PHARMACEUTICAL MANAGEMENT AGENCY LTD v COMMISSIONER OF PATENTS

High Court, Wellington (CP141/97) 16-19 November; 17 December 1998
Gallen J

Patents — "Invention" — Therapeutic treatment of humans — Methods of treatment for human conditions are not patentable — Public utility — Consideration of public good — Cost of development — Statute of Patents 1623; Patents Act 1953.

Patents — Applications — Substance used in therapeutic treatment of humans — Method and substance distinction — Substance patentable in its first use.

Patents — Applications — Known patented substance used in different treatment — Whether known substance used in a new therapeutic treatment can be protected further — Novelty — Substance must satisfy novelty requirements — Patents Act 1953.

The plaintiff, Pharmaceutical Management Agency Ltd ("Pharmac"), determines which pharmaceutical products qualify for subsidy and has obligations to ensure money available is spent effectively for the public utility. Pharmac sought orders regarding a practice note issued by the Commissioner of Patents relating to "Swiss" type patent claims. The practice note stated that these claims, in known pharmaceutical substances used in the manufacture of pharmaceutical compositions, which exhibited previously unknown therapeutic activity, should be patentable. Pharmac claimed that these known patented substances used in medical treatments should not be entitled to further patent protection where a new therapeutic use is discovered. The second defendants, various pharmaceutical manufacturers, opposed Pharmac's action.

Both parties rely on a public utility argument. Pharmac claimed that if a known substance is denied patent protection for a new use, then Pharmac may accrue reduced costs resulting in a benefit to the public. However, the defendants argued that patent protection would encourage expenditure of large sums of money by pharmaceutical companies, based on certainty of return, which may ultimately benefit the public also.

The issue for determination was that if a substance used for a particular purpose is protected by patent, then whether it can be protected by a further patent if it is used in a different way, where both usages are for the therapeutic treatment of a human illness.

Held, declining the application:

(1) The Patents Act 1953 should not be regarded as a code. Patent law in New Zealand is flexible and, although bound by case law and statute, must be able to move with the technological advancements and changing needs of society. (p 595, line 4)

(2) The general rule in patent law in relation to medical treatments is that a method of treatment used for the therapy of a human illness is not patentable, as it is contrary to the public good for such methods to be constrained by patent monopolies since such protection could deny the public the benefit of that treatment. This is too well entrenched in law to be changed by the Courts and any change to this rule should be made by Parliament. The rule does not extend to the production of a substance used in the treatment. (p 605, line 41)
Wellcome Foundation v Commissioner of Patents [1983] NZLR 385 (CA) followed

(3) According to the authorities, there is now no doubt that a substance designed for use in the treatment of human illness is entitled to patent protection in the first use. Substances used in such treatments are not subject to the same public interest argument. (p 605, line 26)

(4) Once it is accepted that the first therapeutic use of a substance is patentable, then it is justifiable to contend that the discovery of a new use for a known substance can also be patentable. (p 609, line 45)

(5) A known patented substance used for a specified new and inventive therapeutic purpose, even where the process of manufacture does not differ from known processes, can be entitled to patent protection provided the requisite novelty can be found. (p 611, line 17)
Re Eisai Co Ltd (Dec Gr05/83) [1985] Official Journal EPO 64 followed

(6) Recent cases have discounted the approach taken by Cooke J in *Wellcome*, that the question of whether there is sufficient novelty depends on whether a substance is invented or discovered. The novelty issue simply requires that the new use is sufficiently different from the use which has always been recognised. The discovery of a new and useful effect rather than a new substance is sufficient. Therefore, the use of the same substance to treat two different human illnesses is sufficient to satisfy the novelty requirements. (p 601, line 36; p 603, line 27; p 604, line 30; p 609, line 21)

(7) In conclusion, known substances used in the manufacture of pharmaceutical compositions, which exhibited previously unknown therapeutic activity can be protected by patent provided the requisite novelty is fulfilled. Therefore, the position of the Commissioner in the practice note was upheld, and the application by Pharmac was declined. (p 611, line 17)

Statutes and regulations referred to
Patents Act 1953
Patents Act 1977 (UK)
Statute of Monopolies 1623
Statute of Patents 1623

Cases referred to
Adhesive Dry Mounting Co Ltd v Trapp & Co (1910) 27 RPC 341
Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 122 ALR 141

Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc 20/8/97, High Court of Justice, Chancery Division, Patents Court, Ch1997 N2698
Ciba-Geigy AG (Durr's) Applications [1977] 4 RPC 83
Dow Corning Corp (Bennett's) Applications [1974] RPC 235
Eisai Co Ltd (Dec Gr05/83), Re [1985] Official Journal EPO 64
Eli Lilly & Co's Application [1975] RPC 438
GEC's Application, Re (1943) 60 RPC 1
John Wyeth & Bro Ltd's Application (1985) 23 RPC 545
Joos v Commissioner of Patents [1973] RPC 59; [1972] 126 CLR 611
Maeder v "Ronda" Ladies' Hairdressing Salon [1943] NZLR 122 (CA)
National Research Development Corp v Commissioner of Patents [1959] 102 CLR 252
Pirrie v York Street Flax Spinning Co Ltd [1894] 11 RPC 429
Swift & Co v Commissioner of Patents [1960] NZLR 775
Wellcome Foundation Ltd v Commissioner of Patents [1979] 2 NZLR 591
Wellcome Foundation Ltd v Commissioner of Patents [1980] 30 ALR 510
Wellcome Foundation Ltd v Commissioner of Patents [1983] NZLR 385 (CA)
Wellcome Foundation Ltd v Plantex Ltd (1974) 17 RPC 514

Application

This was an application for orders against the Commissioner of Patents in issuing a practice note regarding patentability of known substances used in medical treatments.

P J Radich and *R J Dryden* for plaintiff
B W F Brown QC for first defendant
G F Arthur and *S A Fogarty* for second defendants (13 companies)
C L Elliott and *A N Potter* for third defendants
M Doucas for fourth defendant

GALLEN J (reserved):

In these proceedings the plaintiff Pharmac seeks various orders with regard to the action of the first defendant the Commissioner of Patents, in issuing the following practice note:

"PATENT OFFICE PRACTICE NOTE

" 'SWISS' TYPE PATENT CLAIMS

"On 17 September 1990 I issued a decision (*Massachusetts Institute of Technology*, Patent Application No 199328) in which I disallowed a claim, in the so-called 'Swiss' form, to the use of a known pharmaceutically active compound for the manufacture of pharmaceutical compositions in which the compound exhibits previously unknown therapeutic activity. I have now reviewed this practice in the light of the continuing international trend to liberalise the definition of 'invention' and have come to the conclusion that it is now appropriate that claims of the 'Swiss' type should not be refused during the examination process.

