IN THE MATTER OF Application
No 7844527 in the name of
Upjohn Company

53.

DECISION

The examiner having raised objection under Sections 1(1)(a), 2(1), 2(2) and 2(3) that the applicants invention is not new having regard to matter disclosed in UK Specification No 1599280 (referred to as Carlo Erba), the matter came before me at a hearing on 19 May 1982, when Mr R E Perry appeared as agent for the applicants.

The applicants' invention is concerned with prostaglandin derivatives, in particular, analogues of prostacyclin. Carlo Erba refers to such compounds as derivatives of the 6α orβ H-6, 9α-epoxy-11α, 15(S or R)-dihydroxy-16-phenoxy-17,18,19,20 - tetranor-prost-trans-13-enoic acid. Upjohn identifies the same class of compounds as the less or more polar isomers of 9-deoxy-6ξ,9α-epoxy-16-phenoxy-17,18,19,20 - tetranor PGF_1 this being the 15S diastereoisomer, the 15R isomer being referred to as 15-epi. For brevity the trivial name PGI_1 is used herein to identify the basic 6,9α-epoxy-11α,15S - dihydroxy-17,18,19,20-tetranor-prost-trans-13-enoic acid, from which the compounds at issue are derived.

The applicants' specification has already been subjected to amendment and in its present amended form it is concerned only with five compounds in their less and more polar forms. The examiner's allegation of prior publication is directed against claims 1 to 4 which using the above nomenclature claim

1 The less and more polar isomers of 16-phenoxy PGI_1

2 The less and more polar isomers of 16-phenoxy $PG1_1$ methyl ester

3 The less and more polar isomers of 15-epi-16-phenoxy $PG1_1$

4 The less and more polar isomers of 15-epi-16-phenoxy $PG1_1$ methyl ester

The preparation of the compounds of claims 1 and 2 is described in Examples 1 and 2, and physical data of these products are given. Test results showing the biological activity of three of the four compounds of claims 1 and 2 are quoted, which show stimulating effects on uterine and colon muscle and antifertility

activity in animals. Examples 3 and 4 purport to describe the preparation of the compounds of claims 4 and 3 respectively, but they merely state that these compounds are made by the processes of Examples 1 and 2 (using the appropriate corresponding starting materials) and there is no information with regard to the physical or biological properties of the products.

The corresponding disclosures in the Carlo Erba specification are to be found in Example 67. This example opens with the statement that "The methyl esters of the following 15(S)-hydroxy-5 or 6,9α-epoxy-prostenoic acids together with their 15(R) - epimeric alcohols are obtained after reduction of the corresponding 15-oxo compounds using one of the procedures described in Examples 58 to 66:" There then follows a list of products numbered 67/1 to 67/54, of which No 67/22 is cited by the examiner as being identical to the less polar isomer of 16-phenoxy PGI$_1$ methyl ester of Upjohn's claim 2. This example is followed by a statement that in a similar way the corresponding 15(R)-alcohols (the 15-epi isomers) are prepared, numbered 67/55 to 67/108. This would give the less polar isomer of Upjohn's claim 4. Further similar references to the production of the αH-diasteroisomers, using the αH-starting materials, give the more polar isomers of Upjohn's claims 2 and 4 as compounds 67/130 and 67/184 of Carlo Erba, and there is then a statement that all these esters are saponified to obtain the free acids. This would give the corresponding free acid compounds of claims 1 and 3 of the Upjohn specification. The claims of Carlo Erba include a compendium claim numbered 77 to 1778, which is set out as representing 1702 separate independent claims to each of the compounds mentioned in the description. The pharmaceutical properties of the Carlo Erba compounds suggested on pages 18 to 21 are similar to those averred for the Upjohn compounds, and include contractile activity in the uterus and use for the control of fertility.

Although the Carlo Erba specification was not published until 30 September 1981, some time after the filing date of the Upjohn application, the above relevant information is to be found in the Italian Convention Document filed on 21 March 1977 which is before the earliest date to which the applicants can lay claim. Mr Perry did not deny that the Carlo Erba disclosure had an earlier priority date than the Upjohn claims, nor did he deny that the Carlo Erba compounds were the same as Upjohn were now seeking to claim in claims 1-4 of their specification. He contended however that the disclosures in Carlo Erba did not establish that the compounds in question had been made, and therefore did not meet the criteria for 'publication' which were formulated in the House of Lords judgement in E I Du Pont de Nemours and Co (Witsiepe's) Application (1981) FSR 377.

In the Du Pont case the issue was one of prior publication under the Patents Act 1949, whereas the present case falls to be decided under Section 2 of the 1977 Act. The state of the prior art according to sub-section (2) of the 1977 Act is taken to comprise "all matter ..... which .... has been made available to the public .... by written or oral description, by use or in any other way". The publication by Carlo Erba is in the field of Section 2(3) which defines the state of the art as including also matter published on or after the priority date of the invention in an application for another patent, providing that "(a) that matter was contained in the application for that other patent both as filed and as published; and (b) the priority of that matter is earlier than that of the invention". Section 3 of the 1977 Act provides that matter falling within the Section 2(3) field shall be disregarded for the purpose of assessing obviousness and therefore I must exclude all obviousness considerations in deciding the question of novelty under Section 2(3). Mr Parry suggested that the expression "made available to the public" in Section 2(2) implied that a somewhat higher standard of prior publication was intended than in the 1949 Act, but in my view the effect of this expression is no more than to emphasize that the Section is not limited to paper written or oral publication, and the standard to be applied in assessing novelty under Sections 1(1)(a) and 2(3) of the 1977 Act do not differ from those hitherto applied under the 1949 Act.

