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THE PATENTS ACT 1977

0/95/93

IN THE MATTER of Patent Application

No 8900048.3 by Wilhelm Hoerrmann

DECISION

Application 8900048 was filed on 4 January 1989 claiming priority from a patent application filed in the then Federal Republic of Germany on 30 December 1987. This priority date was subsequently held to be invalid since the application was filed outside the twelve month period and the application is proceeding with its own date of filing, viz 4 January 1989.

The application relates to drug compositions containing as active agents at least one isomer of lysine or hydroxylysine. Conventional carriers and adjuvants, as appropriate, make up the remainder of the composition. As originally filed claim 1 read:-

> "Drugs containing, as active ingredients, at least one isomer of hydroxylysine or lysine, or one of their pharmaceutically acceptable derivatives, if necessary together with usual carriers and/or adjuvants."

Objection by the examiner that the phrase "pharmaceutically acceptable derivatives" was unclear resulted in its deletion from the claim. However, of more importance was the fact that drug compositions containing lysine and hydroxylysine were

undisputably known in the art. As a result the applicant filed claims in what has become known as the "Swiss" format and it is against these claims that the examiner has raised objection under Section 14(5)(c) i.e that the claims are not supported by the description.

There being no agreement on the matter the applicant, Dr Hoerrmann, who has prosecuted the case on his own via an address for service in the United Kingdom, was offered a hearing but is unable to travel from Germany. It falls to me therefore to decide the matter based on the papers on file.

Before dealing with the specific issue in dispute it seems appropriate for me to deal briefly with the law as it relates to inventions in the pharmaceutical area.

As a general rule, claims to a compound or composition for a particular purpose are interpreted as claims to the material per se. Thus, if the compound or composition is already known it is more than likely that the only protection available will be for a new method of using that material. In the case that the new method is one of surgery, therapy or diagnosis protection is not available by virtue of Section 4(2) of the Act.

In recognition of this fact, and that much research in the medical area is directed towards finding new uses for known compounds or compositions, an exception to the general rule has been created in Section 2(6) of the Act in the following terms:-

"In the case of an invention consisting of a substance or

composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art."

Both sections 4(2) and 2(6) find their counterparts in Articles 52(4) and 54(5) respectively of the European Patent Convention and by virtue of section 130(7) of the Patents Act 1977 are interpreted so as to have the same effect.

Thus a known substance or composition may be patented **for use** in a method of treatment by surgery or therapy or of diagnosis provided that its use in any such method is new ("first medical use"). It is therefore common in patent specifications to see claims of the type "Substance or composition X....." followed by indication of the use, for instance ".... for use as a medicament", "....for use as an antibiotic", or "....for use in treating disease Y".

This type of claim, however, has been held to be applicable only in the instance that the substance or composition in question has no previously disclosed medical use. In a decision of the Enlarged Board of Appeal of the European Patent Office (Decision Gr 05/83, OJEPO 3/85) it was held that in the instance of a subsequent medical use being disclosed claims of the "Swiss" type were appropriate. This type of claim normally takes the form:-

"Use of substance or composition X for the manufacture of a medicament for a specified new and inventive therapeutic application."

and is applicable even if the process of manufacture of the medicament does not differ from known processes using the same active ingredient.

This decision, though given under the European Patent Convention, has been followed on all cases under the UK Patents Act where a subsequent medical use of a substance or composition has been indicated.

Returning to the present application, the substances in question, namely lysine and hydroxylysine, were at the date of filing, known compounds with known medical indications. Thus in response to the Examiner's objection in the Official Letter of 3 March 1992 that the invention as originally claimed in claims 1 to 4 lacked novelty the applicant filed claims mainly of the "Swiss" type which in their latest form, following further amendment, read as follows:-

1. Use of at least one isomer of hydroxylysine or lysine in the preparation of a medicament for the treatment of diseases of the veins.
2. Use of at least one isomer of hydroxylysine or lysine in the preparation of a medicament for the treatment or adjuvant treatment of endo- or myocarditis and thereof resulting arrhythmias.
3. Use of at least one isomer of hydroxylysine or lysine

in the preparation of a medicament for the treatment or adjuvant treatment of one of the following inflammatory conditions: scarlatina, rheumatic fever, septic arthropathias, erysipelas, impetigo, prostatitis, adnexitis.