"Accordingly, from the date of this Practice Note, 'Swiss' type claims, of the general form:

> 'The use, in the manufacture of a medicament, of [the active compound] as an active ingredient in a [the newly invented activity] composition in admixture with an inert carrier or similar constructions, will not be rejected by patent examiners.'

"Claims to therapeutic treatment of humans will continue to be disallowed, a practice confirmed by the Court of Appeal in *The Wellcome Foundation Ltd (Hitching's) Application* [1983] FSR 593. The Practice Note published on page 249 of Patent Office Journal No 1402 explains this practice in more detail."

The second defendants in their various groupings which are all pharmaceutical manufacturers, oppose the plaintiff's action. While the action has proceeded in the form of an application for review of a decision of the Commissioner, in fact the proceedings raise a question of law for determination for the Court arising out of the actions of the Commissioner. The proceedings may more conveniently be seen as at least analogous to an action for a declaratory judgment.

As a matter of background it is appropriate to commence by noting that both plaintiff and defendants rely upon what is contended to be the public utility of the position which they take and there are of course good grounds for seeing the question in that light, since in one form or another such matters have been a consideration since the Statute of Patents in 1623, the principles of which are incorporated in the New Zealand Patents Act 1953.

Pharmac is the body responsible for the determination of which pharmaceutical products qualify for subsidy and to what extent in the administration of national health services. It is unnecessary to go into the responsibilities and concerns of Pharmac in detail, other than to say that I accept that Pharmac has a responsibility to administer a limited amount of money in the most effective way possible for the benefit of New Zealanders generally. In doing so, it is obliged to ensure that the moneys available to it are expended effectively and where possible there is an obligation to make savings. If a new use for a substance which has already had the advantage of patent protection cannot be made the subject of a monopoly for a further protected period, then it follows that considerable savings in cost may result. Clearly it is to the benefit of the public that the scheme should be administered as economically as possible and it follows that Pharmac can justify the approach which it adopts by reference to the words of the Statute of 1623, that what it opposes ought not to be a matter of public inconvenience. On the other side, I accept that the public benefits by the expenditure of moneys on the development of pharmaceutical products and in the absence of the limited monopoly provided by the patent legislation, the companies concerned might well be much less disposed to venture the costs of research into products which have no certainty of yielding a return.

The evidence makes it clear that a number of the products for which protection is or will be sought, although the subject of the protection of patents when first devised, for one reason or another never proceeded into production, so that the initial costs of research and development were never recovered. It is also clear from the evidence that the costs of development are very substantial. While actual figures were given in confidence with regard to particular products, it is enough for the purposes of this decision to indicate that they may well exceed several hundred million dollars.

From the point of view of Pharmac then, the limit of patent protection may result in reduced costs to Pharmac and therefore to the New Zealand population as a whole. From the point of view of the pharmaceutical companies, the protection of a patent may be necessary to not only encourage, but justify the expenditure of very significant sums of money, to develop products which may in the end be of

very considerable benefit to the community as well. I accordingly start from the proposition that on both sides, the requirements of patent law as to public utility are met and the two positions in this regard may be said to be equally supportable.

I agree with counsel's submission that the Patents Act 1953 is not to be regarded as a code. The Statute of Monopolies of 1623 and the principles which have developed over the centuries, remain significant but varied by the subsequent statutes. It is also important to note that patent law has developed. Principles which were seen as fixed and orthodox in one century, have been completely reversed by subsequent decisions of the Courts. A good example is the recognition in this century of the patentability of a process. Further, the Courts have themselves been prepared to approach significant principles in a different way from earlier decisions, in a recognition that patent law has moved on. An example is the decision of the Court of Appeal in the *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA), compared with the earlier decision of the Court of Appeal in *Maeder v "Ronda" Ladies' Hairdressing Salon* [1943] NZLR 122 (CA).

While therefore I accept that precedent is important and of course I am bound by superior Courts, I also accept that it is apparent in patent law that development has not reached an end and that the law is sufficiently flexible, even bounded as it is by both statute and judicial precedent, to meet the changing needs of society, a matter which becomes of great significance in a period of technological development in which we live. In that context there are a number of principles which have been seen as decisive in different cases, principles which overlap and which in some cases appear to be in conflict.

Further there are ample dicta to the effect that patent law reflects international trends and it is important that it should do so, because intellectual property is not bounded any more than physical international trade and development is circumscribed by national boundaries. While I accept that the legal position in New Zealand is not necessarily affected by the position overseas where the state of the law reflects different statutory provisions, nevertheless it is important as far as possible to keep patent law in harmonisation with international trends and patentability with international obligations.

Finally, as counsel pointed out, in patent law precise definition is important. The extent of protection is strictly determined by the words which describe what it is sought to protect in the application and supporting documents. In the same way it is contended the ambit of a legal decision will be confined to the precise situation before the Courts and there are dangers in extrapolating general principles from particular decisions. The way in which cases have been presented on particular occasions, may be seen as affecting the outcome to a greater degree than would ordinarily be the case where it is possible to isolate a specific principle from the confined situation which is under consideration.

Having stated those matters, the question for determination may be set out as follows:

Where a substance has been identified and given the protection of a patent in its revealed formulation with a particular use or purpose disclosed, is the same substance entitled to further patent protection in combination with a different use or purpose discovered later, where in each case the use or purpose is the medical treatment of a human condition?

It might be thought that as a matter of logic, it is the substance which has obtained protection, so that it is inappropriate for there to be a second period of monopolistic protection. That is not however the way in which the law has developed and the reason is that the Courts have been able to find the necessary novelty for patentability in such situations. An important decision for the purposes of this case is the leading Australian case of *National Research Development Corp v Commissioner of Patents* [1959] 102 CLR 252. In that case the High Court accepted that it was possible to patent by one means or another, a discovery that a previously known substance could be used for some purpose which had not previously been known. The judgment makes it clear that in that case, what was sought was the protection of a new process for ridding crop areas of certain kinds of weeds, not by applying chemicals the properties of which were formerly well understood so that the idea of using them involved no inventive step, but by applying chemicals which formerly were supposed not to be useful for this kind of purpose at all. The Court said (at p 265):

"This is not a claim which can be put aside as a claim for a new use of an old substance, true though it be that the chemicals themselves were known to science before the applicant's investigations began. It is a claim which denies that the chemicals are old substances in the sense in which the expression has been used . . . It treats them as substances which in the relevant sense are new, that is to say as substances which formerly were known only partially and, so far as weed-killing potentialities are concerned, were unknown."