Although the disclosures in Carlo Erba lack specific chemical and/or physical data that would confirm that the compounds in question had been prepared, the statement in the preamble to Example 67 is a more positive assertion of the preparation of the named products than there was in the Du Pont case, where there was only a mention of the 1,4-butanediol starting material. As stated in the judgement of the Court of Appeal, neither the general description contained in the prior (ICI) specification nor any of the six examples given in it specifically directed attention to making a copolyester using 1.4 butanediol. This case differs in that a product in question is specifically named in Example 67/22 and the other such products are implied in the concluding paragraph of Example 67. The form of wording, ie "are prepared", used in Carlo Erba, while not positively asserting that the compounds in question were prepared, does not justify the assumption that these are merely speculative compounds that may be prepared, although the large number involved raises natural doubts as to whether all these derivatives have been made.

The House of Lords judgement in the Du Pont case, approved the approach of the New Zealand Court of Appeal in Beecham Group Ltd's Application (1982) FSR 181, in particular the passage from that judgement reading: "A making of the compound and

a discovery of its properties is necessary before the "invention" has occurred and can be published" and Lord Wilberforce pronounced that ".... in order to leave open a field for selection by a subsequent inventor, it does not matter whether the original field is described by formula or enumeration". The present applicants therefore argue that in the absence of any information as to the properties of the specified compounds of Example 67 of Carlo Erba, that document must be regarded merely as a general disclosure of a field of compounds, defined by general formula and enumeration, leaving the field open for subsequent selection invention. Mr Perry then contended that since the Carlo Erba specification had not been published by the filing date of Upjohn's application, the latter could not have been framed as a selection patent and therefore the applicants could not be required to meet the criteria for a valid selection.

If I am to accept Mr Perry's argument I must be convinced that Carlo Erba merely discloses a general field of compounds and that the references to individual compounds in Example 67 are speculative and do not effectively publish the applicants' invention. The applicants have not suggested that the methods for making these compounds described in Carlo Erba do not work, nor have they indicated any other defect in the cited specification sufficient to justify the assumption that the compounds in question have not been made. Further, if I accept the applicants' argument and allow the specification before me to go to grant, then in view of the claims to individual compounds per se in claims 77 to 1778 of Carlo Erba, this will result in two identical grants of monopoly. In my view this cannot be justified unless there is reasonable ground to suppose that the later grant will be valid while the earlier one is not.

Whereas I accept Mr Perry's contention that where the prior document was not published at the later applicants filing date the latter cannot be expected to have framed his specification in the form of a selection patent, it is also clear that whatever the nature of the earlier publication the later application must contain additional matter of practical utility if the grant of a patent is to be justified. Thus if the result of subtracting the substance of the prior document from the disclosure of the application in suit is that there is nothing of practical utility left, then the applicants' invention cannot be new.

Turning first to claims 3 and 4 of the applicants' specification, I find that these claims are supported only by Examples 3 and 4, which merely state that by following the procedures of Examples 1 and 2 the title compounds, ie the compounds of claims 3 and 4, are obtained. No physical or pharmacological data relating to these compounds are quoted and I do not find any specific disclosures

relating to these compounds which go substantially beyond the matter published in Carlo Erba. Therefore I find that the invention claimed in claims 3 and 4 is not new.

The applicants' position with regard to claims 1 and 2 appears to be rather stronger, since the preparation of the products of these claims is described in some detail and some of their physical characteristics are given. In addition the Table on page 8 gives test results for biological activity. The physical properties quoted in the examples are confirmation that the compounds in question have been isolated, but in terms of practical utility they do not add patentable subject-matter. The biological tests showing contractile activity on colonic and uterine muscles and antifertility activity do not go substantially beyond the properties averred for compounds of this type by Carlo Erba. The applicants' specification does not give any further information with regard to dosages and practical utility which goes beyond that indicated in the cited prior document. I therefore conclude that in the case of claims 1 and 2 also there is no patentable disclosure beyond that of the Carlo Erba specification and the invention claimed in these claims is not new.

At the hearing Mr Perry raised the question whether in the event of my refusing to allow claims 1 to 4 I would be prepared to allow corresponding claims to pharmaceutical compositions containing the compounds of these claims. Since pharmaceutical compositions are referred to and described at some length in Carlo Erba and there is no additional information relating to such compositions in the Upjohn specification it is clear that any such claims would be open to the same objection under Section 2(3).

In the result therefore I refuse to allow the application to proceed to grant unless it is amended to meet my findings. It should be noted that the normal period for placing the specification in order allowed under Rule 34 expires on 5 June 1982.

Dated this 1st day of June 1982

G O Byfleet

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Superintending Examiner,
acting for the Comptroller

PATENT OFFICE