

PATENTS ACT, 1977

BLO/116/84

IN THE MATTER OF an application  
by Schering AG to amend European  
Patent (UK) No 0002535

DECISION

During the course of examination of UK application no 78/48989, the examiner became aware of European patent (UK) no 0002535, in the name of the same applicants and having the same priority date. The applicants were in consequence warned that revocation action in respect of the UK application under Section 73(2) might thereafter be necessary if the UK application were to proceed to grant.

Publication of grant of EP (UK) 0002535 appeared in the European Patent Bulletin on 30 September 1981 and notification of grant of application no 78/48989, under patent no 2010276, appeared in the Official Journal on 4 August 1982, this being the date of the grant under section 25(1). Subsequently, after the relevant date as defined in section 73(3) had passed, the proprietors of GB 2010276B were notified that revocation under section 73(2) was indeed under consideration; and they were given three months to make observations or amendment.

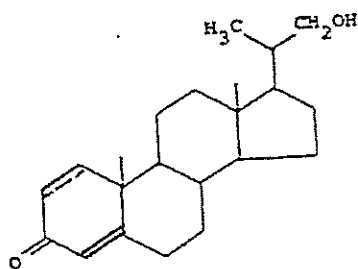
After making, and subsequently withdrawing, an offer on Form 18/77 to surrender European patent no 0002535 (UK), the proprietors, on 11 April 1983, filed a request on Form 14/77 to amend the EP (UK) specification under section 27 with a view to avoiding the section 73(2) objection, together with a revised text in English (the original text being in German). The section 73(2) proceedings were then suspended pending consideration of the allowability and pertinence of the section 27 proposals. In order to meet the requirement of Rule 113(4) a verified English translation of the original German text, showing the requested amendments in red ink was then filed, but the examiner considered that they were not allowable since they introduced matter which extended beyond that disclosed in the application for the European patent as filed, contrary to section 76(2).

No resolution of this conflict having been arrived at through correspondence,

the issue of the allowability of the red ink amendments in the English translation came before me at a Hearing on 4 July 1984 at which the proprietors of EP 0002535 (UK) were represented by Mr T A Blanco White QC; Mr P L Eggington appeared as the examiner in the case. It was common ground that the question of whether the proposed amendments, if allowed, would overcome the outstanding section 73(2) objection was not relevant to these immediate proceedings, and I shall therefore make no finding on that, but confine myself to the question whether or not the proposed red ink English language amendments are allowable under section 27(1) having regard to the requirements of section 76(2).

The invention of EP (UK) 0002535 is directed to a process for producing certain 21-hydroxy-20-methyl pregnane derivatives which are said to be useful in the synthesis of pharmacologically active steroids and which are acknowledged in the specification to have been produced in trace amounts from zoo- and phyto-sterols by fermenting them with certain microorganisms, the invention being based on the discovery that the yields from this fermentation can be significantly enhanced by carrying it out in the presence of certain boron compounds. Claim 1 of the EP (UK) specification as granted reads, *in translation*, as follows:

"Process for the manufacture of 21-hydroxy-20-methyl-pregnane derivatives of the general formula (I)



(I)

in which the bond ..... denotes a single <sup>bond</sup> or a double bond, by fermenting zoo- or phyto-sterols with a culture of Mycobacterium spec. NRRL B-3683 or NRRL B-3805 or variants and mutants thereof, characterised in that the fermentation is carried out at a pH of from 6.0 to 8.0 in the presence of borate ions or organic boron compounds."

the remaining claims being directed to preferred features.

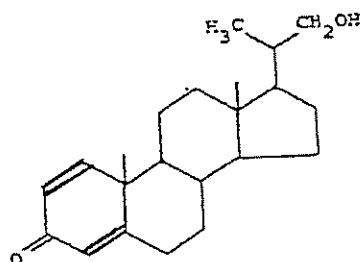
In the description the sterol starting materials are elaborated at page 1, lines 18-25 of the translation in the following terms:

"Suitable zoo- or phyto-sterols for the fermentation are, for example, cholesterol, stigmasterol, campesterol, brassicasterol or the sitosterols, the 3-acyl compounds such as, for example, the acetates of these sterols, or the 3-keto- $\Delta^4$ -steroids obtained from these sterols by Oppenauer oxidation, such as, for example, 4-cholesten-3-one, 4-stigmasten-3-one, 4-sitosten-3-one or 4-campesten-3-one."