At p 268 the Court said:

"If credit be given to the case which is made, the process differs from the previously-known processes of its kind in this, that it employs substances the suggestion of which for the purpose in hand was new, was not obvious, and was to be arrived at only by an exercise of scientific ingenuity, based upon knowledge and applied in experimental research. The fact that the substances themselves were already known to man affords no valid reason for denying that the suggestion was inventive."

The conclusion was that by an application of scientific ingenuity, combining knowledge, thought and experimentation, not only in relation to the chemicals but in relation also to the enzyme systems of certain weeds and plants, the applicant had evolved a new and useful method of destroying weeds without harming useful vegetation amongst which they were growing. The decision was followed relatively quickly in New Zealand in *Swift & Co v Commissioner of Patents* [1960] NZLR 775, although that case dealt with a different situation and is largely irrelevant for the purposes of this case.

National Research Development Corp v Commissioner of Patents was followed in *Wellcome Foundation Ltd v Commissioner of Patents* [1980] 30 ALR 510. Those two cases were cited as authoritative in New Zealand by Cooke J (as he then was) in *Wellcome Foundation v Commissioner of Patents* [1983] NZLR 385 (CA) and were the basis for the comment at p 388 where he said:

"But the suggestion in part of the argument for the Commissioner that a discovery of a new use for a known product cannot provide a basis for a grant must, in its bald form, be rejected as outmoded."

Cooke J quoted in particular from the decision in *Wellcome Foundation v Commissioner of Patents* [1980] 30 ALR 510, where the High Court said at p 515:

"a discovery, itself involving ingenuity or novelty, that an old substance may be used so as to produce a new result may ground a patentable invention. In such a case the old substance is treated as if it were new, its hitherto unknown or unsuspected potentialities being revealed by the discovery which is itself a consequence of scientific ingenuity. This principle extends to a process which does not produce a new substance but results in 'a new and useful effect'. If the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s6 of the Statute of Monopolies."

It may therefore be seen that to this point there is acceptance in New Zealand of the principle that it is possible to obtain protection for a new use of an old substance in the circumstances outlined. Mr Radich submits however that the decision of the Court of Appeal in the New Zealand *Wellcome* case is authority for the proposition that that does not extend to a new medical use of a substance originally patented for medical purposes.

In *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA), the Foundation made an application for protection in respect of a substance which had been developed and used for the treatment of malaria, but which had subsequently and quite unexpectedly, been found to have specific advantages in the treatment of meningeal leukaemia or neoplasms in the brain, because it had the capacity of passing the blood brain barrier, which other substances did not. The claims filed with the Assistant Commissioner were as follows:

- Claims 1-12 which related to a method of medical treatment of a human being.
- Claims 13-28 relating to a package, plus instructions as to suitability of use.
- Proposed claims 29-34, being claims to a new use of a known substance for the purpose of medical treatment of a human being.

It is important to note that only claims 1-12 were the subject of appeal to the Supreme Court and therefore subsequently to the Court of Appeal. The importance of that is that the claims contained in claims 29-34 which were obviously similar in nature to the question now before the Court, were not the subject of a direct decision from either the Supreme Court or the Court of Appeal.

The first 12 claims were forwarded to an examiner in terms of the Patents Act 1953, but were objected to on the basis that they did not relate to an invention within the meaning of the Patents Act, as they related to a method of treatment of man and that the invention did not result in a vendible product. The vendible product aspect followed from an earlier decision of the Court of Appeal in New Zealand in *Maeder v "Ronda" Ladies' Hairdressing* (supra), which itself followed a line of authority to that effect. The objections were maintained and in the decision of the Assistant Commissioner with respect to the first 12 claims (see *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591), the following statement occurred:

"Claims 1-12 inclusive relate to a method of medical treatment of a human being and are hence not allowable as they do not relate to a manner of new manufacture."

The foundation appealed and the matter came before Davison CJ who accepted the reasoning of the High Court in the *National Research Development Corp* case (supra) and concluded following the further comments of Barwick CJ in *Joos v Commissioner of Patents* [1973] RPC 59; [1972] 126 CLR 611 at p 62; p 617:

> "that it is not essential for the grant of a monopoly for a process that the use of the process should produce or improve a vendible article. It is enough that the process has a commercial application."

He therefore rejected the vendible article test and then went on to consider the question of novelty. The Chief Justice specifically accepted a statement from the *National Research Development Corp* case (supra) where it is stated (at p 263):

> "the inventiveness which is essential for a valid grant of a patent may be found in the step which consists of suggesting the use of the thing for the new purpose."

Having accepted that the applicant had established the necessary novelty, he was then required to deal with the contention that the Courts would not recognise the patentability of a process for the treatment of human beings. After an analysis of relevant decisions, he came to the conclusion (at p 620) that:

> "(1) There is no statutory provision in New Zealand prohibiting the grant of a patent for a process of medical treatment of a human ailment or disease in a human being.
> "(2) There is no decision of a New Zealand Court prohibiting such a grant.
> "(3) In the Australian jurisdiction I am unaware of any case where a process for the treatment of a human ailment or disease had arisen for consideration, but in both the *NRDC* case and the *Joos* case whilst Judges have referred to such a process, they have at least expressed in very tentative language their doubts about its patentability
> "(4) The English cases ... do not provide a satisfactory basis on which to halt the development of the law relating to patentability of process for medical treatment ...
> "(5) The Courts in current decisions have gone a long way forward in granting patents for processes of medical treatment but they have stopped short of granting such patents for processes relating to human ailments or disease."

He concluded that the applicant was entitled to require that the process proceed.

The decision was taken on appeal and the decision of the Court of Appeal appears in the well-known case of *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA), to which reference has already been made. It is around the decision in that case and comments made in the three judgments delivered by the members of the Court, that the arguments in this case have largely revolved.

All three Judges came to the conclusion that a method of treatment of human illness or disease did not qualify for the granting of patents. Cooke J (as he then was) said at p 391:

> "If the practice of not granting patents for methods of treating human illness or disease is to be altered or modified, it is best left to Parliament."

McMullin J having surveyed the relevant cases, concluded that a patent should not be granted in the case before him. He concluded by saying (at p 398):

"Whether methods of treatment of the kind contemplated should be patentable should be left to the legislature."

Somers J stated at p 401 that the central question in the case was:

"whether letters patent may be granted in New Zealand for a method of treating human ailments."

He stated at p 404:

"the treatment of human ailment — is of a special character. Parliament has recognised that for there are particular provisions in the Patents Act 1953 relating to medicines and surgical and curative devices. Next, one of the features of the Statute of Monopolies is the embargo on patents 'generallie inconvenient'. That concept still informs the law. It is no doubt true in one sense that the resolution of the present question is a matter of law. But its policy content is obviously great and a value judgment is required on issues of social advantage.