4. Use of at least one isomer of hydroxylysine or lysine in the preparation of a medicament for the adjuvant treatment of dental caries.
5. Use of at least one isomer of hydroxylysine or lysine in the preparation of a medicament for the adjuvant treatment of hernias.
6. Use according to claims 1 - 5 in which hydroxylysine or lysine are present as L-hydroxylysine or L-lysine.
7. Use according to claims 1 - 5 in which the hydroxyl group of hydroxylysine is in the delta carbon atom position.
8. Use according to claims 1 - 5 in which the hydroxyl group of hydroxylysine is in the alpha or beta isomeric position.
9. Use according to claims 1 - 5 in which the isomer of hydroxylysine or lysine is in the form of salts, ethers, esters, amides or peptides thereof.
10. Use according to claims 1 - 5 in which the isomer of hydroxylysine or lysine is combined with a pharmaceutically acceptable carrier.
11. Use as claimed in any preceding claim further containing N-methyl-amino-ethanol and/or N-dimethyl-amino-methanol

both in the form of acid addition salts as activity enhancer.

It is important for me to emphasise at this stage that there is no dispute about the acceptability of the wording of this latest set of claims. They are worded correctly as "Swiss" type claims and are appropriate to the situation wherein lysine and hydroxylysine are known compounds having a previously known therapeutic use. What is in dispute is that the claims, limited as they are to those compounds having therapeutic use in a number of medical indications, are not supported by the description.

The examiner has advanced this argument consistently from the time that the specification was amended to contain the "Swiss" type claims. He has done so on the basis that the description is totally silent about any pharmacalogical data to show that lysine or hydroxylysine is active against any of the ailments specified in the claims.

Dr Hoerrmann in his letter of 12 January 1993 does not deny that the seeming lack of pharmacological data is of great importance but points to the fact that the only way to prove usefulness in his cases is by means of clinical trials. Almost by definition such trials take a long time and are expensive and for these reasons he states expressively that "there is the earnest intention to perform this(sic) trials as soon as ever possible." He goes on to say that he does not expect to have a patent granted without the result from these trials, but on the other

hand cannot go into trials without any legal form of protection.

The examiner in the official letter of 19 February 1993 expresses appreciation of the dilemma in which Dr Hoerrmann has been placed but being unable to offer him a way out of the dilemma suggests that the matter might be resolved at a hearing.

A further letter from Dr Hoerrmann dated 5 April 1993 reinforces the points made in his earlier letter and states that the invention of the present application has actually been made whilst again asking for time to perform the clinical trials so that its usefullness may be demonstrated. In Dr Hoerrmann's opinion the essentials of the invention, namely the chemical nature of the compounds, the dosage and the new medical indications are all to found in the specification.

It is these points made by Dr Hoerrmann that I will consider in reaching my decision.

From the decision of the Enlarged Board of Appeal of the European Patent Office that I have referred to previously it is clear that it is the new and non-obvious use of a product that constitutes the invention when that product is already known. The problem for the Board in the particular case they were considering was, in effect, the type of protection available when the use was a further medical use, a problem solved by allowing claims of the "Swiss" type.

That being the case, in considering what is adequate support in the description for medical inventions having at their heart a

further medical use the emphasis must be towards finding description that demonstrates that use not by mere reference to a condition that may be treated but by reference to tests that show that treatment to be a reality. Only in this way, it seems to me can it be shown that invention has been made and not merely contemplated as a possibility.

Dr Hoerrmann refers in his letter to the fact that in his opinion the essentials of the invention, namely the chemical nature of the compounds, the dosage and the new medical indications are all to be found in the specification. I would not want to disagree with Dr Hoerrmann that these are indeed the essentials of the invention but the effect of their disclosure and the extent to which they are disclosed are matters which I must consider in coming to a decision as to whether they provide support for the invention claimed.

In any case relating to the medical use of a compound or composition it is obviously necessary for there to be adequate disclosure enabling the compound or composition to be identified. It would also be expected that information concerning the dosage to be administered would be disclosed as enabling a full understanding of the invention. This information, in itself, might provide adequate support for a claim that is not purpose limited. However, in my opinion, it cannot provide support for an invention in which the only form of protection is via a "Swiss" type claim. Resort to such a claim is an indication that the compounds or compositions as well as the

dosage amounts and forms in which they are administered are well known in the art.

