step . . ."[13]; the word "clearly" is not used, and its inclusion in the earlier section relating to opposition proceedings gives the applicant the benefit of the doubt so far as consideration of his application by the Patent Office is concerned. Certainly the inclusion of so indefinite a qualification and the difficulty of proving a negative must make a potential objector pause before opposing on this particular ground. The present wording represents a compromise between the views of those who hold that the Comptroller, as an executive officer, should not have power of a judicial character on his own initiative to refuse applications on the ground of lack of subject matter, and of those who think it wrong that a patent should be granted for an alleged invention which obviously lacks inventive merit[14].

Chemical Inventions

This question of an inventive step acquires a different significance when applied to chemical inventions such as those with which the pharmaceutical industry is concerned for it is rare for a new chemical process to be involved. Most chemical process patents are concerned with the manufacture of a new compound or group of compounds by procedures well known in themselves—for example a Grignard reaction or the oxidation of an alcohol to an aldehyde—although not hitherto applied to the manufacture of the particular new compounds. In such cases it might be argued that there is no invention in applying procedures which would be obvious to any chemist desiring to make the new compound. The position was explained in the well-known "sulphathiazole case"[15] where it was pointed out that an invention consisting of the production of a new substance from known materials by known methods is not patentable merely because the product is new, but it may be held to possess subject matter provided the substances are truly new (not being all merely additional members of a known series) and useful, and their useful qualities are the inventor's own discovery. In other words, in chemical process cases the real inventive step is often the discovery of the value of the products.

It follows that in chemical patents the question of subject matter is often inextricably bound up with the question of "utility"—the fourth requirement for patentability. An invention can be the subject of a valid patent only if it is useful and two aspects are involved. The procedure described must be useful in the sense of producing the result stated by the inventor and that result itself must be useful, in the sense of giving some advantage to the public. Lack of utility is one of the grounds on which the Court can revoke a British Patent[16], but provided the process "works" a very small degree of usefulness in the result is sufficient. In other countries, especially the United States, Germany, and recently Denmark, this question of utility is of the utmost practical importance and it is dealt with in detail later.

Scope of Provisional Specification

If then a patentable invention has been made, a description of it has to be filed at the Patent Office. This description is known as the "specification" and in the U.K. and other, mainly Commonwealth, countries which follow British practice the specification usually filed with the application when it is first filed is known as a "provisional" specification. The only legal requirements about a provisional specification are that it shall describe the invention and begin with a title indicating the subject[17]. At a later date a complete specification must be filed. It must "particularly describe" the invention and the best method of performing it known to the applicant; it ends with claims defining the scope of the invention claimed[18]. The complete specification is required to be filed within a year of the filing of the provisional although by paying additional fees an extension of up to a further three months can be obtained. The general theory behind this two-specification practice is

that in the provisional the inventor discloses the general features of his invention and early experimental results, and then he has a period of several months to work on it so that in the complete he can disclose the full details and indicate the exact scope of the monopoly claimed. His priority runs from the date of filing the provisional so far as he describes the invention in it. Before 1950, when the Patents Act, 1949, came into operation, the invention could undergo "legitimate development" between the filing of the provisional and the complete specifications without losing the priority date of the provisional. Under the present Act, a claim which is "fairly based" on the provisional specification has priority from the date of filing the provisional; otherwise the priority date is that of filing the complete which, as indicated above, is usually a year later. Although the application to particular cases in the pharmaceutical industry of the principle of "legitimate development" was fraught with uncertainty, the change in the law has not, in my experience, reduced it from a commercial point of view. If, for example, in a reaction for which a patent was sought before 1950, an alkyl group was introduced and the provisional specification disclosed that valuable compounds were obtained when the alkyl group contained up to, say, 8 carbon atoms, one would feel that disclosure in the complete that a valuable compound was obtained with an alkyl group containing 10 carbon atoms was "legitimate development", and therefore a claim covering this compound would have priority from the date of filing the provisional. But what would a Court have decided about a compound with a C_{16} alkyl group? Under the present law it has been held[88] that in deciding whether a complete specification is "fairly based" on a provisional answers to three questions are required. The first one is: Is the alleged invention as claimed broadly described in the provisional? If the answer is in the affirmative the next question is: Is anything included in the invention claimed inconsistent with the provisional? If there is no such inconsistency, the third question is: Does the claim include as a characteristic of the invention a feature as to which the provisional is wholly silent? Although this guidance is undoubtedly helpful, its application in particular chemical cases often leaves a feeling of uncertainty. Perhaps it is the uncertainty which is the main worry, for in this kind of case neither the patentee nor his competitor can be confident whether a compound is patented from the date of the provisional or from a year later. In a rapidly developing field—and in our industry most fields of research can be so described—a difference of one year in priority can be of the greatest importance.

In some countries, for example Holland and Australia, unlike this country, the priority date is inserted after each claim and in just such a case as I have mentioned the Australian Patent Office has refused to give the earlier priority to a claim to a compound which had not been specifically mentioned in the provisional although clearly within its scope. This does not necessarily mean that it would not be possible to restrain a competitor who discovers the C_{10} compound between the date of the provisional and the date of the complete. He will be barred by a valid generic claim to alkyl compounds as a group, but if for any reason the

generic claim is held to be invalid, perhaps because a research chemist once made a compound in the group, one cannot fall back on the more specific subsidiary claim.

Difficulty in deciding the scope of a provisional does not only arise from uncertainty on chemical grounds. I have pointed out that the inventive step in most medico-chemical inventions is the discovery of the value of the products. If, at the time the provisional is filed in my hypothetical case, the value of alkyl products as a group has not been ascertained it does not seem to me that priority for the alkyl compounds as a group can fairly be claimed.

I understand that those with wide experience of patents in various fields do not accept the view that chemical cases present greater difficulties than others in regard to the scope of the provisional. Be that as it may, the problem in practice is often one of the greatest difficulty. The research team make a few compounds of a group and biological investigation shows that each of the compounds has significant activity of the same type. It is obviously desirable to file a patent application immediately. But what should be covered in the specification—all the compounds in the group, only those actually shown to have activity, or some intermediate selection such as those which seem fairly easy or cheap to manufacture? And of course I have simplified the practical problem by referring to compounds of a "group". Bearing in mind the infinite variety of substitution that is possible in organic chemistry it is impossible to define a group in terms which will include all the compounds reasonably likely to be active and exclude the rest even if "reasonable likelihood" of showing activity was sufficient justification for a patent. It was of course just this dilemma which created the circumstances that led to the "sulphathiazole case" although the point on which it was fought was different. The problem was referred to by Lord Justice Somervell in the Court of Appeal[19] who said that he thought he appreciated the point that difficulty arose for chemical inventors if they could claim only one or more specific tested compounds when the probability is that other similar compounds have the same qualities but then he went on to say: "The conclusion I have come to . . . does not I think preclude the possibility of a chemical inventor obtaining adequate protection under existing patent law if he will take the proper steps". I do not know what steps the learned Lord Justice had in mind.

A legal authority with much experience in these matters recently suggested to me that the provisional should include a statement expressing the reasonable expectation of the extent to which the invention will apply to compounds other than those specifically mentioned. A claim to such compounds would then probably be regarded as "fairly based" on the provisional and the inventor would therefore have the additional year to find out how far the expectation was justified and to draft his claims accordingly. This suggestion may go a long way to solving the problem in drafting many chemical patent specifications in the U.K. When, however, the invention resides in the discovery of therapeutic activity, the unpredictability of the relation between the degree of activity and,

say, the length of side chain may often make it extremely difficult to formulate the expectation. Further, insofar as foreign applications are concerned, I suspect that in many countries there would be difficulty in securing acceptance of the "reasonable expectations" as being within the scope of the invention.