. . . . . .

"All in all I am of opinion that to allow the application to proceed would be to alter the patent law as it is presently understood in a field which now properly belongs to the legislature."

Counsel for the defendants asserted that the *Wellcome* case has always been seen as holding that a patent is not available for methods of treating human ailments, but contend that that is a very different thing from holding that it is not possible to obtain a patent to protect a process which starts with a particular compound and is designed and intended to conclude by treatment. In other words, it is the contention for the defendants that the question before the Court of Appeal in the *Wellcome* case was clearly and unequivocally, whether or not *methods of treatment* (as distinct from substances used in that treatment) were entitled to protection and that the case is authority only for the proposition that they are not.

Mr Radich for the plaintiff however contended that the *Wellcome* case was determinative of the present proceedings. First he submitted that because the factual situation in this case was precisely the same as that which occurred in the *Wellcome* case the outcome ought not to be different depending upon the mere basis of presentation. Secondly he contended that there were general observations in the *Wellcome* case which formed part of the ratio decidendi or were in any event authoritative and which must be regarded as decisive against the defendants' position.

Dealing with the first proposition, at first sight at least it has much to commend it. In both the *Wellcome* case and this case, what the Courts are concerned with when the matter is stripped from the detail, is a factual situation where a substance which has already had the benefit of patent protection, has been subsequently discovered to have curative properties for the treatment of human beings which were not previously suspected. Mr Radich contends that in such a situation, to hold that no protection was available in the *Wellcome* case but that it was available in the circumstances of this case, is illogical and although he did not use the expression, is likely to bring the law into disrepute, since it must be dependent upon an assertion that the outcome of the case depends on the way in which it is presented to the Court. In other words, it is like the old cases where the form of pleading was determinative.

The defendants contend by contrast, that what was sought in the *Wellcome* case was a ruling on the disputed point as to whether or not with the development of patent law, a prohibition of patent protection on methods of treatment of human beings, was still determinative of such applications. The refusal of the Courts to allow patent protection in such cases, is dependent upon the principal proposition that humanitarian considerations require methods of treatment designed to alleviate human suffering, to be generally available. The proposition is discussed in the *Wellcome* case itself. It is also analysed in the Australian case of *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] 122 ALR 141. It is a concept which is clearly entrenched in the law and it may be thought to have derived, at least initially, from the concern expressed in s 6 of the Statute of Monopolies 1623, which referred to the consideration:

"so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient."

It is apparent from the discussions in the cases, that the concern relates directly to treatment. In the *Rescare* case, Shepherd J who dissented, referred specifically to a surgical procedure which patent protection might deny to many persons who could benefit. An example is a new method of surgical incision. A surgeon who sees its advantages ought not to have to consider that its initiation may give patentable rights. The importance of this observation is that it relates the concept directly to the final stage of the process, that is the treatment of the human patient and imports the concept of a concern at the risk of infringement, where that risk lies and the undesirability of it arising in the circumstances contemplated. The concept is however a confined one, since it is possible to obtain a patent to protect the production of a substance designed for use in the medical treatment of human beings. This concept is clearly accepted in the *Wellcome* case itself. Cooke J for example, said at p 388 that:

"this Court need no longer insist on the *Maeder* limitation and should also reject the more sweeping part of the argument put before us for the Commissioner wherein it was propounded that there cannot be patent protection for even a first therapeutic use."

Somers J said at p 403:

"That is to say while ordinarily there is no novelty in a known substance a first therapeutic use may be protected."

There is ample authority for those propositions and it must follow that the development of a substance intended for the treatment of human beings, is now clearly entitled to protection. This of itself then as a matter of logic, must lead to the conclusion that the principle already referred to is confined to the method of treatment.

When the matter is looked at in that light and when the necessity for precision of expression which applies in the case of patent laws, is borne in mind, then there are grounds for the contention of the defendants that the ambit of the decision in the *Wellcome* case has always been confined to a determination that *methods* of treatment of a human being, as distinct from substances intended for such treatment, are not patentable as an exception to the general rule. The reasons have been explained in the cases and are substantially humanitarian. They involve

concepts of public benefit, but this does not extend to the production of the substance used in the treatment.

I therefore reject Mr Radich's submission that the distinction between the nature of the application in the *Wellcome* case and the nature of the application in this, is merely one of semantics. I do not accept that the *Wellcome* case necessarily, because of the factual material upon which it was based, determines the outcome of this. That is however not the end of the matter.

It is Mr Radich's submission that there are clear dicta in the *Wellcome* case (as distinct from the subject matter) which must mean that an application of the present kind cannot lead to patent protection and that accordingly the approach of the Examiner was wrong. Mr Radich draws attention to the fact that in all three of the judgments, while there is an acceptance that the first use of a substance may be seen as being patentable, a subsequently discovered use where that use is for the purposes of medical treatment, is not.

I propose to deal first with the dicta originating in the decision of Somers J ([1983] NZLR 385) at p 400 where he said:

> "In the *NRDC* case the weed killing potentialities of the substances had been unknown.
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> "The opinion of the High Court on this point in my view states the law in New Zealand also. In the instant case however the compound in question has been previously used for the treatment of malaria. It is argued that the advantage now claimed is so far removed from that previously known that the necessary inventiveness is established. I am unable to agree. Each is but a kind of therapy."

It follows from that, that Somers J considered that there was insufficient novelty in a second therapeutic use to justify the protection of a patent. Somers J gave no reasons for that conclusion, nor does his judgment contain any analysis upon which it could be said to be based. In context it was a view unnecessary for the resolution of the question before the Court, since Somers J himself says that the central question in the case is whether letters patent might be granted in New Zealand for a method of treating human ailments and that was the sole issue raised in the proceedings. It may be that particular emphasis on the treatment of human ailments was what Somers J had in mind and since the purpose in both cases was the same, he considered that there was a lack of novelty, so that in a case where method of treatment was the subject of consideration, there was an insufficient differentiation. Whether that is so or not, the particular observation was unnecessary for the decision, nor did it assume any importance in his analysis or final conclusion. If he meant to say that there was an insufficient differentiation between the use of a substance for the treatment of malaria and the use of the same substance as a means of treating leukaemia because of quite different properties, to show sufficient novelty to justify patent protection, then reluctant as I am to disagree with a Judge so well known for his acuity of intellect and precision of expression, I am nevertheless obliged to do so. In my view the two uses are quite sufficiently distinct to satisfy the requirements of novelty in patent law.

