(81)

PATENTS ACT 1977

IN THE MATTER OF Application
No 18493/79 in the name of
Wellcome Foundation Ltd

DECISION

The Examiner having objected that since a grant of a patent in respect of the invention had already been made to the present applicants in Specification No 1604554 under the Patents Act 1949, the grant of a patent for the same invention under the Patents Act 1977 should be refused, the matter came before me at a hearing on 12 November 1982, Mr M Garrett, Agent, appearing for the applicants. Mr N Jacobs, Examiner, also attended.

The applicants' invention resides in the discovery that the compound (All-Z-)-5,8.11,14.17-eicosapentaenoic acid or a salt, ester or amide thereof can be used in the treatment or prophylaxis of thrombo-embolic conditions, and claim 1 of the present specification reads:-

"A formulation as an active agent for use in the treatment or prophylaxis of a thrombo-embolic disorder or disease in a mammal, comprising (all-Z-)-5,8,11,14,17-eicosapentaenoic acid or a pharmaceutically acceptable salt, ester or amide thereof, at least 50% by weight of the fatty acid content of the formulation being provided by (all-Z )-5,8,11,14,17-eicosapentaenoic acid or a pharmaceutically acceptable salt. ester or amide thereof". Claim 2 relates to a formulation in which at least 90% of the fatty acid content is comprised by the specified acid or derivative thereof, claim 3 relates to the formulation of claim 1 containing a pharmaceutically acceptable carrier and there are further claims relating to similar formulations containing or being free from various other ingredients or being in forms such as capsules or tablets and so on.

The 1949 Act specification No 1604554 referred to by the Examiner, which is of course also in the name of Wellcome Foundation Ltd, claims in claim 1:-

"A pharmaceutical formulation comprising (all-Z-)-5,8,11,14,17-eicosapentaenoic acid, or a pharmaceutically acceptable salt, ester or amide thereof, and at least one pharmaceutically acceptable carrier, at least 50% by weight of the fatty acid content of the formulation being (all-Z-)-5,8,11,14,17-eicosapentaenoic acid". Claim 2 relates to a formulation in which at least 90% of the fatty acid content

comprises the specified acid, and further claims relate to other percentages of fatty acid content, to the presence or absence of other ingredients, and to forms such as capsules, tablets and so on. The specification states at page 1 lines 6-7 that the formulation is for the treatment or prophylaxis of thrombo-embolic conditions.

The history of the two applications is as follows. On 26 May 1978, the applicants filed an application 23575/78 under the 1949 Act accompanied by a Complete Specification, and on the same day they also filed a Provisional Specification 23574/78 which was substantially identical so far as the description was concerned. The Provisional Specification was then used under the provisions of Section 127(4) of the 1977 Act to establish a priority date for a later application under that Act which is the application now in suit. During the proceedings on both the 1949 Act application and the present application, the Examiners pointed out to the applicants that under the principle involved in Dreyfus's Applications 44 RPC 291 both the applications could not be allowed to proceed to grant, and in their letter dated 6 February 1981 on the 1949 Act application (23575/78) the applicants noted the objection and stated that they would ensure that any conflict between the applications was removed at the appropriate time. In view of this clear commitment, the applications were allowed to proceed normally and a patent has now been granted on the 1949 Act application.

The Examiner's objection to the present application is that since the applicants, the priority date and the invention are the same as in the now granted 1949 Act application, then in accordance with the principles laid down in Section 18(5) of the 1977 Act and also in accordance with the long-standing practice under the 1949 Act which follows the decision in Dreyfus's Applications, a second grant should not be made.

At the hearing, Mr Garrett did not dispute that the priority dates and the applicants of the two applications were the same but he argued that in his view the inventions were different. The scope of claim 1 of the present application, Mr Garrett said, was different from that of claim 1 of 1604554 and defined a different invention. Thus the present claim 1 is limited by the words "for use in the treatment or prophylaxis of a thrombo-embolic disorder or disease in a mammal", and this, said Mr Garrett, limits the claim to the formulation when presented or packaged for such a use. In support of this contention Mr Garrett referred me to Section 2(6) and to the Guidelines for Examiners in the European Patent Office at Part C, Chapter IV [illegible]. In contrast, Mr Garrett said, claim 1 of 1604554 is a straightforward per se claim to the formulation and is unrestricted by

any reference to use. Further, he said, claim 1 of 1604554 specifies the presence of a pharmaceutically acceptable carrier whereas the present claim 1 does not, and thus although there is some overlap between the claims, they in fact relate to different inventions.