The only safe procedure seems to be to make and test as wide a range of compounds as possible before filing the application so that it can be based on ascertained facts, or else to file a succession of applications as the biological results are obtained. Commercially, the delay entailed by either procedure may mean that someone else gets in first and you lose your patent and much of the financial benefit of your research. It seems to emerge clearly from this that the larger the research team, and the greater the speed with which the ramifications of a chemical invention can be followed up, the greater the prospect of obtaining broad and valid patent cover. But anyone familiar with the problems of getting clinical trials carried out on the products of industrial research will know that a year in which to determine the scope of a patent, so as to be able to claim all—and only—the useful compounds, is often inadequate. A patent agent with considerable experience in the pharmaceutical field has said[20] that it is almost impossible to pay more than lip service to the legal principles for validity and pointed out that the effect is to encourage what he called "dishonest" statements although I should prefer to describe them as "optimistic without much foundation". He expressed the hope that in any case where validity is challenged because some of the compounds claimed do not have the virtues alleged, the Courts will take a generous view of the difficulties—and we must leave it at that.

Convention Patents

In industrial practice this problem does not end with consideration of the scope of a provisional in comparison with what it is intended to include in the complete specification in the United Kingdom. It affects the position overseas. As many of you will know, under the International Convention for the Protection of Industrial Property, first arranged in 1883 and subsequently amended, a British inventor who has filed an application and a provisional specification in the U.K. can apply for a corresponding patent in any country which has adopted the Convention —known as a "convention country"—within one year of his U.K. application, and still obtain priority as from his U.K. filing date. Similarly an inventor who files a patent application in an overseas convention country can file a corresponding application in the U.K. within one year of his original date of filing, and obtain priority as from that original date. Advantages of this arrangement for the British inventor are that the British complete specification and the corresponding foreign specifications can be prepared at the same time, and the inventor has a year after making his invention within which to decide whether its commercial value is such as to make it worth while to incur the quite substantial expense of applying overseas. The invention claimed overseas must be the same as that disclosed in the British provisional, and at

once the old problem arises—what is the scope of the invention described in the provisional? Practice varies in different countries—some Patent Offices take a liberal view as to the scope of the invention described in the provisional, others take a narrow view; and inevitably, as the human element is concerned, the same Patent Office does not always seem to be consistent.

Although applications filed overseas in accordance with the Convention can claim priority as of the date on which the corresponding application was filed in the country of origin, in all other respects such applications are subject to the same law and practice as apply to an original application in the country concerned, and these often differ from British law and practice. I should like, therefore, now to refer to a few of the outstanding examples of such differences.

"*Interferences*"

First, I will mention the law in the United States on priority. Whereas in most countries the priority date is that on which the application is filed, the date in U.S.A. is that on which the invention was discovered or thought of by the inventor— the "date of conception". The inventor can even publish his invention but still get a valid patent if his application is filed within a year of such publication[21], although he will not be able to obtain a valid patent in any country outside U.S.A. where the publication becomes available before the U.S. filing date. The determination of priority by reference to date of conception obviously creates a difficulty when two or more inventors file applications covering the same ground, for the Patent Office examiner cannot know which inventor had the earliest date of conception. In such instances the procedure by which the applicant with the earlier date of conception is ascertained is known as an "interference", the inquiry being conducted by three "examiners of interferences"[22]. I have sometimes come across research workers in this country who have had an impression that all that is necessary for a U.S. worker to show the date of conception of his invention is to produce the appropriate laboratory notebook—and there may even be the faintest suggestion that the date appearing in the notebook is not above suspicion. Any such impression is quite without foundation, and Americans themselves have the greatest respect for the thoroughness of the procedure by which priority is determined. The effective date is not merely that on which the idea occurred to the inventor—the invention is not complete until it has been "reduced to practice"—a physical act as distinct from the mental act. In chemical cases this means that it must have been shown that the reaction took place as described. The inventor's own and uncorroborated evidence is useless; corroboration must be by someone other than a co-inventor who understands what is being written and can testify from his own knowledge that the work described in the notebook was actually done[23].

In an interference the first stage is that each party submits a sworn preliminary statement specifying the dates when the acts relied upon as

showing he had completed his invention were done, and the party will not be allowed to claim earlier dates in the subsequent procedure. After the statements have been accepted by the Patent Office each party can see the other's patent application but not his preliminary statement so that neither knows as yet the other's claimed priority date. The next stage is the collection of sworn evidence, which is given in the form of question and answer each witness being questioned by the attorney for his own side and cross-examined by the attorney for the other side. Finally, there is a hearing before the Board of Interference Examiners. I understand that in practice the result of most decided interferences is that the party who files first obtains priority and one wonders whether such an expensive and lengthy procedure is really worth while in comparison with the law in our own country and most others which gives priority to the first applicant. I have earlier mentioned that in a keenly competitive industry such as ours any delay in obtaining a patent may lead to other manufacturers marketing the same product and one would expect that the considerable delay created by the interference procedure would greatly facilitate this kind of competition. It is therefore not surprising that a large proportion of interferences, especially it is understood in the pharmaceutical industry, are settled by negotiation between the parties. Before leaving this subject I must point out one anomaly from the point of view of the non-American inventor. If the interference declared is between an original application in the United States by, say, an American inventor and an application under the International Convention by, say, a British inventor, the latter cannot claim his "date of conception" —his priority date is that of the original U.K. application, but the American can go back to his date of conception. Furthermore, as the British priority date can be ascertained from Patent Office records, the American inventor knows the latest date he can claim if he is to win the interference. He can use this information to claim for himself a later date than he otherwise would have done and thereby be able to produce more adequate evidence of reduction to practice before the British filing date. In Canada, where a modification of this interference procedure is in force, the convention applicant from overseas is not restricted to the convention date, and proof of "reduction to practice" is not required. The Board of Patent Interferences decides the issue on the basis of an affidavit filed by each applicant setting out the history of his application.

Utility

Another matter on which difficulties arise in prosecuting overseas applications is that of utility. I have mentioned that, in general, everything within the scope of a claim must be useful and in the case of a British patent the extent of the usefulness can be quite small. In some countries, this question of utility is of the utmost importance, especially in America, where, in connection with chemical patents in the pharmaceutical industry, it has been the subject of much controversy in recent years. A U.S. patent can be granted for a "new and useful process, machine, manufacture or composition of matter"[24] and the specification

is required[25] to describe "the manner and process of making and using" the invention.

It has been held in the U.S. Courts[26] that the specification must include an assertion of utility and an indication of the use intended. If the invention is a pharmaceutical chemical—does this mean that one must indicate in the specification the pharmaceutical use or is it sufficient to show that the invention is useful as an aid to further research—in the words of the U.S. Constitution[27] "to promote the progress of science"? And if a pharmaceutical use is required, is it sufficient to show pharmacological activity without tests on human beings? Until relatively recent times the U.S. Office, like the British, were content with a very slight showing of utility and in fact they adopted the concept that an invention had utility provided it was not inoperative. Then a few years ago the U.S. Office—or at least some examiners in it, for they were not consistent—tended to require proof of clinical value. Recently, in my experience, assertion of pharmacological activity of a kind which would lead one to expect useful action in man has been accepted, perhaps because of a case in 1957[28] in which the demonstration of antispasmodic activity in laboratory animals was held to be sufficient. It must however be said in defence of the Patent Office's former attitude that there are numerous cases in which the Court has indicated that the Office must satisfy themselves that an assertion of therapeutic value is justified—and whatever may be thought of such judicial opinions the executive officers can scarcely be criticised if they act upon them even though no comparable proof is required in non-medicinal fields.

Utility of Intermediates

The question of utility in connection with applications in U.S.A. arises in a particularly troublesome form in connection with patents for intermediates. Until after the war, a statement that a compound was useful in organic synthesis was sufficient. Then it became necessary to indicate the compound which it was proposed to make from the intermediate, and that compound had to be of known value or its value had to be shown in the specification. The objection to this from the manufacturer's point of view was that it necessitated making further progress in a research project—in fact making a second invention—before patent protection could be obtained for the intermediate. A year or two later the U.S. Patent Office stiffened the requirements arguing that the intermediate itself had to have some valuable property. This led manufacturers to engage in quite useless research work to find some activity in the intermediate which could be put forward for patent purposes however inadequate commercially. It was permissible to supply this kind of information when the examiner asked for it, usually quite a long time after the patent application had been filed, and by that time the final product had probably been made and tested so that one knew whether it was worth while spending time and money on obtaining adequate patent protection for the intermediate. Then a further stiffening occurred and for the last year or two the Patent Office has adopted the

attitude that the utility of the intermediate—the method of converting it into a useful end-product—must have been included in the original specification as filed and where this has not been done a patent has been refused. Quite recently a further step has occurred. Priority in accordance with the International Convention has been refused in a case where the British provisional did not include this U.S. type of utility statement.