It is perhaps noteworthy that at p 404, Somers J said:

> "The qualification about novelty expressed in the European Patent Convention and the Patents Act 1977 — that a first therapeutic use of a known substance does not deny novelty

— may not be much removed from the principles discussed in the *NRDC* case mentioned above."

It is not wholly clear what he meant by this. It may be that he was suggesting a substance which had not previously been used for a therapeutic purpose, might be patentable if a new therapeutic use was discovered for it.

Somers J then dealt with the question of vendible product and referred to *Re GEC's Application* (1943) 60 RPC 1. He went on to refer to the *National Research Development Corp* case and accepted the comments in that case that whether a claimed process or product is within the definition is not found by asking whether it is a new manner of manufacture, but whether it is a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies. He then indicated that the central question in the case was whether letters patent could be granted in New Zealand for a method of treating human ailments. After a survey of the cases he referred to the European Patent Convention and arts 52(4) and 54(5). He also referred to provisions of the Patents Act 1977 (UK). He concluded that a method of treatment of a human being was not patentable and that any change to that principle would have to be carried out by Parliament.

Cooke J began his consideration by reference to an Israeli case, *Wellcome Foundation Ltd v Plantex Ltd* (1974) 17 RPC 514, quoting in particular from Kahn J at p 540 where he said:

"It is therefore my conclusion that an invention by which a known substance, a known composition or a known device is used for the therapeutic treatment of the human body is patentable. However, where a substance, composition or device has already been used for the therapeutic treatment of the human body or where it is obvious on the basis of existing knowledge that they are capable of so being used for the therapeutic treatment of humans, no patent is to be granted to an inventor who discovers a new and until then unknown use for medical treatment. For example, it is possible to grant a patent to an inventor who discovers that a known substance which had been used in the food industry and for which it was not known that it can serve for curing humans, is suitable for the treatment of intestinal diseases; against this, no patent will be granted to an inventor who discovered that a medicine used for the treatment of the kidneys can also serve for the treatment of mental diseases."

At p 389, Cooke J said:

"In a broad sense, however, the discovery of a new drug is different from the discovery of new uses for an old one. It is not absurd that the law should reflect this distinction."

After a survey of the situation in England, Canada, the US and Germany, Cooke J said at p 391:

"The current variations in national patent laws bring out that this is the class of problem for which no one can say that any particular resolution is necessarily right. In all the circumstances I think, in agreement with the other members of the Court, and with the measure of regret already mentioned, that we should resist any temptation to break new ground. If the practice of not granting patents for methods of treating human illness or disease is to be altered or modified, it is best left to Parliament . . .

"But we could not realistically shut our eyes to the possibility that in the language of the Statute of Monopolies the change sought by the respondent might result in 'raising prices of commodities at home' or be 'generally inconvenient'.

"I do not think that the application should fare any better if presented as a use claim. The application is a convention one, based on an application made in the United States on 23 March 1973. The date of the filing of the New Zealand application accompanied by a complete specification was 22 March 1974. In May 1976 the Foundation applied for leave to amend the specification by adding six claims seeking a patent for known compounds or compositions whenever used in the treatment or prevention of meningeal leukemia or neoplasms in man or other mammal. The Commissioner informed the Foundation by letter of 7 July 1976 that these additional claims were not satisfactory, as they related to nothing more than the discovery of a further use for known pharmaceutical compounds and were thus not patentable. I would uphold this ground as in accord with existing law and practice in New Zealand, so that the proposed additional claims could not improve the application."

These quotations indicate that Cooke J was considering the matter before him on two bases. The first was whether or not a method of treating human ailments was patentable and the second, whether the discovery of a new use for a previously known substance satisfied the requirements of novelty for the purposes of the grant of a patent. Plainly the first was the specific question at issue being so defined by the nature of the claims under consideration. It was also the principal basis of the decision of the Chief Justice at first instance, which was under appeal. It is plain from the decision of Cooke J, that his principal reason for arriving at the conclusion which he did, was that the weight of authority was such that it was not open to the Court to change what was seen as an established principle. That principle is that a method of treatment of a human ailment is not entitled to the protection of a patent and that was of course the conclusion arrived at by all three Judges in the Court of Appeal. It does not follow that that conclusion requires as a corollary, that a substance intended for such use, is not entitled to patent protection and indeed Cooke J specifically accepted that a substance intended for therapeutic use was patentable provided it was the first such use which was under consideration. If that is so, then it is difficult to see why a second and distinct use for treatment purposes, should be regarded any differently. It cannot be a question of public welfare since arguments which relate to benefits to the public apply equally to the first as to the second or any subsequent use.

Cooke J referred in the quotation set out above, to the decision of Kahn J in *Wellcome Foundation Ltd v Plantex Ltd* (supra) and the particular paragraph would support the contentions of Mr Radich in this case. It is appropriate however to point out, that that paragraph itself specifically deals with methods of therapeutic treatment of the human body and Kahn J simply asserts that a second use of a known substance, is not to receive patent protection. In his analysis of the Israeli law, he refers to the undesirability of any restriction with regard to medical treatment, but he accepts that at least a first use is subject to the protection of patent law without giving any reasons why a second or subsequent use cannot be so protected.

In the same case, Witkon J said at p 536 that he considered under Israeli law, there was no ground in either law or logic for holding that a method of therapeutic treatment was unpatentable, but he went on to say (at p 536):

"Even on the assumption that no patent should be granted for a therapeutic method, this rule would not be applicable in the present case, since:

"(1) the method encompasses the use of a known compound for a new, hitherto unknown purpose, in combination with a conventional pharmaceutical carrier;
"(2) the inventive step resides in the new use."

From that, it follows that Witkon J did not arrive at the same conclusion as Kahn J. Kister J also delivered a short judgment in which he considered the problems in the light of Hebrew law and the Hebrew conditions. In doing so he does not set out any principle which throws light on the present dispute. The Israeli case then provides support for both approaches.

Cooke J went on to survey decisions in various comparable jurisdictions and came to the conclusion that the matter was finely balanced, but it is clear that in the end his resolution of the matters in dispute was that the Court was dealing, as in precise terms it clearly was, with a claim that a method of treatment of human ailments, was patentable. That is a different question and has consistently been interpreted differently in the cases from the question of whether or not a second or subsequent use of a previously patented substance, was entitled to protection.

I do not overlook the fact that in the paragraph referred to above from p 392 of the decision, Cooke J indicated support for the conclusion of the Commissioner in terms which would suggest that he was deciding as to the further use of known pharmaceutical compounds. This comment referred to an application for amendment made to the Commissioner, which would have raised a contention similar to that now before the Court. Technically, since the appeal related only to the first 12 claims, the question was not before the Court, but the observations are obviously entitled to weight. Nevertheless it should be noted that the basis adopted by the Commissioner for the rejection of such claims and upheld by Cooke J, was that such claims related "to nothing more than the discovery of a further use for known pharmaceutical compounds". The Commissioner has clearly therefore relied upon those authorities to which Mr Radich also referred, which concluded that there was insufficient novelty to justify patent protection when what was relied upon, was merely discovered, as distinct from being invented.

