

BLO/117/85

PATENTS ACT 1977

In the matter of Application  
No 8208840 in the name of  
National Research Development Corporation

STATEMENT OF REASONS

The Examiner having objected that claim 1 at least of the application was not novel contrary to Section 1(1)(a), the matter came before me at a hearing on 14 August 1985 and, after an adjournment, again on 23 August 1985. The Agent, Mr G Parker, appeared for the applicants and the Examiner, Miss J E Evans, was present.

At the reconvened hearing I decided to refuse to allow the application to proceed with the claims then before me and that decision was communicated to Mr Parker. The following are the reasons for my decision.

The application relates to apparatus for diagnosing abnormalities in a joint by analysis of the vibration emission from the joint when moving. At the date of the first hearing, claim 1 of the applicant's specification read as follows:

"Orthopaedic diagnostic apparatus comprising transducer means engageable with a patient's body adjacent a joint to detect from that joint, when moving, vibration emission extending into the subsonic frequency range, such means providing electrical signals representing the vibration emission, and means for frequency analysing said signals to determine whether they involve a characteristic of predetermined form indicative of a pathological condition in said joint".

Claims 2 to 9 are further apparatus claims which are all dependent on claim 1. As described, the transducer means consists of a piezoelectric accelerometer and the analysing means consists of a tape recorder and a frequency analyser coupled to an auxiliary recorder.

The prior publication cited by the Examiner consists of an article published under the title "International Conference on Biomedical Transducers. November 3-7, 1975, pages 213-218, J Pugh et al. 'The use of piezoelectric accelerometers in the analysis of human gait characteristics'". This article describes the use of piezoelectric accelerometers in conjunction with stroboscopic techniques in a gait study programme involving "diagnosis of joint problems, effectiveness of surgery, effectiveness of physical therapy, and patient management". More particularly, a piezoelectric accelerometer is shown strapped to a knee and a system of data acquisition is disclosed which includes a tape recorder and a spectrum analyser. The frequencies detected appear from the graph of figure 6 to extend from 0Hz up to nearly 300Hz and so the accelerometer is clearly sensitive to vibrations extending into the subsonic range.

In communications with the Examiner, Mr Parker had indicated that, in his opinion, the apparatus features per se of claim 1 were known and, at the hearing, Mr Parker confirmed that this was indeed so. In view of this, he relied on the provisions of Section 2(6) of the Act to avoid an objection of lack of novelty.

Section 2(6) reads "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".

Mr Parker argued that Section 2(6) saved the claims under consideration from an objection of lack of novelty for the following reasons: firstly, the expression "substance or composition" used in the Section should be given a broad interpretation embracing apparatus; and, secondly, the diagnostic use referred to in claim 1 was a new and inventive diagnostic use.

In support of the first limb of this argument, Mr Parker referred me to a decision of the European Patent Office, namely that of the European Technical Board of Appeal 3.3.1 dated 25 January 1983 (T09/81). This decision concerns a combined preparation of chemical substances for use in therapy. The constituent chemicals are stated to be for simultaneous, separate or sequential use in cytostatic therapy and individually represent known therapeutic agents. In allowing a claim directed towards such a combined preparation, the Board of Appeal, in paragraph 9, drew attention to various dictionary definitions. Thus, "according to the Oxford English Dictionary (vol. III, page 736) 'composition' is characterised as a product as follows: 'A condition consisting in a combination or union of several things: a combination, aggregate or mixture". Further, "according to Le Robert, Dictionnaire Alfabétique et Analogique de la Langue Française (1980, pages 862 and 830) 'composition' may also have the meaning of 'combinaison' - especially in chemistry - or in general terms 'assemblage'".

Mr Parker had been referred to an earlier unreported Office decision in connection with Application 8114024 (Yeda) wherein it was held that "the provisions of Section 2(6) do not extend to devices or apparatus but are limited to substances or compositions as the wording of the Section clearly states". However, he argued before me that this Office decision, which was issued in January 1982, should not now be followed in view of the more recent European decision.

I carefully considered Mr Parker's submissions but did not find myself persuaded to accept this interpretation of the wording of Section 2(6). It seems to me that it is unacceptable to take paragraph 9 of the European decision out of context and attempt to apply it in the more general sphere. That decision was concerned solely with chemical compositions and I do not believe that it provides grounds for such a radical extension of the protection afforded by Section 2(6) as Mr Parker proposed. In my opinion I would not be justified in going against the Yeda decision in the absence of a positive statement in the European decision that "substance or composition" was broad enough to include "apparatus". As it is, the dictionary definitions appear to have been considered only in the narrow context of deciding whether compositions extended to chemical components applied simultaneously, separately or at intervals.