These changes in U.S. Patent Office practice have stemmed from court decisions, although they have been much criticised by the industry and have caused a good deal of irritation. For example, in a case in 1954, the Examiner had rejected an application claiming a compound which was stated to be of value in preparing more complex phosphorus derivatives and as a constituent of parasiticidal compositions. On appeal the rejection was upheld on the ground that there was no disclosure of the nature or of the utility of the more complex derivatives which could be obtained from the new compound, even though the specification referred to two other applications in which the intermediate was used[29]. Although not germane to the present point, the second kind of utility disclosed—the use in parasiticidal compositions—was also held to be insufficient because the specification did not say what kind of organisms were killed and therefore the applicant did not give an adequate disclosure as to how to use his compound. The Board of Appeals even suggested that a parasiticidal composition ought to have been exemplified. As a result of many protests from the pharmaceutical industry the Commissioner of Patents in 1956 defended the Office attitude in an address to the Division of Medicinal Chemistry of the American Chemical Society. On the question of proving therapeutic efficiency he claimed that the Patent Office had always sought proof of efficacy where a compound was claimed to be of value in a disease known to be difficult to treat and cited a case in 1940[30] in which a patent was refused for a preparation alleged to promote the growth of hair. He also argued that as the public believed that the grant of a patent implied that the patented product had value for the indicated uses and that it had Governmental approval, it was a responsibility of the Patent Office to protect the public by an appropriately cautious attitude. The Commissioner's arguments in relation to intermediates and to therapeutic efficiency were subsequently refuted in a memorandum to the U.S. Patent Office by the Sub-committee on Utility Practice of the Committee on Chemical Practice of the U.S. Patent Law Association in which a large number of legal decisions were reviewed, but little change has so far resulted, perhaps because the criticisms in the memorandum applied more to the decisions than to the Patent Office which is guided by them. It is not appropriate for anyone in this country to comment on the U.S. Commissioner's conception of the duties imposed upon him by the laws and Courts of his own country. We can, however, be thankful that our own Patent Office does not find itself obliged to be a judge of clinical trials, and pharmaceutical manufacturers, whether in America or elsewhere, may fairly doubt whether the highly effective work of the U.S. Food and Drug Administration in

controlling the marketing of new compounds in that country really needs supplementing by the presumably less expert activities of the U.S. Patent Office.

The latest stage in the controversy occurred about a year ago when the Court of Customs and Patent Appeals gave a decision which if it is accepted as representing the law makes the position in regard to patents for intermediates much more satisfactory[31]. The case was concerned with claims for two derivatives of 14-hydroxy-Δ^5-androstene. The specification referred to the presence of a 14-hydroxy group in the cardiac glycosides and said that the compounds claimed in the patent were valuable intermediates in the preparation of analogous 14-hydroxy steroids into which they could be converted by hydrogenation. The application was rejected by the Patent Office on the ground that the specification failed to show how these intermediates could be converted into useful compounds. The rejection was upheld by the Board of Appeals but the C.C.P.A. by a majority allowed the application and said the Office had been confusing the need for "utility" with the separate legal requirement that the specification should indicate the manner of using the invention. They returned to the old concept that "utility" in patent law means simply "not frivolous, or mischievous or immoral".

A lighter touch in the judgment of the Court was a comparison of the action of the Board of Appeals in rejecting this application because of lack of utility although it provided "new building blocks of value to the researcher . . . which have utility as intermediates in the search for cheaper and shorter routes to the synthesis of useful steroids", with their action in allowing a patent for a lacquer for changing the contour of the human nose[32] on the ground that the improvement of the features of a person had utility. On the question of revealing how the invention is to be used, the Court said that the specification told those skilled in the art that steroids having analogous structures were made by hydrogenation, and that was enough. Research workers would know how to use the new compounds. To require that the specification should show how to make at least one therapeutically valuable compound from the compounds in the patent would be "quite an effective way to remove the stimulus of the patent system from this kind of research".

The Court went on to refer to the problems of the Patent Office in handling applications in the field of pharmaceuticals where assertions are made of beneficial therapeutic effects on human beings and said that it is entirely proper that such assertions be carefully investigated. Thus, the Patent Office's incursions into the field of therapeutic trials seem to be supported.

It is understood that this decision is to be the subject of an appeal, but as the law stands at the moment in U.S.A. as a result of this case a patent for an intermediate cannot be rejected for lack of utility merely because the compounds are not themselves of therapeutic value. It is however necessary in the specification to indicate how the new compounds may be used to give compounds which are, or may be, of value, though, it may be, merely as intermediates for yet other compounds. It is a

further effect of this case that the Patent Office are supported in requiring proof of clinical effectiveness in any case where the Examiner thinks there is a doubt.

Perhaps a foreign observer may be permitted to express the hope that a reasonable view will be taken of what constitutes such proof. In a recent case of mine, admittedly not a strong one, an examiner rejected an application on the ground that the evidence of more than one medical man was necessary, and that each doctor should have treated at least ten patients. While the latter may be somewhat arbitrary there is judicial support for a requirement of thorough testing and successful trial by at least two physicians[33]. On the other hand the Board of Appeals decided in favour of an applicant in a case in which a product for the treatment of duodenal ulcer was stated in a doctor's affidavit to relieve some of the symptoms. The Patent Office claimed that radiological evidence of cure should have been presented, not merely the subjective statements of patients, but the Board held that relief of symptoms such as flatulence and pain could only be shown by questioning the sufferers[34].

America is not the only country where the patenting of intermediates may run into difficulty. Germany is another example where in general such patents are refused and the Patent Office attitude has recently been vigorously defended by the Chairman of the Senate in the German Patent Office[35]. Patent applications in Germany are rejected if they relate to processes for making intermediates which processes are analogous to known processes. An "analogy process" is one in which the mode of operation is the same as in a known process and the problem to be solved is the same, so that a chemist could assume with a probability bordering on certainty that the conversion of the new starting materials will proceed in the known way and give a product of the kind expected. A patent is allowed for an analogy process by the German Patent Office only if the product is new and has a novel, beneficial and not obvious use. It is considered that an intermediate does not have this kind of use, even if it can be used industrially.

Earlier this year, the highest tribunal in patent matters in Denmark came to the same conclusion.

Examination of Applications

Let us now return to the U.K. and assume that the foregoing hurdles have been borne in mind and a complete specification filed. In spite of skilled professional help in drafting a specification it almost invariably happens that the patent office examiner will find some fault—be it an ambiguity, a lack of clarity or just a plain error—in the wording. Sometimes a claim will be criticised as being too broad having regard to what is stated in the body of the specification. Although by the nature of his job an examiner has to be a somewhat severe critic, it must be borne in mind that his comments help to reduce the risk that any patent eventually granted will be held to be invalid. Further, if sometimes a criticism is

difficult to deal with, a discussion with the examiner will often produce a mutally satisfactory answer and I must include examiners at the Patent Office among the most helpful of our often unfairly maligned civil servants. A provisional specification is not examined until the corresponding complete specification is being considered. It used to receive its own attention and a common criticism was that there was disconformity between the complete and the provisional. As indicated above such disconformity no longer matters in the U.K. since matter in the complete specification but not in the provisional is acceptable, but its priority runs only from the date of filing the complete. One of the commonest criticisms is of the title, the legal requirement being[36] that the title shall indicate "the subject to which the invention relates". A list of applicants and the titles of the applications is published weekly and in order to avoid disclosure of the direction of one's research, it is usual to give as vague a title as possible when filing the original application—such as "Improvements in or Relating to Organic Compounds"—and the Patent Office in due course requests something more specific but this will not be published until the application is accepted.

Eventually if all the objections are overcome, the applicant is notified that his application is accepted by the Office and that the specification will be published. Three months then elapse during which the grant of a patent can be opposed, but if no opposition is filed "letters patent" will in due course be received.