Such is the case with the present application. There is no doubt that hydroxylysine and lysine are known compounds and that the dosages in which they are used as well as the form of their administration are well known. This much is evident from the specification on pages 6 and 7 where it is stated:-

> "The drugs according to the invention are to be administered in ways basically similar to those normally employed in usual amino acid treatment, i.e. preferentially per os or intravenously, or by the central intravenous route. Administration by way of tablets, coated tablets, injection or infusion solutions would likewise be identical."

and

> "In view of the fact that the compounds in question are non-toxic, dosages may range widely even though they might initially be based on normally used therapeutical amino acid dosage levels of between 0.01 and 0.1 g of substance per kg of bodyweight."

Clearly then in an application like the present where the invention resides in finding a further medical use for a known compound or composition, administered in conventional amounts and in a conventional manner, support for a claim based on that new use is going to be found primarily in that part of the description which provides evidence that the new use has been

effected.

In the present application, and with particular regard to claims 1 to 5,it is contemplated that something like twelve different medical conditions may be treated by administration of hydroxylysine or lysine. If those claims are to be considered as supported by the description then, in my opinion, that description should demonstrate by relevant in vivo or in vitro tests that the specified compounds are indeed effective against each one of those twelve conditions.

However, on turning to the description all I can find under the heading "Fields of application for the drugs according to the invention:" on page 5 is a list of conditions in very much the same terms as that of claims 1 to 5. There is a complete absence of any pharmacological data to demonstrate that the invention, which I take to be the treatment of the specified conditions, has in fact been carried out, let alone has proved to be effective. The examiner, in paragraph 3 of the Official letter of 8 October 1992 raised objection in these terms:-

> "In amended Claims 1-5 (which now take the form of what are generally known as "Swiss Type Claims") the claimed therapeutic activities of the isomers of Lysine or Hydroxylysine are not supported by the description where there is a complete lack of any pharmacological data to show that Lysine or its hydroxy derivative is active against the ailments specified in Claims 1-5. Without such data it is not clear how such new therapeutic

indications have been arrived at. Any patent application in which claims are dependent for their novelty on new therapeutic uses would be expected to include in its description in vivo or vitro pharmacological tests to demonstrate the new activities, otherwise the new uses claimed could be construed as being merely speculative."

I have come to the conclusion that this objection must be right. That is not to say that I do not sympathise with Dr Hoerrmann's problem of having to conduct long and expensive clinical trials but unless there is some indication in the description of applications of this type of tests, however rudimentary, demonstrating that the invention has been carried out in an effective manner then the application must fail for lack of support for the invention claimed.

In coming to this decision I have paid careful attention to all that Dr Hoerrmann has said in his correspondence with the Office and particularly that in his letter of 12 January 1993 where he says:-

"It is only logical that first an invention must be made, only then the value of it can be proven."

and in his letter of 5 April 1993 where in similar terms he says:-

"The proof of the usefulness of an invention is not the same as the invention itself. I can only reiterate that the invention was actually made as an interconnected part of other inventions of mine and is described in my

application. The essentials of the invention namely the chemical nature of the compounds, the dosage, the new medical indications, it is all there."

However true it is that the real value of an invention may only be proved long after the invention has been made I cannot see how in this area of technology and in the circumstances of the present case that an invention can be said to have been made until some sort of trial has been conducted. Thus, in order to support claims relating to the treatment of further medical indications I am inevitably led to the conclusion that the description of a patent application must do more than cite a list of those indications. This is I believe consistent with precedent and as an example I would choose to refer to the words of Dillon L J in Genentech Inc's Patent [1989] RPC 147 where he observed (at page 236-7) "the Patent Office ought to have very clearly in mind that it is undesirable to allow claims the object of which is to cover a wide and unexplored field or where there is no disclosure in the specification which is in any way coterminous with the monopoly indicated in the claims."
I therefore find that none of the claims of the application are supported by the description as is required by Section 14(5)(c) of the Patents Act 1977.

Dr Hoerrmann has asked in his letter of 5 April 1993 that if the claims cannot be allowed he may be granted time to perform the necessary clinical trials and that the application should remain pending in the meantime. Apart from the fact that the normal

Section 20 period, which expires on 4 July 1993, would be long past by the time those trials were completed, this would seem to be a wholely inappropriate way of allowing the situation to be resolved. It would, in my opinion, be allowing an invention that had only truly been made at a much later date to take the filing date of the originally filed application and that cannot be right.

In conclusion I can see no other form of claim, based on the present description and taking into account the strictures imposed by the prior art, that would allow the application to proceed to grant and I therefore refuse the application. Any appeal should be lodged within 6 weeks of the date of this decision.

Dated this 2nd day of June 1993.

D L Wood

D L Wood

Principal Examiner acting for the Comptroller.