At lines 28-31 on the same page, suitable boron compounds are exemplified by boric acid, sodium metaborate, disodium tetraborate, calcium metaborate and triphenyl borate. Moreover, claim 3 refers to orthoboric acid, metaboric acid, polyboric acid and the alkali metal and alkaline earth metal salts thereof.

*in translation,*  
In its proposed amended form, claim 1 reads:

"Process for the manufacture of a 21-hydroxy-20-methylpregnane derivative of the formula I



(I)

by fermenting  $\Delta^4$ -brassicaster-3-one with a culture of *Mycobacterium spec.* NRRL B-3683, characterised in that the fermentation is carried out at a pH of from 6.0 to 8.0 in the presence of orthoboric acid."

It can be seen that the amended claim sets forth a combination of one specific starting material, one specific microorganism, one specific boron compound and one specific product. It was accepted by both sides that each of these integers had been explicitly disclosed in the original specification, with the exception of the starting material which could

only be arrived at by inference from the description at page 1 lines 18-25, it apparently being the 3-keto- $\Delta^4$  steroid notionally obtainable by Oppenauer oxidation of brassicasterol. The substance of the examiner's objection was that neither the starting material nor the combination of features now sought to be claimed had been specifically disclosed in the European application as filed.

Mr Blanco White argued that the original specification in effect teaches that all embodiments of the invention work, that therefore the particular embodiment in question, which falls within the scope of the original claim 1, works, and consequently that it could not constitute added subject-matter. He also suggested that if the amendment had instead been submitted in the form of a disclaimer to all processes except those in which the sterol is the 3-keto- $\Delta^4$  steroid obtained from brassicasterol by Oppenauer oxidation, and the agent that produces borate ions is orthoboric acid and the mycobacterium is NRRL B-3683, then the Office might well not have objected, since although this disclaimer would have precisely the same effect as the existing proposed amendment, it is long-standing practice to allow amendment by way of disclaimer, for instance to avoid "accidental" anticipations. If I should prefer it, he would be prepared to substitute a disclaiming amendment along these lines for the amendments under consideration.

The examiner argued that the purpose of section 76 was to protect the interests of unrepresented third parties, and that if the proposed amendments were allowed, it would for example deny a later inventor the opportunity to claim the embodiment in question as a selection invention (assuming, of course, that it satisfied the accepted selection criteria); in this connection he referred me to the judgement in E I Du Pont de Nemours & Co (Witsiepe's) Application 1982 FSR 303.

It seems to me that although the proposed embodiment undoubtedly falls within the scope of original claim 1, its specific combination of features is nowhere set forth in the description as filed; indeed, if anything, the description seems to point away from it by omitting  $\Delta^4$ -brassicasteron-3-one from the list of  $\Delta^4$ -3-ketones at page 1 lines 24-5.

I am reinforced in this line of reasoning by the judgement of the Patents Court in the case of Glatt's Application 1983 RPC 122 in which Whitford J upheld the Hearing Officer's decision that a claim was not supported by the

description because it put forward something which "quite plainly ..... was never within the contemplation of the invention as described in the specification".

Although Du Pont and Glatt are rather different types of case, the common broad principle I think one can extract from them is that an applicant or patentee may not later seek to draw from <sup>an</sup> originally generalised disclosure in such a manner as to create post hoc a teaching, or a specific disclosure, or a specific combination which could not have been plainly derived from the specification at its filing date.

Applying this approach, I find that the proposed amendments do not meet the requirements of section 76(2), and therefore cannot be allowed; my conclusion in this regard does not of course depend upon the form of the amendment proposed, but on its substance, so that it follows that any proposed amendments of equivalent effect, such as that by way of disclaimer proposed as an alternative by Mr Blanco White at the Hearing would also not be allowable for the same reasons.

Dated this

17<sup>th</sup>

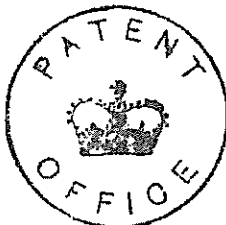
day of

July

, 1984

C S RICHENBERG

Principal Examiner, acting for the Comptroller-General



PATENT OFFICE