The length of time during which an application is being considered is of course dependent on the time taken to reply to objections raised by the Examiner. The specification is required to be in order for acceptance within $3\frac{1}{2}$ years of filing the complete specification, subject to a maximum extension of three months on paying the appropriate fee[37]. Failure to comply entails rejection of the application. Damages for infringement can be obtained only from the date on which the specification is published[38] and the marketing of the product before that date may result in competition from imitators who are quick off the mark. The greater the usefulness of the product and the easier it is to make, the more likely it is that such competition will occur. Subject to the possibility of obtaining a licence under the patent, a matter which is dealt with later, legal action can be taken against the competitor to force him to withdraw the imitation when the patent is granted but in the meantime the patentee may suffer considerable damage for which he has no redress. In America it is possible to secure early consideration of an application in certain circumstances, such as where an infringement is occurring or the absence of a patent hinders commercial negotiations for exploitation of the invention. This seems to be a precedent which might with advantage be adopted in this country.

As a matter of interest I may mention that the average time for a representative half dozen patents with which I have recently been concerned to go through the Patent Office, from the date of filing the provisional specification to the date on which the patent was granted, is nearly $2\frac{1}{2}$ years, and any inventor here who is thinking of filing a patent

application may like to know that the average cost—in the United Kingdom only—was nearly £80.

Employees' Inventions

A matter that may be mentioned at this point is the ownership of patents as between employer and employee. It is of course possible for the question to be dealt with in a written agreement or contract of employment in any way the parties may decide, but in the absence of specific agreement the general rule is that "where the employee in the course of his employment (that is, in his employer's time and with his materials) makes an invention which it falls within his duty to make . . . he holds his interest in the invention, and in any resulting patent, as trustee for the employer"[39]. This rule covers most of the cases in the pharmaceutical industry since obviously it *does* fall within the duty of research workers to make inventions. But sometimes the position is not quite so simple. Suppose for example a senior employee such as a manager in change of a packing department invents, say, a machine for counting tablets. In such cases the law regards it as inconsistent with good faith that the employee should own the invention. As a senior employee he is expected to use all his abilities in the service of the employer. But if the same kind of invention is patented by a relatively junior employee, the patent would belong to the employee and the employer would have no right to it even though the employee used some of the employer's materials and time. In America in such cases the employer has what is known as the "shop right" to use the invention in his own business without payment, while the employee can exploit it for his own benefit outside the employer's business, but in British law the patent usually belongs wholly to the employer, or, rarely, wholly to the employee. Prior to 1949, disputes as to ownership between employer and employee could be settled only by an action in the High Court, a procedure which would naturally be beyond the financial resources of the employee. Under the current Act these disputes can be heard by the Comptroller, with a right of appeal, although the Comptroller can decline to deal with the matter if he thinks it could more properly be dealt with by the Court[40]. Further, the Comptroller has power to apportion the benefit, but only if he is not satisfied that one or other of the parties is "entitled" to the benefit to the exclusion of the other[41]. In the Patchett case[39], the word "entitled" was held to mean "having a legal right", and since the law, whether fairly or not, has almost always given the sole right to one of the parties, usually the employer, the power of apportionment is likely to be exercised only very rarely—perhaps only when there is a written contract of employment which provides for sharing the benefits of the employee's inventions without specifying the respective shares.

It may be that employees not engaged on research who make inventions have some justification for regarding the law on this matter as being unfair to them. Certainly before the Patchett case it was widely thought that under the 1949 Act disputes of this kind between employer and

employee would often be settled on the basis of sharing the benefits and this view of the intention of those responsible for that Act is supported by the Final Report of the Swan Committee (see especially para. 27). There does not seem to be the same objection to the vesting in the employer of the exclusive right to an invention made in the course of his employment by an employee engaged in research. Even if an employer in the pharmaceutical industry wishes to give some reward to the employee who "invents" a new and valuable compound, it is difficult to do so fairly. There is no certainty that a new compound will have the therapeutic value it is hoped it will have and major factors in the success of research work, however well-informed the concept, are volume of work and just plain luck. Success in research, in the commercial sense, cannot therefore be regarded as an indicator of special merit, for the worker who makes the compounds that turn out not to have the hoped for properties may well be as brilliant a chemist and have made as significant a contribution to the total research effort as his more fortunate colleague.

Who is the Inventor?

While on the subject of employees I should like to mention a problem to which there seems to be no simple answer. In applying for a patent the name of the "true and first inventor" must be disclosed. If untrue information is given the Crown is deceived and the patent is invalid[42]. I am told that inspiration comes to a chemist at quite unlikely times and places. He discusses the idea with his colleagues over the morning coffee; a plan of work is formulated and the various jobs given to members of the team. In the course of the research some ideas are found to work, others have to be changed. Eventually a compound emerges which is tested by the pharmacologist and found to have a useful action, following which it is tried out clinically and shown to have a valuable therapeutic effect. Who is the true and first inventor? Is it the chemist who originally thought the compound would be worth making and testing? And are those who followed to be regarded as the mechanical means of carrying out and verifying his ideas? I have already quoted high authority for the proposition that the process of making a new chemical compound by known procedures may be patentable if the new compound has useful properties which are the inventor's own discovery. It may be the pharmacologist who discovers the useful properties although it is the chemist who devises the manufacturing procedure that is patented. It is submitted that in such cases the chemist and pharmacologist are joint inventors.

Again, some organisations carry out as a routine a wide range of pharmacological tests on every compound made, including compounds made for completely non-medical purposes. Suppose in the course of such routine work a compound unexpectedly turns out to be of value for, say, treating cancer. Assuming that as a result of that discovery the method of manufacture constitutes a patentable invention, it seems that the pharmacologist would be the inventor.

The application can be made by the true and first inventor or by his assignee, and in each case either alone or with any other person In industrial practice the application is often made by the company as assignee of its employee, but the official application form requires a declaration that the inventor assents to the application being made. When a complete specification is filed a further declaration of inventorship must be made whether or not the specification contains new matter invented by someone other than the original inventor[43]. When making these declarations it is common practice to include among the applicants those who have made the main contributions to the conduct of the chemical research and to regard this limited group as being a collective first and true inventor. But it does not seem certain that a Court would take a benevolent view of this practice. It can be argued that making an invention, being a mental act, cannot be made by a team. It can also be argued that the group should include all who have contributed ideas that have been utilised in the course of the work. The point has not been tested in the courts but if there is a vital legal significance about naming the inventor correctly it seems desirable that the law should be modified to accord with modern research practice and to eliminate a somewhat technical trap which confers no particular benefit on anyone.

Before 1949, an application could not be prosecuted by an assignee so that the employer was not free to deal with the invention before the patent was granted. The employer could take an assignment of the application so that the patent was issued to him, but his rights were not recognised before the issue took place. Difficulty therefore occurred during the application stage if an employee applicant changed his employment or went abroad and the employer desired to grant a licence or otherwise deal with the invention. This has now been altered and an employer can claim sole ownership from the date of the application while the inventors can have their names shown on the specification when it is published and thus secure the personal credit attaching to the invention—a simple change in the law that has saved a great deal of unnecessary trouble.

Product Patents

From the chemical and pharmaceutical point of view the outstanding change made by the 1949 Act was the introduction—or, rather, reintroduction—of product patents, as a result of which patents became obtainable for two kinds of product, previously unpatentable.

Perhaps the most important prohibition removed was that on the right to obtain a patent for a new chemical compound as such, as distinct from a compound when made by a particular patented process. Before 1919 it was the practice for patent specifications to include claims to chemical substances at large. The compound, however made, was then the monopoly of the patentee. The British chemical industry at that time was very much in its infancy and, especially in the section concerned with the manufacture of dyes, was struggling against the post-war

rejuvenescence of German competition. The industry in general welcomed the statutory prohibition contained in the Patents and Designs Act, 1919, of "claims for the substance itself, except when prepared or produced by the special methods . . . claimed or by their obvious chemical equivalents"[44]. Some difficulty subsequently arose over the interpretation of the word "special"[45] and the wording was changed in 1932 to "except when prepared . . . by the method or processes of manufacture particularly described. . .".