Turning now to the second limb of Mr Parker's argument, reference was made at the first hearing to a recent judgment of the Patents Court sitting en banc in the cases of Schering A G and John Wyeth and Brother Limited. In the judgment the Patents Court indicated that it considered the decision of the UK office in Sopharma S A's Application 1983 RPC 195 to be correct. That decision stated that on its

proper construction Section 2(6) "means that a known substance can only be claimed for use in a method of medical treatment the first time that it is disclosed as being useful in medical treatment. Once the use of the compound in a method of medical treatment has formed part of the state of the art, it cannot then be claimed a second time in respect of some new medical use".

Accordingly I indicated that I could not accept this argument either and that I was not prepared to allow the claims to proceed to grant in the form then before me. Some discussion then took place upon possible forms of amendment during which Mr Parker suggested incorporating a reference to the inclusion of a comparative element in the apparatus.

The Examiner however considered such an amended claim to be open to objection under Section 1(1)(b) on the ground of lack of inventive step having regard to the disclosure of the cited article. In this respect my attention was drawn to the statement on page 218 of the Biomedical article to the effect that all of the data obtained from the tests performed is "directly comparable to data previously taken on the same test subject".

I could not myself see that such an amendment would confer an inventive distinction on the claim over the prior art since it seems to me inevitable that results of this type must be compared with some standard in order to permit a meaningful interpretation of the results to be obtained.

In the event, since an allowable amendment could not be agreed upon, the hearing was adjourned to give Mr Parker an opportunity to prepare amended claims.

Subsequently amended claims were filed, claim 1 of which reads as follows:

"The use of transducer means engageable with a patient's body adjacent a joint, to detect from that joint when moving, vibration emission extending into the subsonic frequency range, such means providing electrical signals representing the vibration emission, and means for analysing said signals, in the manufacture of a product for application in orthopaedic diagnosis to determine, without an associated gait motion analysis, whether said signals involve a characteristic of predetermined form indicative of a pathological condition in said joint".

Claim 7 reads as follows: "A product manufactured in accordance with any preceding claim wherein said transducer means comprises a plurality of individual transducers for detecting said emission from different locations around said joint, and said analysing means enables comparison of the respective signals provided by the transducers".

Claims 2 to 6 are appendant to claim 1, and claims 8 to 11 are appendant to claim 7.

The Examiner considered these claims to be unacceptable and accordingly the hearing was reconvened on 23 August 1985.

At the hearing Mr Parker pointed out that the claims were now presented in the so-called "Swiss form" which was considered by the Patents Court in the Schering A G and John Wyeth and Brother Limited judgment referred to above. The Patents Court adopted the approach of the Enlarged Board of Appeal of the European Patent Office in case no. Gr5/83

and allowed a claim to the use of a substance, already known for use in making a medicament for one medical use, in the manufacture of a medicament for a second and novel medical use.

Mr Parker drew my attention to remarks in the Patents Court judgment which indicated the need to take judicial notice not only of decisions of the European Office, but also of "expressions of opinion" by them. This last point, he argued, was relevant to the afore-mentioned paragraph 9 of the Technical Board of Appeal decision where dictionary definitions of "composition" were considered. However, for reasons I have already indicated, I do not consider that that decision or expressions of opinion therein should override the earlier Office decision in the Yeda case, with which I agree. That being so, I do not consider that an approach using the "Swiss" form is available to the applicants in this case, since they are in my view debarred from making use of the provisions of Section 2(6).

Quite apart from that fundamental reason, however, I would point out that the description does not appear to disclose a method of manufacture of a product for application in orthopaedic diagnosis and so the claims are open to objection on the grounds of not being fairly based on the original disclosure.

Moreover, claim 1 states that the diagnosis is determined "without an associated gait motion analysis" and the claim is in my view objectionable under Official Ruling 1922 (c) 39 R.P.C. Appendix V wherein it was stated that "as a general rule, the prior publication of a description of one particular arrangement or construction of apparatus for

effecting a given purpose in a certain way would prove an effective bar to a subsequent general claim to all other arrangements or constructions for effecting that purpose in that way".

For all these reasons, I refused to allow the application to proceed to grant with the amended claims 1 to 11 before me at the reconvened hearing.

As I consider that it would be possible to draft an acceptable claim which would not be open to the fundamental objection considered above, I allowed the applicants an opportunity to propose further amendments in order to meet my findings. Any such proposals should be made by 3 October 1985, this being the last day of the unextended period allowed under Rule 34 for meeting the requirements of the Act and Rules.

Dated this 30th day of August 1985

D C L BLAKE  
Superintending Examiner, acting for the Comptroller

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