The utility of that distinction has been questioned, see for example the comments in *Pirrie v York Street Flax Spinning Co Ltd* [1894] 11 RPC 429 at p 452. While I accept that there may be circumstances where the question of whether or not sufficient novelty has been established may depend upon that distinction, in the generality of cases the reasoning in the *National Research Development Corp* case (supra) and the more modern cases which have followed upon that decision, discount the value of that approach.

Cooke J did not pursue this aspect, nor did he analyse it beyond citing the decision of the Commissioner. In my view then it follows that his conclusion in the case rests upon the principal basis to which reference has already been made, that is, that methods of treatment as distinct from the substances used in that treatment, are not in the present law at least in New Zealand, entitled to the protection of a patent. That was after all the question before the Court. While therefore I accept that the observations of Cooke J as to the second or subsequent use are entitled to the weight which attaches to any observation from that source, they are not determinative of the question now under consideration.

McMullin J also examined the relevant authorities and pointed out that the English cases were notable for their reluctance to accept the patentability of

treatment of animals and human beings. He referred to the decision in *Eli Lilly & Co's Application* [1975] RPC 438 where the Appeal Tribunal at p 444 said:

"Speaking generally, if chemical compounds are old the only 'manner of manufacture' within section 101 of the Act which can be claimed in respect of them must be directed to some newly discovered and unexpected valuable property or use of the compounds in question. A claim to such a use will normally qualify as an invention or alleged invention within section 101 of the Act, so that the application can succeed."

He noted that they had added:

"There is, however, an exception to this generality in the case of compounds where the new use sought to be claimed is some treatment with the compounds to cure or prevent disease or illness in human beings. As our law stands at present no patent can be granted for such a use, see our decision in *Schering*, (1971 RPC 337) mentioned above. This exception may seem technically anomalous and therefore illogical but its legal justification seems to us to be as follows.

"The Statute of Monopolies, 21 Jac 1 C 3, generally declares all monopolies void, but by the proviso to section 6 excepts grants of letters patent for inventions or manners of new manufacture as therein defined. This exception in favour of and preserving letters patent for novel inventions, however, itself contains a proviso in the following words: 'so as also they be not contrary to the law or mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. The definition of invention in section 101 of the Patents Act, 1949, which now consolidates the existing law, specifically preserves and embodies the definition of invention contained in section 6, in the following words: 'Invention means every manner of new manufacture, the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies . . .'. This must, as a matter of construction, import also the proviso at the end of section 6 quoted above."

As I have already stated, that argument applies with equal force to a first use of a substance designed to treat human ailments and once it is accepted (and the law is clear that this is the case), that such a substance is entitled to protection, then the argument as to second uses loses its force. McMullin J noted that patent law is "a rather artificial, highly complex and somewhat refined subject" and he concluded like the other members of the Court, that a patent should not be granted for methods of treatment.

Mr Radich submitted that the kind of application under consideration in this case, is indistinguishable from a claim to a method of medical treatment of human beings. The distinction between the two however is recognised in the *Wellcome* case itself since if there were no distinction, it would not be possible to justify the conclusion that it was possible to obtain even first patent protection for the production of a substance designed to be used for treatment of human beings. There can now be no doubt on authority that such a substance is entitled to patent protection.

In summary then, it is clear that the basis of the decision is that the principle that *methods* of treatment of human ailments are not patentable, is too well entrenched in the law to be changed by the Courts. It is true that there are observations in the decisions of all three members of the Court, that although it is accepted that a substance intended for use in treatment, is entitled to a protection for a first use, it is not so entitled for a second or subsequent use. That was a secondary concern of all three Judges and in no case was the concept analysed or the distinction made

between methods of treatment and the protection of a substance intended to be used for such treatment. Further, the logical difficulties to which such a concept gives rise, were not explored. It follows then that this conclusion was not necessary for the determination of the case and is not necessarily concluded in favour of the position for which Mr Radich contends. Since the question is not therefore finally determined, it is appropriate to look at subsequent developments.

The application in the *Wellcome* case was formulated in terms of a method of treating human beings. This was precisely the point at issue with respect to claims 1-12 and it is worth repeating, that claims 29-34 which specifically raised the question at issue in this case, did not proceed to the Courts. The Commissioner of Patents no doubt in view of comments contained in the *Wellcome* case as well as the factual material upon which it was based, took it as authority for the proposition that it was not possible to obtain patent rights in respect of a substance for which protection had already been obtained, but in respect of which a new use intended for the treatment of human beings was subsequently discovered. It is the case for the defendants that he was not entitled to rely upon the *Wellcome* decision as authority for this conclusion, which went beyond the question at issue for the Court and of course the Commissioner now takes a different view, as is indicated by the practice note, the subject of these proceedings.

There can be no doubt that the decision in the *Wellcome* case represented the general trend of authority, not only in New Zealand, but elsewhere and it will have been noted that in coming to his conclusion, Cooke P referred to an Israeli case. Such a position was however unattractive to pharmaceutical companies and various attempts were made to avoid it. In *Dow Corning Corp (Bennett's) Applications* [1974] RPC 235 an attempt to avoid the principle was made by seeking protection for a pack with instructions. The Judge saw this as being a disguised form of claim to a process for the medical treatment of human beings and rejected it. As to novelty, in *Ciba-Geigy AC (Durr's) Applications* [1977] 4 RPC 83, protection was sought for a herbicide which although already known as a herbicide, was subsequently discovered to be usable as a selective herbicide for killing weeds in particular crops. From the judgment it appears that protection was sought on the basis that the claim was a claim to a pack or package of the material concerned. This was rejected, both by the Patent Appeal Tribunal and by the Court of Appeal. Reference was made to the *Dow Corning* case and Russell LJ at p 89 said specifically:

> "There seems to us to be nothing inventive about parcelling up the known material in any and every convenient package or container having written thereon the information that it can be used for the stated purpose in the stated loci. There is no interaction between the container with its contents and the writing thereon. The mere writing cannot make the contents in the container a manner of new manufacture."

There was no reference in the decision to the Australian case of *National Research Development Corp* (supra) which had been decided in 1959 and the decision in *Ciba-Geigy AC (Durr's) Applications* was not referred to by the Court of Appeal in New Zealand in the *Wellcome* case which specifically accepted the decision in the *National Research Development Corp* case. However leaving aside novelty, the packaging method adopted to avoid the operation of the principle that methods of treatment of human beings were not patentable, failed.