Under this provision a firm which discovered a valuable compound made by a chemical process and patented a method of making it might find itself in competition with another firm which had devised an alternative method of manufacture. One result was that the discoverer of a new compound endeavoured to patent all the possible ways of making the compound that he could think of, thereby wasting much effort and obtaining patent protection for a number of processes which would not be used. Further, legislation of this type must tend to deprive the discoverer of a new and valuable compound of the fruits of his invention. Indeed, as I have indicated, the object of the provision was to enable British chemical manufacturers to make useful compounds, especially dyes, discovered by foreign competitors provided they could devise a non-infringing method of manufacture.

By 1946, the attitude of the chemical industry had changed and we find the Joint Chemical Committee on Patents, a body representing a number of industrial and scientific organisations concerned in the practice of chemistry, including the Association of British Chemical Manufacturers and the Wholesale Drug Trade Association, recommending the restoration of the power to patent substances[46]. The Committee pointed out that the inventive step is often the conception of the compound and that the method of making it may well be obvious to a chemist. The recommendation was accepted by the Swan Committee[47], and the 1949 Act made the appropriate alteration in the law. In America and Canada product patents have always been obtainable, and some Commonwealth countries have followed the current British Act, but most countries in Europe still limit the scope of their patent protection to chemical processes. The desirability of product patents for chemical substances is a matter for endless argument. If it be considered that patents in the chemical field are beneficial as facilitating and stimulating research then the better protection afforded by a patent for a substance however made as compared with a patent for the substance when made by a specified method must be regarded as desirable. If on the other hand you regard a patent as conferring a monopoly which must be conceded reluctantly and to the minimum practicable extent then you may think that the removal of a limitation on the scope of patent protection is unfortunate. And it can of course be argued that there is a definite stimulus to research if it is open to others to exploit alternative methods of manufacture, while the reply to this will be that a greater good is served by devoting the research effort to the discovery of new valuable compounds than to the evasion of a competitor's patent.

Patents for Food or Medicine

On whichever side the balance of advantage to the public may be thought to lie, the history suggests that an industry which is confident of its future and actively carrying out research prefers the product patent.

The second restriction on the grant of product patents which was removed by the 1949 Act was that relating to substances intended for food or medicine. In patents for new chemical compounds of therapeutic value it is now a common practice also to include a claim to pharmaceutical compositions incorporating the new compound which, it is submitted, would not have been allowable before 1949 as being substances intended for medicine. The following is an example[48]:

> "A therapeutic composition having prolonged adrenal cortical hormone-like activity comprising a sterile solution of 17-hydroxy-corticosterone 21-beta-*cyclo*pentylpropionate in a non-toxic fluid vehicle".

A further advantage of this change in the law is that it is now possible to obtain here, as in U.S.A., a patent for a therapeutic composition based on the discovery that a known chemical compound has a valuable therapeutic action which was previously unsuspected. The "composition" may be made by some well-known procedure, such as tabletting or mere mixing, which cannot be patented because it is not new; but if the resulting composition has not hitherto been made, and if it is useful because of the newly discovered therapeutic value of the active ingredient, then a product patent is obtainable for the composition.

Patents are however still refused if the invention claimed is a mere mixture of known ingredients possessing only the aggregate of the known properties of the ingredients[49] and a claim to a new substance does not extend to the substance when found in nature[50].

Use of Patent Monopoly

Let us now turn to the ways in which a patentee can make use of his patent. The wording of letters patent indicates that the grant confers on the patentee the sole right to "make, use, exercise and vend" the invention. *The Times*[51] has suggested that a patent is "sometimes cynically described as a passport to litigation in the courts", for the inventor must himself enforce his right, and the practical effect of the grant is only to entitle him to take legal action to restrain anyone who is making, using, exercising or selling his invention without permission. In recent months I have come across more than one pharmacist who is under the impression that if a substance or preparation which is the subject of a patent is included in the B.P. or B.P.C., the patent can be ignored. This impression is completely without foundation and I may remind you of the "Notice Concerning Patents" in the B.P.[52] which states that the inclusion of such products "neither conveys, nor implies, licence to manufacture".

The right conferred by a British patent continues for a period of 16 years from the date of filing the complete specification provided that

the requisite annual renewal fees are paid. A period of four years from this filing date is allowed before any renewal fees are due and thus the patentee has a little time within which to decide whether it is worthwhile maintaining the patent. The renewal fee payable before the end of the fourth year is £5, and thereafter it increases each year up to £20 for the final year. In America there are no renewal fees and the patent continues in force for 17 years. Canada, as in many other patent matters, follows the American practice, but most countries require that renewal fees be paid if the patent is to remain in force.

In the United Kingdom only half the normal renewal fee is payable if the patent is at the request of the patentee endorsed "licence of right", which means that anyone can obtain a licence to use the patent on terms which, if not agreed between the patentee and the licensee, will be fixed by the Comptroller[53]. Little use seems to be made of this provision in the pharmaceutical industry although one might think that in view of the special position of medicines in regard to licensing, which I shall mention in a moment, the facility is especially suitable for patents in the medical field.

The patentee who brings an infringement action must prove infringement and where a process is involved proof is often difficult, since it is necessary to show what is being done in the alleged infringer's factory. In the case of an imported substance proof of infringement of a process patent is virtually impossible—another reason why product patents give more adequate protection. In America the Customs authorities have power to prevent the importation of a product which if made in America would constitute infringement of a U.S. patent[54].

When it does occur, infringement is likely to be accidental. I remember being asked by a colleague to arrange for a patent application in respect of an improvement in a certain process and the details seemed vaguely familiar. To his utter astonishment I eventually turned up in my files a copy of a specification describing the improvement which had been signed and dated by him, showing that he had read it some two years earlier. He had long since forgotten the patent and then some quirk of memory had recalled the idea which he had developed, incidentally on slightly different lines from those of the original inventor, but still based on the patented principle so that the improvement in question had to be discontinued.

It has been pointed out by the Patents Manager of the National Research Development Corporation[55] that the modern tendency in industry is to file patent applications to cover individually every little improvement in a process without giving overmuch thought to the question of validity. "The complexity involved in challenging such a 'web' would daunt a would-be trespasser". The author goes on to say that this tendency "is commonly expressed by saying that firms tend to respect each other's patents". I should like to think that in industry in general such respect rests on something more creditable than the complexity of challenging another's patents. In our industry, since the re-introduction of product patents 10 years ago, infringement of a patent

for a chemical compound is of course immediately obvious unless the compound is an intermediate which is not offered for sale. Infringement is therefore extremely unlikely, but even when patents were granted only for processes, and compounds when made by the patented processes, infringement actions were rare.

The usual answer to an allegation of infringement is that the patent is invalid—that for one or more of a dozen reasons specified in the Act[56], not all of which were considered by the Patent Office when dealing with the application, the Court ought to revoke it. The mere fact that the patent was granted has no bearing whatever on the question of validity. Meinhardt[57] states that during the period 1919 to 1949 the patentee was unsuccessful in 72 per cent of the infringement actions reported in *Reports of Patent Cases*, and in most instances the patent was held to be invalid.

Licences

If a patentee does not wish to keep for himself the exclusive right to exploit his invention he can either assign it to someone else or license one or more other people to exploit it on whatever terms as to remuneration and other matters are mutually agreed. He can, for example, specify the price at which the licensee may sell the product, and a licence agreement is not required to be registered under the Restrictive Trade Practices Act, 1956, if the restrictions which would otherwise necessitate registration relate only to the invention or articles made by the invention[58]. One kind of condition is not permitted in a patent licence, namely what is called a "tying clause", that is, a requirement that the licensee shall purchase other goods, not covered by the patent, from a specified person, or that he shall not use any articles or process except such as belong to the patentee[59]. Any such condition is void, but further it is made a defence to an action for infringement to show that a contract including such a void condition is in force at the time of the infringement, even with a third party. Of course the sting of this provision is somewhat lessened by the difficulty of proving the existence of a contract of that kind, but the possibility of the clause being invoked probably reduces the likelihood that a patentee will try to enter into such an agreement. If, however, after the action, the objectionable condition is eliminated from the licence the patent again becomes fully effective and the infringement cannot continue but of course the patentee may not be free under his agreement with the licensee to eliminate the condition. The sanction would, however, be more effective if the infringer, having successfully defended the action on the ground that an improper provision was included in a licence, was himself entitled to a licence for the remainder of the life of the patent.