I do not agree with this argument for two reasons. Firstly, I do not agree that the words "for use in the treatment or prophylaxis of a thrombo-embolic disorder or disease in a mammal" necessarily limit the claim in the way Mr Garrett says. The passage in the EPO Guidelines suggests a view to be taken of such a claim when the composition already forms part of the state of the art, ie when it is a known composition. There is no suggestion in the present case that the formulation is in any way known, indeed claim 1 of 1604554 could not be sustained in its present form if it were. I referred Mr Garrett to a passage in the EPO Guidelines at Part C, Chapter III, 48, which indicates that a claim to a composition for a particular use should be construed as meaning a composition which is suitable for such a use, and this I believe is the correct interpretation to be placed on this claim.

Secondly I do not agree that a difference in scope between the claims necessarily means that the inventions are different. It is clear to me that although claim 1 of 1604554 does not mention a use, the formulation of that claim must be suitable for use in the treatment or prophylaxis of thrombo-embolic conditions since the specification describes in great detail the use of the formulation in such treatment and in fact refers to no other use. In this respect, I note that Section 125(1) of the 1977 Act states that an invention shall be taken to be that specified in a claim of the specification "as interpreted by the description", and it is clear that in identifying the invention the claims cannot be considered in isolation but must be considered in the light of the description.

With regard to the matter of the pharmaceutically acceptable carrier, although this is not mentioned in claim 1 of the present application it is present in claim 3. Such differences as are present between the main claims and also the other claims seem to me to be mere variations in the manner of claiming what is in fact the same invention, viz a formulation containing a particular active agent effective in the treatment or prophylaxis of thrombo-embolic conditions. I therefore agree with the Examiner that the two applications do relate to the same invention.

Mr Garrett also put forward a second argument of quite a different nature. Section 18(5) of the 1977 Act, he said, does not apply to the present case since the word "patent" in that Section (by virtue of the definition in Section 130(7)) means a patent under the 1977 Act. Since only one application under the 1977 Act

is involved, ie the present application, the other being under the 1949 Act, Section 18(5) does not apply. Further, he went on, the provisions of Section 18(5) do not apply to 1949 Act applications by virtue of Section 127(3) since Section 18 is not one of the Sections listed in Schedule 2, para 1(2), and it is clear from the last part of Section 127(3) that the 1977 Act cannot apply. With regard to the practice followed under the 1949 Act, Mr Garrett agreed that under Section 6(2) of that Act the Comptroller could refuse an application not only because the requirements of the Act and rules were not met but also if there was any lawful ground of objection to the grant. But under the 1977 Act, he said, this is not so, and by Section 18(4) if the examiner reports that the requirements of the 1977 Act and rules are complied with, the Comptroller must notify the applicant and grant him a patent. The decision in Dreyfus's Applications, Mr Garrett said, is therefore not applicable.

Mr Garrett also drew my attention to the observations of Lord Diplock in the appeal against the Assistant Comptroller's decision in the case of Energy Conversion Devices Inc as reported in the Times Law Reports of 2nd July 1982, in which his Lordship said that no tribunal or court had any discretion to vary the meaning of the words of primary or secondary legislation from case to case.

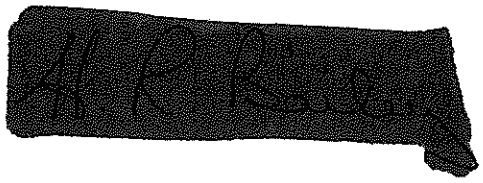
In considering this argument, I am aware that i) the practice under the 1949 Act was to follow the ruling derived from Dreyfus's Applications that more than one patent for the same invention should not be granted to the same applicant, and ii) that Parliament has clearly upheld this general principle by enacting Section 18 (5) in respect of 1977 Act applications, and Section 73 in respect of 1977 Act applications and EPO applications designating the UK. What Mr Garrett is in effect asking me to do is to allow an anomalous grant of two patents for one invention because of a lacuna in the provisions of the 1977 Act which apparently does not comprehend the possibility of grants under both the 1949 and 1977 Acts. Such an anomalous grant would clearly be contrary to practice and, I think. contrary to the wishes of Parliament as generally expressed in Section 18(5).

The Comptroller has a general responsibility for the administration of the Patents Acts to ensure that the principles of patent legislation are upheld. As I see it the principle established by precedent that a single monopoly should be granted in respect of each invention has been confirmed by specific provisions in Section 18(5) and Section 73 of the 1977 Act.

On these grounds I am persuaded that a grant of a second monopoly would be wrong

in law, and I therefore refuse to allow this application to proceed to grant.

Dated this 24th day of November 1982



H R BAILEY
Principal Examiner, acting for the Comptroller General

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