The next attempt however was made in Europe under the provisions of the European Patents Convention and has come to be known as the "Swiss" type application. *Re Eisai Co Ltd (Dec Gr05/83)* [1985] Official Journal EPO 64, was a decision of the enlarged Board of Appeal of the European Patents Office. A question of law had been referred to the enlarged Board of Appeal as to therapeutic use claims for substances and compositions in general, with the central problem being what the Board referred to as inventions of the so-called second medical indication. The Board was required to determine the matter in terms of the European Patents Convention and it started by concluding that by virtue of the provisions of art 51(1) of that convention, methods for treatment of the human or animal body by therapy, were not to be regarded as inventions, susceptible of industrial application and therefore could not obtain protection. The Board held however that the use of a substance or composition for the manufacture of a medicament for a specified new therapeutic application, did not conflict with the article and noted that where there was some new formulation, then there was no problem as to novelty. In the case of no new formulation, it went on to find that the required novelty could be found in the new pharmaceutical use.

The decision therefore is relevant to the matters at present before the Court in two ways. First, it accepts that the manufacture of a medicament for a specified new therapeutic application, does not constitute a method of use of that substance or composition for the treatment of the human or animal body by therapy and therefore does not come within the prohibition on the granting of patents for such purposes. Secondly, that the novelty which is required for patentability, can be found in the manufacture for a second or subsequent therapeutic use. The enlarged Board of Appeal therefore, was able to draw a distinction between the manufacture for a use and the therapeutic use itself and to find the requisite novelty from the intended use. The case is of course not decisive of a matter arising in New Zealand. The European Patents Convention differs in wording from the law as it exists in New Zealand, both in terms of the development of that law through cases and in Statute. Nevertheless in so far as it involves a logical analysis, it has significance and supports the position for which the defendants contend.

The distinction which the enlarged Board of Appeal was prepared to draw, not surprisingly led to a number of other cases which relied upon a similar approach. I refer first to the decision in *John Wyeth and Bro Ltd's Application* (1985) 23 RPC 545. In that case, there was an unexpected discovery that certain drugs known to be active in lowering blood pressure, were also useable for treating or preventing diarrhoea in mammals or poultry. At p 563 in the judgment of the Court, it was stated:

> "But, as the Swiss form of claim is directed to the use of the known substance in the manufacture of the medicament for a new therapeutic use, and is not directed to claiming the or any instruction for the new therapeutic use as the invention, it seems to us that such a claim, even in the form of the modified Wyeth claim which specifies manufacture of the antidiarrhoeal agent 'in a package together with instructions for its use in the treatment or prevention of diarrhoea' is not excluded from patentability under s 1(2)(d)."

At p 564 the Judges stated:

> "the UK Patent Office has always allowed claims to a known drug formulated for a second medical use provided that the formulation claimed was novel and not obvious in view of the

first (known) medical use. But the difficulty arises when the medicament or pharmaceutical agent to be manufactured is not novel and neither the Wyeth claims nor the Schering claims in the Swiss form and now under consideration specify any novelty in the agent or medicament to be manufactured. In each case the applicants' invention is based on the discovery of a new and unexpected therapeutic activity of the known compounds, already known, or some of them known, for other therapeutic activity, and the novelty and inventive step of the claimed invention must lie in that aspect of the claim."

The conclusion of the Court was that under the provisions of the 1977 Act in England (at p 565):

"we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself novel, for a second or subsequent and novel medical use would not be patentable as lacking the required novelty."

These expressions of opinion in that case would favour the position taken by Mr Radich, since they suggest that under the statutory provisions in England (and the differences in the statutory provisions do not in my view assist the defendants), the necessary novelty could not be found in the nature of the therapeutic use. However the Judges went on to note that the approach to novelty adopted by the Board of Appeal in *Eisai* was equally possible under the corresponding provisions of the 1977 Act.

The Court referred to the decision of the enlarged Board of Appeal in *Eisai* and said at p 567:

"That approach to the novelty of the Swiss type of use claim directed to a second, or subsequent, therapeutic use is equally possible under the corresponding provisions of the 1977 Act and, notwithstanding the opinion expressed earlier as to the better view of the patentability of such a Swiss type claim under the material provisions of the Act considered without regard to the position, as it has developed, under the corresponding provisions of the EPC, having regard to the desirability of achieving conformity, the same approach should be adopted to the novelty of the Swiss type of claim now under consideration under the material provisions of the Act."

As I understand the reasoning in that case, what the Judges are saying is that the trend of authority under the English statutory provisions, bearing in mind earlier expressions of opinion in the Courts and in particular in the cases of *Adhesive Dry Mounting Co Ltd v Trapp & Co* (1910) 27 RPC 341 and *Ciba-Geigy AG (Durr's) Applications* [1977] 4 RPC 83 would lead to the conclusion novelty could not be found in a new use. Nevertheless the conclusion at which the enlarged Board of Appeal had arrived in *Eisai* was an equally possible interpretation and that it was desirable to follow the trend of authority under the European Patents Convention.

There are three aspects of this which justify comment. The first is that there are problems in accepting the general authority in the *Adhesive Dry Mounting* case (supra) in the light of the decision in *National Research Development Corp v Commissioner of Patents* (supra). The second is that while the European Patents Convention is obviously not binding in this country, there is ample authority to the effect that where developments in patent law in other countries are not inconsistent with the law in this country, it is clearly desirable for interpretations which have found favour, to be reflected in consistency in New Zealand interpretations in so

far as this is appropriate, in the legal situation which exists in this country. The third is that the application was not defeated by the fact that it involved a new therapeutic use of a previously known substance.

As counsel noted, New Zealand is a party to the agreement on trade related aspects of intellectual property rights, referred to as the TRIPPS agreement. While the extent of the obligations which that agreement may in the future impose, is not necessarily yet defined, its acceptance emphasises the fact that in the modern world the law as to intellectual property cannot be confined. The Court in the *Wyeth* case considered that the trend in earlier English authority on the provisions of the English Act was contrary to an interpretation allowing the application of the "Swiss" approach, nevertheless the Court found that that approach was not excluded by the earlier law and that it was desirable to accept that alternative interpretation in order to ensure consistency with the European approach embodied in the *Eisai* case. Although there is a suggestion that the Court may have been influenced by the intention to adopt provisions embodied in the European Patent Convention, nevertheless the judgments clearly refer to the interpretation as being possible on the law prior to the contemplated changes. The same approach is clearly possible in New Zealand, unless it were prevented by the *Wellcome* case.