As the patentee has the sole right to use and sell his invention, those who purchase the patented product from him, and any subsequent possessors, are deemed to have acquired a licence, so that they are able to use and sell it as they please. The patentee can attach conditions to the sale, and these conditions are binding on subsequent purchasers if

they acquire the patented article with knowledge of the conditions. The subsequent purchasers are said to have a "limited licence" and those of you who are in retail practice will no doubt recall having seen notices on patented articles on your shelves indicating that they are sold under a limited licence and subject to specified conditions. The commonest of such conditions is that the article shall not be sold below a specified price. If you sell such an article in breach of the condition you are no longer protected by your limited licence, and it is not generally realised that such sale is an infringement of the patent rendering the seller liable to an infringement action. An interesting example of this was the infringement of a patent for a tube by the sale of a brand of tooth paste in the patented tube at less than the price fixed by the patentee[60].

Contributory Infringement

In this country it is not an infringement to sell an unpatented article knowing it is going to be used for a purpose which is the subject of a patent. Suppose, for example, there is a patent covering an agricultural spray based on substance X, X itself not being the subject of a patent. No infringement action can be brought against anyone selling X with instructions for using it to make the spray. The farmer who uses it as instructed is infringing the patent, but it is obviously impracticable for the patentee to enforce his rights against a large number of individuals. A hospital pharmacist who manufactures a patented tablet may unwittingly be sheltering under the same umbrella. In America the person who sells a product, knowing that it is specially made or adapted for use for a patented purpose, is liable as what is called a "contributory infringer[61]". The doctrine of contributory infringement may provide valuable protection when a new use is discovered for a known substance and at least from the patentee's point of view might with advantage be incorporated in British patent law.

Cost of Litigation

Complaints are often made of the cost of patent litigation, usually on the ground that it prevents a relatively poor individual inventor from enforcing his rights against a large company whom he believes to be infringing his patent. It seems to me that however unfortunate this situation may be it is inevitable. Obviously any company alleged to be infringing will utilise the best technical and legal advice it can obtain—and such advice is necessarily expensive. The same is true if it is a company that makes the allegation. If the patent is commercially important the cost of litigation, however large by private standards, may well be insignificant in comparison with the financial effect of the decision. Some small changes in procedure were introduced by the Patents Act, 1949, with a view to reducing cost, but little can be done by legislation, unless it be the nationalisation of the patent agents, the legal and other professions. One rather curious alleged protection for the "small man" is that it is actionable to threaten anyone with proceedings for infringement although it is permissible to draw attention to the existence of a

patent[62]. I find it difficult to believe that a threat of proceedings is more intimidating than a mere reference to a patent which the recipient knows to mean the same thing, and it seems to me that this provision provides more of a trap for the unwary patentee than protection for the small inventor.

Abuse of Monopoly

In general the word "monopoly" arouses an emotional antagonism in the mind of the average member of the public and this is just as true of the monopoly conferred by a patent as of any other kind of monopoly. The law attempts to give some protection against abuse of a patent monopoly. This protection stems from the Statute of Monopolies which, as we have seen, did not extend permission for the grant of monopolies to those that were "mischievous to the State, by raising prices of commodities at home, or hurt of trade or generally inconvenient". The protection consists in giving the Comptroller authority[63] to grant compulsory licences or to mark patents "Licence of Right" if he is satisfied that abuse occurs. In accordance with an international agreement the patentee is given 3 years after his patent is granted before anyone can apply to the Comptroller. The kinds of abuse which can form the basis of an application are specified in the Act[64]. As the guiding principle in exercising these powers the Act states[65] that the object is to secure that the inventions which in the public interest should be worked in the U.K. are in fact worked without delay and to the fullest practicable extent. If the demand for the patented article is not being met or is being met only by importing it, if another invention cannot be worked without a licence under the patent and a licence on reasonable terms is refused, or if a condition attached to the grant of a licence prejudices some other industrial activity, an application for a licence can be made to the Comptroller.

At the same time the Act specifies that the patentee shall receive reasonable reumuneration having regard to the nature of the invention, while the ability of the proposed licensee to work the invention and the risks he will undertake in providing capital are also to be taken into account. The law thus imposes on the Comptroller the responsibility of acting as a financial and technical expert as well as a patent and legal authority, although evidence on these matters would of course be given.

The right to seek redress if a patent is used in an unfairly restrictive manner contrary to the public interest has been very rarely used. The Swan Committee[66] said that popular attention in regard to abuse of patent rights had been concentrated mainly on the deliberate suppression of inventions. The kind of allegation they had in mind was that a manufacturer might buy a patent with the deliberate intention not to use the patented invention because it would render obsolete some profitable activity he was carrying on. The Committee reported that several persons who had made public statements about this alleged practice did not accept an invitation to give evidence, and they suggested that the allegations might be explained on the basis of "the unfulfilled expectations

of an over-sanguine inventor" or on a failure to appreciate some of the commercial problems involved.

Compulsory Licences for Medicines

So far as patents relating to medicinal substances are concerned the provisions for preventing abuse of monopoly are never likely to be invoked while the law continues to provide, as it has done for 40 years, for the grant of compulsory licences under such patents. This provision deserves to be quoted in full[67]:

> (1) Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of—
>
> (*a*) a substance capable of being used as food or medicine or in the production of food or medicine; or
>
> (*b*) a process for producing such a substance as aforesaid; or
>
> (*c*) any invention capable of being used as or as part of a surgical or curative device,
>
> the comptroller shall, on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.
>
> (2) In settling the terms of licences under this section the comptroller shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights.
>
> (3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as or as part of a surgical or curative device, but for no other purposes.

The main points to be noted about this section are

(i) The mandatory wording—"the comptroller shall . . . unless he sees good reasons to the contrary".
(ii) "Any person interested" can apply.
(iii) The comptroller is required, in settling the terms of the licence, to secure that the public can obtain the substance at the lowest price consistent with the patentee's deriving a reasonable advantage.

It is generally considered that a licence under this section would be granted to any reputable firm who filed an application with the intention of manufacturing the patented product as distinct from merely importing it.

The section was first enacted by the Patents and Designs Act, 1919. It arose from the realisation during the 1914–18 war that Britian had become dependent on other countries, especially Germany, for many essential drugs, and it was thought that if compulsory licences were obtainable fairly easily that dependence would cease.

Medical Inventions

In the report of the Departmental Committee which preceded the Patents Act, 1932, it was stated[68] that the provision for giving the inventor "due reward for the research leading to the invention"—the wording in 1919, modified in 1949 to that quoted above—had met with the strongest criticism "as recognising and sanctioning the principle of deriving private gain from the patenting of medical inventions". This criticism came from the medical profession. One can appreciate and up to a point admire the attitude, but its effect in practice has been most unfortunate. As was pointed out in evidence to the Sargant Committee[69] "British industry and research were being handicapped in that the results of British investigations were being exploited by foreigners who had not the same objections to medical patenting as the British medical worker". No doubt there will be some here this morning who can recall, as I can, instances where a medical man has been reluctant to conduct clinical trials on a substance made by a patented process, and if this attitude was still adopted it could have an even worse effect on industrial research than the exploiting by foreigners of British inventions. The Sargant Committee recorded that they felt strongly that any ethical code enforced by medical men among themselves "should not operate to discourage that full co-operation between laboratory and clinical investigations which is essential to progress in this important field of human welfare"[70].

The evidence about the patenting of medical discoveries which was submitted to this Committee included a memorandum from the Medical Research Council which can be taken as expressing the views of at least the higher ranks of the medical profession at that time. The M.R.C. recognised that patenting of medicines might be desirable in order to exercise control over the application of the invention or to prevent improper exploitation. In accordance with this view they had accepted the patent rights covering the manufacture of insulin so as to be able to control its strength and quality. This control became unnecessary when the Therapeutic Substances Act, 1925, was passed, and the patent had been allowed to lapse. The M.R.C. considered that such cases were unlikely to recur in future.

The memorandum expressed disapproval of the action of Prof. Steenbock in obtaining patent protection for the method of making vitamin D, the disapproval being based not so much on an objection to medical patents as on the argument that the invention owed a great deal to the prior work of others (including M.R.C. workers), a comment which is true of most inventions. The Council's conclusion was that it was desirable to "secure either the total abolition of the right of patenting in the medical field, or some nearly equivalent restriction of that right". They claimed that patenting medical discoveries did not stimulate research because the incentives to research were other than pecuniary. Further, they claimed that "the Patent Law here works mischievously, because of the undue advantage obtainable by the few, mainly foreigners, who resort to it". As a further reflection of the pre-war attitude to patents in the medical field I may remind you that compounds of which the

processes of manufacture were the subject of patent rights were not included in the British Pharmacopoeia (except if the patent rights were due to expire within a short time of publication) until the issue of 1948.

This attitude to medical patents was not very different from that of other official bodies and academic workers to patents in general. It was war-time experience that led government departments, and eventually others, to realise that it was not in the national interest to make free gifts of British inventions to manufacturers in other countries. Accordingly the Development of Inventions Act, 1948, provided for the establishment of the National Research Development Corporation, the object of which is to secure the development and exploitation of inventions resulting mainly from public research, such as that carried out in government research establishments, universities and hospitals, and by the M.R.C. In 1950 the Council of the British Medical Association endorsed the report of a special committee which stated that there was no longer any objection to patenting inventions made by members of the medical profession provided the patents were assigned to the N.R.D.C.[71] The acceptance by non-industrial workers of the principle of patenting their inventions has been accompanied by a gradual but now complete disappearance of the former reluctance on the part of medical men to co-operate with industry in conducting clinical trials merely because the products to be tested were patented.

Penicillin

Perhaps the greatest single cause of a change of front on the part of the medical profession was the case of penicillin as its seems to be commonly understood. Penicillin is frequently regarded as a British discovery which was exploited in America because the discoverers did not protect their invention by patents. Sir Howard Florey has been reported[79] as regretting his "failure to patent the drug". At that time, as I have already mentioned, product patents were not obtainable in this country. A product patent would have been obtainable in U.S.A. but it seems doubtful whether a patent for the product known as penicillin in 1940 would have covered the products developed later such as the alkali metal salts of benzylpenicillin. According to the report just mentioned Florey said "If the process of extracting penicillin had been patented it would have saved me a good deal of worry in subsequent years. It seems to me that only by having available funds obtained by this means is it possible in Great Britain at the present time to be sure of keeping tried research workers and providing with certainty the income, security and facilities which first-rate people in their thirties are surely entitled to".

Processes of manufacture could of course have been patented, but again it would not have been possible, in any specification drafted before Florey and Heatley went to America to interest manufacturers there in the new drug, to have forestalled the innumerable patents relating to deep fermentation and extraction which those manufacturers afterwards obtained.

Although therefore I do not think Florey would have been able to save himself as much worry as he appears to believe, the second sentence of the above quotation presents in striking simplicity the whole case for a patent system for medicines as for any other products. He draws attention to what anyone in industry, but unfortunately not always elsehwere, would regard as self-evident fact. Unless a product resulting from industrial research can be protected, at least for a time, so that the firm concerned can recoup itself for the cost of research, it will not be able to conduct research in future. The public recognition of this by so eminent and experienced a member of the medical profession as Florey shows how great is the change in the attitude of the leaders of the profession during the 30 years that have elapsed since the M.R.C. gave evidence to the Sargant Committee.

The case for retaining the right to acquire patents for medicines is precisely the same as that for having a patent system at all. The object in either case is to stimulate new manufacture. If medicines are regarded as being of greater importance than other items considered to be essential in civilised communities, the incentive to produce new medicines should be made greater, not less. This point was well expressed in the report of the Sargant Committee[73]:

"We fully recognise . . . the *prima facie* desirability that any important invention in the medical field should be available as speedily and freely as possible for the relief of human suffering. But a corresponding importance attaches to the encouragement of industry and invention for the purpose of discovering methods of alleviating this suffering. And if, in general, the disadvantages of the monopolies granted by a patent system are more than counter-balanced by increased stimulation of industry and invention we see no reason for thinking that the same result should not equally obtain in this particular field".

On this view there is no justification for the inclusion in our patent law of the provision for compulsory licensing under patents for food and medicines. The reason for its inclusion is emotional rather than logical—the fear that the sick (and that includes us all at one time or another) will be held to ransom by some wicked patentee who will demand our health or our money. The safeguard against this possibility seems to lie in the provisions for controlling abuse of monopoly in general, provisions which seem to be accepted as adequate when other essential goods are involved. As mentioned above a compulsory licence under any patent can be obtained when "a demand for the patented article in the United Kingdom is not being met on reasonable terms"[74]. It is no doubt difficult to decide what is "reasonable" in regard to prices, but even if a Court adopted what a patentee would regard as a more liberal attitude than that taken by a politician concerned with the cost of the N.H.S., the public would seem to be adequately protected so far as the law can do so. It is a matter for speculation how the interpretation of "reasonable" in this section would compare with that in the section relating to the compulsory licensing of patents for medicines, which requires that the public shall be able to obtain the medicines at the lowest

prices consistent with the patentees' deriving a reasonable advantage from their patent rights.

It should be mentioned that an application for a compulsory licence under a patent relating to food or medicines can be made as soon as the patent is granted[75], whereas under the abuse of monopoly provisions the application cannot be made for 3 years so as to give the patentee time to organise himself.

Although the compulsory licensing provision for medicines has been part of British patent law for 40 years, it has been invoked on only two occasions, apart from one case[76] where an applicant intended merely to import a food ingredient covered by a patent, and on appeal from the Comptroller's decision the application was refused. In the first case[77], the product concerned was vitamin B_1 and a licence was granted with a royalty of $7\frac{1}{2}$ per cent of the net invoice price. In the second[78], which concerned chloramphenicol, the Comptroller invited the parties to make an agreed suggestion as to what the royalty should be.

A variety of reasons have been advanced to explain why the section has not been used more frequently. Among those mentioned to the Swan Committee[79] were the fear of retaliatory action by the patentee in respect of patents owned by the licensee, a feeling of uncertainty as to the principles upon which the Comptroller would exercise his powers, and the fact that the product made under licence could not be sold under the trade mark used for the original product, and would therefore have to compete initially under the handicap of an unknown proprietary name.

To these must be added the very unconvincing reason advanced by a member of Parliament a few months ago[80] that "many manufacturers are quite unaware of the existence of the opportunity afforded by this branch of legislation". This is certainly untrue so far as the medium and large firms are concerned, and if perhaps it applied to one or two of the smaller ones it is fairly certain that any firm who is unaware of the provision would not have the knowledge and resources to exploit it. As I am in what is, I think, the unique position of having been concerned in both the compulsory licence applications that have been made I think I can suggest that while a licensee's inability to use the established trade mark is one of the difficulties which must necessarily be taken into account, it is merely one aspect of a much broader commercial problem. The question that must be answered before a decision is reached as to whether to apply for a licence is simply "Can the product be made and sold profitably?" A licence will not bring any "know-how". This has to be acquired the hard way and it is impossible to foresee the time it will take. Even if cost estimates look promising when compared with the patentees' existing selling prices, an allowance of unknown magnitude must be made for price reduction. But the prospective applicant's real problem arises from the fact that the licence will be effective only in the U.K. Most of the firms with patents likely to be the subject of applications of this kind will be of substantial size and their business conducted on a world-wide scale. The patentee will be supplying the requirements of this country from a plant which will be large enough to

supply the requirements of several other countries as well and he will therefore have the great advantage in production costs that goes with large scale manufacture. The licensee must be able to compete after paying a royalty and in spite of the fact that he can make the product only on the scale required to supply a part of the U.K. market. Although his available market is so limited he will have all the headaches inseparable from making a new product and selling it under a new trade name—and some account must be taken of the irritation of both chemist and doctor at having another brand of the product to stock and another name to remember. It seems obvious that in the absence of special circumstances a manufacturer will prefer to devote his energies to the development of his own products which he can sell in all his markets at home and overseas.