In my view, bearing in mind the way in which the case was presented on that occasion, including the formulation of the questions at issue and for the reasons which I have endeavoured to discuss above, I do not think that the *Wellcome* case is contrary to the conclusions in *Eisai* and may properly be seen, as I am informed it always has been seen, as maintaining that principle which in one form or another may be found in various jurisdictions, that it is contrary to the public good for methods of treatment of human ailments to be constrained by patent monopolies. That does not prevent a patent protecting the manufacture of a substance previously recognised for a new therapeutic purpose where there is a sufficient degree of novelty to permit this to take place.

While none of that is decisive of the questions in this case, they are good reasons why the Court ought, where more than one interpretation is open, as was the case in *Wyeth*'s case (supra) to follow that interpretation, which is more in accord with that adopted internationally. I am reinforced in that view by the acknowledgement of Cooke J that in *Wellcome* itself, the outcome was finely balanced. I consider international trends have altered that balance.

Mr Radich submitted that the *Eisai* case was not binding on the New Zealand Courts and that in any event, it depended upon the specific provisions of the European Patent Convention. He noted that the decision had largely depended upon the provisions of art 54(5) of that convention, which specifically provided the general rules of law relating to novelty did not exclude the patentability of any substance or composition comprised in the state of the art for use in a method referred to in art 52(4) (which referred to the treatment of human beings) and I accept that that is an argument which is not without strength. It was not however sufficient to result in a different decision in the *Wyeth* case, nor in my view is it sufficient to arrive at a conclusion contrary to the *Wyeth* case in the present circumstances for the reasons already expressed, namely that once it is accepted that a first therapeutic use is patentable, that principle in combination with the decision in *National Research Development Corp v Commissioner of Patents* (supra), justifies the conclusion for which the defendants contend.

Mr Radich placed some reliance on the English decision in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc and Napro Biotherapeutics Inc* 20/8/97, High Court of Justice, Chancery Division, Patents Court, Ch 1997 N2698. That was a case involving the substance taxol. The Judge noted that the application was brought in a form designed to take advantage of the Swiss form and of the decision in *Eisai*. He referred to the example of the newly discovered use for aspirin and asked the question as to why the manufacture was rendered new because there was a new use? He noted the reservations which the Court had had in *Wyeth*, but that the Court in that case had decided that because of the decision in *Eisai* and having regard to the desirability of achieving conformity, it would follow the decision in *Eisai*. Jacob J in the *Bristol-Myers Squibb* case decided on that basis that if *Eisai* was not to be followed, that was a matter for the Court of Appeal and accordingly accepted it as it had been in *Wyeth*. He noted that the claim did not amount merely to a method of treatment, but was to the manufacture of the medicines to be used in the treatment. In the end however, he came to the conclusion that there was no novelty because the particular use which was relied upon to establish novelty, was in fact insufficiently different from the use which had always been recognised. He considered all that had been put forward in support of the application for patentability was new information about the old use. The Judge noted there was a distinction where the purposes were different.

Mr Radich also referred to the decision of the Full Federal Court in Australia in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (supra). In that case the majority after a consideration of cases from a number of jurisdictions came to the conclusion that if a process which does not produce a new substance but nevertheless results in a new and useful effect so that the new result is an artificially created state of affairs providing economic utility that may be considered a manner of new manufacture within s 6 of the Statute of Monopolies. The majority went on to conclude that in Australia the exclusion referred to in English and New Zealand authorities which related to the method of treatment of human beings, did not prevent patentability.

Mr Radich however relied upon the decision of Shepherd J dissenting, who followed the decision in the *Wellcome* case, considering that the law in Australia as in New Zealand, did not permit the patentability of a method of treatment of human beings. That conclusion was not accepted by the majority of the Court. It could be argued therefore that the case determined that the law in Australia differed from that in New Zealand. Lockhart J in the majority at p 159 said:

> "Although a 'mere new use for an old thing' is not patentable, a discovery which itself involves ingenuity or novelty, that an old substance may be used so as to produce a new result, may ground a patentable invention. In such a case the old substance is treated as if it were new, its hitherto unknown or unsuspected potential being revealed by the discovery which is itself a consequence of scientific ingenuity (*Wellcome* at 528). If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s6 of the Statute of Monopolies: *NRDC* at 265 and 277 and *Wellcome* at 528."

That is of course a restatement of the principle already arrived at in the *National Research Development Corp* case (supra), but it is restated in the context of the new use for medical purposes of a substance previously patented. While therefore the Court determined the case on the basis that the law in Australia differed from

New Zealand (and England) as to the patentability of a method of treating human beings, the statement indicates an acceptance of the approach which found favour in *Eisai* and in the context of Australian statutory provisions which are much closer to the New Zealand statute than the European Patent Convention. There is much to be said for a consistency of approach in Australia and New Zealand in matters of this kind.

During the course of argument, counsel placed some emphasis on the significance of the concept of infringement in arriving at conclusions on the disputed questions. Attention was drawn to the problem which arises in protecting the patent if the substance is not specifically directed to the newly discovered use. There may very well be practical difficulties when questions of infringement arise, where a known compound is manufactured for a new use but has lost protection when manufactured for some other use. Those are however practical questions which must arise in any situation when a new use provides the basis of novelty, but the Courts from *National Research Development Corp* on, have been prepared to accept situations where this kind of practical difficulty may arise.

Accordingly, it is my view that using the words in *Eisai*, in New Zealand:

(1) It is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient, provided of course the requisite novelty (which did not exist in the *Ciba-Geigy* case (supra)) can be found;

(2) That such a conclusion is not in conflict with the decision of the Court of Appeal in the *Wellcome* case; and that

(3) Accordingly the approach of the Commissioner in the advice note, the subject of these proceedings, is upheld.

That leads to the question of remedies. These proceedings were formulated in terms of an application for review. During the course of argument, it became clear that there were also possible factual points in contention as to whether or not certain substances, processes and uses, whether singly or in combination, met the necessary requirements for patentability and counsel for the defendants were appropriately concerned to ensure that I was aware from the affidavits, of the bases upon which protection was sought in respect of specific subjects. In the circumstances of this case as it developed, it became clear that the real question was not the specifics, but rather the general principle and it seems to me that since a declaration was sought, it is most appropriate to deal with the questions at issue by way of a general declaration on the analogy of a declaratory judgment application.

There will therefore be a declaration in terms of the findings set out in the preceding paragraph.

Because of the complexities of the case and the way in which it developed, all further questions as to the formal resolution of these proceedings and all questions of costs, are reserved. Counsel may submit a draft order.

Application for orders declined

Reported by Claire Ongley