Although a compulsory licence has so rarely been applied for, it is of course possible that the existence of the provision has had the effect of making patentees more ready to grant licences voluntarily in the belief that more favourable terms could be negotiated with the licensee than would be fixed by the Comptroller. There is no means of knowing whether there has been any such effect.

It will be realised that the reasons which, I suggest, have resulted in only two compulsory licence applications having been made in 40 years apply also to the safeguards against abuse of monopoly. The law provides the machinery, but only the industry can apply it and it is only if there is the grossest abuse that it is a practicable proposition to do so.

The whole subject of compulsory licensing in regard to medicines seems to have suffered from confused thinking. The position may be described as follows. Monopolies in general are contrary to the public interest but so far as they provide an incentive to introduce new manufactures they are a good thing, and so we have patents. But an inventor may patent something really useful which the public come to regard as essential and exploit his invention in a way which is contrary to the public interest, so we have protective provisions against abuse of monopoly. Medicines, however, are so exceptionally important to the public as compared with other essential goods that the inventor of a medicine, even if he does not abuse his monopoly, should share the benefit of his successful research work with other firms in return for a royalty, although of course those other firms are not called upon to share the cost of his unsuccessful research work. The other firms must not import the product but must go to a good deal of trouble to find out how to make it and must undertake quite substantial commercial risks; the law cannot help in these matters so the original patentee has a sporting chance of maintaining his monopoly.

We need to develop a clear conception of where the balance of public interest really lies. I may remind you of the recent report of the Hinchliffe Committee[81] in which it is said "Firms should be encouraged to increase their research effort. The conditions which favour profits for research, such as patent rights . . . should be accepted". On the one hand, therefore, is the desirability of stimulating research on the widest possible scale, on the other hand there are safeguards against abuse of monopoly.

Between these two there seems no logical place for any special arrangements for medicines, or indeed for anything else. If compulsory licences were available under all patents, the effect would be to make it more profitable to let the other fellow spend money on research and then to copy his product and pay him a royalty—unless of course he was able to keep his invention secret and not patent it.

It is submitted that the logical conclusion is that this type of compulsory licence should be abolished and that we should rely on the abuse of monopoly provisions in the same way as we do in the case of patents outside the medical field. Perhaps those provisions need reconsideration —for example it might be advantageous to reduce the 3 years delay before they can be applied. But I invite you to consider whether it should not be a requirement of the law that there should be some act or default on the part of the patentee, contrary to the public interest, before he can be required to share with competitors the results of his research work. At present, all that is required is that he should have patented a meritorious invention.

In their Second Interim Report the Swan Committee accepted the logic of the situation and recommended the abolition of the special compulsory licensing provision for food and medicines[82]. In their Final Report[83], however, they seemed again to adopt the emotional rather than the logical approach. Having argued themselves into a recommendation that chemical substances in general should be patentable as such, and that for the sake of uniformity no exception should be made for substances used for food or medicine, they said that their recommendation could be "safely" adopted if the compulsory licensing provision were retained, and their previous recommendation was withdrawn.

Medicinal Patents Overseas

While therefore there is no clear line of policy in this country as to what the public interest really requires it may be some consolation that other countries treat patents for medicines in a different way from patents for other things.

Italy has the unique distinction among the large manufacturing countries of the Western world of not allowing patents for medicines. The absence of patents for medicines has made it possible for the Italian pharmaceutical industry to make a number of important drugs evolved in industrial research laboratories in other countries. No doubt the ability to make these compounds without incurring the cost of research has played a significant part in re-establishing the Italian industry since the war. The apparent paradox that in Italy industry has been helped by the absence of patents, whereas normally industry is helped by the grant of patents, is of course explained by the fact that Italy is the odd man out. An Italian manufacturer can make and sell products which are patented in other countries not only in Italy but also in territories where the inventor has not sought patent protection and even in countries where patent applications are pending, although he may have to withdraw from the market when the patent is granted. At the same time, in

countries other than his own, he can enjoy the benefits of patent protection for his own inventions.

The absence of patents for medicines in Italy has been the subject of numerous commercial and diplomatic representations from many countries especially America and Switzerland, but so far without success. It is to be expected that the position will change when the Italian industry is sufficiently well established to originate new products and wishes to protect them at home as well as in foreign countries. Another situation can occur which may lead the Italian pharmaceutical industry to accept the re-introduction of patents for medicines. This is where a firm enters into an agreement on a royalty basis to make the product of a foreign inventor who provides the requisite know-how and then another firm works out how to make the product. Not having to pay royalty the latter can compete successfully with the licensee. If and when Italy does take patents for medicines into her system it is probable that the fear of being dependent on foreign sources for essential medicines will lead to the adoption of compulsory licensing and if that is done the British industry, at least, will not be in a position to complain.

In France, patents have been obtainable for processes for manufacturing medical products, except when the product was identifiable only by reference to the process so that the grant of a patent for the process would have given the patentee a monopoly of the product. Apart from this, a partial monopoly of a new medicinal substance has been possible by means of the visa system, but product patents for pharmaceutical compositions and medicines were forbidden as long ago as 1844.

This position was altered by an Ordinance published last February[84] which rescinded the prohibition of product patents in the medical field, although procedural details have yet to be announced.

An explanatory statement[85] declared that the ordinary patent system could not be applied to medical products without modification; production, quality and price, it was said, could not be left to normal market mechanisms. Provision was therefore made for the grant of compulsory licences if a French or foreign inventor delays manufacture or manufactures on too small a scale, or if his product is unsatisfactory in quality or price—in other words if the monopoly conferred by the patent is abused.

In the official statement I have mentioned the view was expressed that the compulsory licensing provision would rarely be used because the possibility that a licence might be granted would be sufficient to bring the patentee to a better realisation of his responsibilities. It was also claimed that the change in the law would have the following advantages—the inventor would have proper protection, research would be encouraged, multiplication of identical products would be prevented, and the international repute of France would be enhanced by the termination of a system which has enabled French industry to copy foreign inventions. These are large claims. Perhaps the most interesting having regard to the fact that in Italy not even processes are patentable in the medical field, is the reference to the international repute of France. In view of

what I have said about the British compulsory licensing provisions it is also interesting to note that France considers compulsory licences should be granted only if the patent monopoly is abused.

In continental countries in general, chemical processes can be patented but not the products, and chemicals having therapeutic properties are treated in the same way as others. In most South American countries, new chemical compounds can be patented as well as the processes of making them, but a distinction is made in the case of medicines so that that only the processes of making them can be protected.

In Canada substances made by chemical processes and intended for food or medicine cannot be claimed as such, except when prepared by the method described in the patent specification[86], but there is no bar on patents for therapeutic compositions not made by chemical processes. While, therefore one cannot obtain a patent for a new drug itself however made, one can patent a pharmaceutical preparation of the drug and thus obtain virtually all the protection that would be given by a patent on the drug.

In America, as perhaps one would expect, the full commercial logic of the matter is applied and a new drug or process for making it can be patented in the same way as any other chemical. There seems to be no suggestion there that the public would gain by weakening the patent monopoly of a medicine by the grant of compulsory licences, neither is there any worry about abuse of monopoly by a single manufacturer—and it would certainly be difficult to demonstrate by reference to the American pharmaceutical industry that patents do not provide a stimulus to the discovery of new drugs.

Commonwealth countries have tended to follow the United Kingdom practice of providing for compulsory licences, but so far as I can ascertain the provision has not been used. In India the matter is under review and the authorities have been seeking the views of the pharmaceutical industry.

Of 18,450 complete specifications accepted by the Patent Office in 1958, more than 2,000 were classified as being primarily concerned with chemical processes or compounds[87]. No figures are available to show how many of these were in the pharmaceutical field but it is certain that pharmaceutical manufacturers who undertake research are making considerable use of the patent system. In this highly specialised field I cannot claim any status other than that of a keenly interested amateur, but it is my hope that this review will have shed some light on a branch of law which to a greater extent than we may realise effects us all both as pharmacists and as citizens.

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