BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 1 February 2007

Case Number: T 0658/04 - 3.3.01

Application Number: 97111277.6

Publication Number: 0864569

IPC: C07D 309/30

Language of the proceedings: EN

Title of invention:
Process for manufacturing simvastatin from lovastatin or mevinolinic acid

Patentee:
RANBAXY LABORATORIES, LTD.

Opponent:
Merck & Co., Inc.

Headword:
Simvastatin/RANBAXY LABORATORIES

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
"Sufficiency of disclosure (yes)"
"Remittal to the first instance (yes) - opposition ground under Article 100(a) EPC not examined yet"

Decisions cited:
G 0009/91, T 0182/89, T 0270/90

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0658/04 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 1 February 2007

Appellant: (Patent Proprietor)
RANBAXY LABORATORIES, LTD.
19, Nehru Place
New Delhi 110 019 (IN)

Representative:
Cronin, Brian Harold John
CRONIN Intellectual Property
Route de Clémemty 62
CH-1260 Nyon (CH)

Respondent: (Opponent)
Merck & Co., Inc.
126, East Lincoln Avenue P.O. Box 2000
Rahway
New Jersey 07065 (US)

Representative:
Horgan, James Michael Frederic
Merck Sharp & Dohme Limited
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 16 March 2004 revoking European patent No. 0864569 pursuant to Article 102(1) EPC.

Composition of the Board:

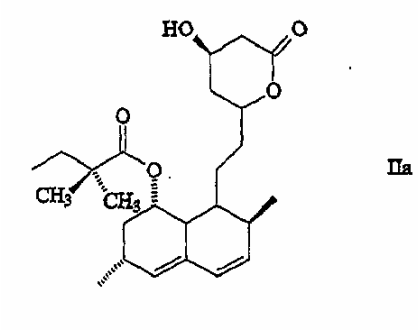
Chairman: A. Nuss
Members: P. Ranguis
D. S. Rogers

Summary of Facts and Submissions

I. This appeal lies from the decision of the Opposition Division to revoke under Article 100(b) EPC the European patent No. 0 864 569.

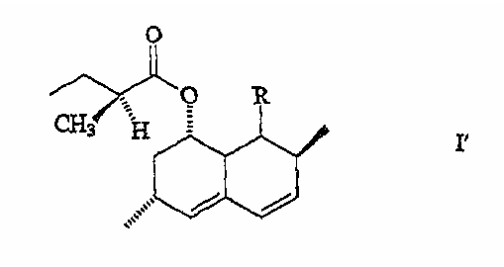
II. The patent in suit comprises nineteen claims. Claim 1, the sole independent claim, reads as follows:

"1. A process for producing a compound of structural formula IIa:



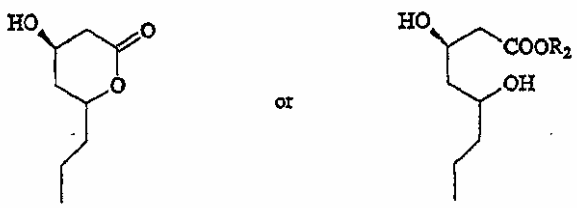
IIa

comprising:
(i) treating a compound of structural formula I':

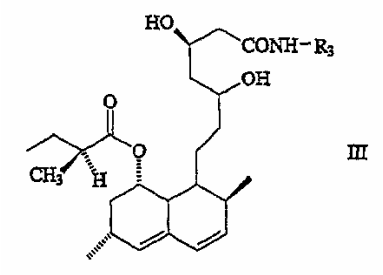


I'

wherein R is:

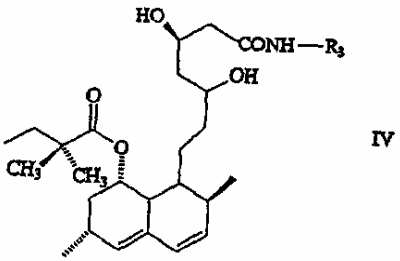


and R_2 is H, Na, K or NH_4, with an alkyl amine having the formula R_3NH_2, wherein R_3 is a C_3-C_6 n-alkyl or cycloalkyl group, to produce a compound of structural formula III:



III

(ii) treating said compound of structural formula III with a methylating agent to produce a compound of structural formula IV:



IV

wherein R_3 is as defined above:
(iii) removing the R_3NH group and closing the open pyranone ring of said compound of structural formula IV to produce said compound of structural formula IIa, wherein step (ii) and step (iii) are performed without protecting and deprotecting the two hydroxy groups of the open pyranone ring of said compounds of structural formulae III and IV."

For the sake of the understanding of particular aspects of the present decision, dependent Claims 8, 10 and 11 are set out below:

"8. The process of Claim 1 wherein said methylating agent is methyl halide."

"10. The process of Claim 8 wherein said compound of structural formula III is treated with said methyl halide in the presence of a base."

"11. The process of Claim 10 wherein said base is lithium pyrrolidide."

III. Notice of opposition had been filed by the Respondent (Opponent) requesting revocation of the patent in suit in its entirety under Articles 100(a) (lack of inventive step only), 100(b) and 100(c) EPC in view of *inter alia* the following documents:

(1) T. W. Greene and P. G. M. Wuts, "Protective Groups in Organic Synthesis", 2nd Ed, John Wiley and Sons, (1991), 1,

(2) J. March, "Advanced Organic Chemistry", 3rd Ed, John Wiley and Sons, (1985), 221-222,

(3) J. March, "Advanced Organic Chemistry", 3rd Ed, John Wiley and Sons, (1985), 228-229 and 324-325

(4) Kornblum et al, J. Am. Chem. Soc, (1963), **85**, 1148-1154,

(5) Seebach et al, Liebig's Annalen der Chemie, (1986), 1281-1308,

(6) Seebach and Wasmuth, Helv. Chim. Acta, **63**, (1980), 197-200,

(7) J.L. Hermann and R.H. Schlessinger, Tetrahedron Letters (1973), No. 26, 2429-2432,

(8) EP-A-0 299 656

(9) D. Askin et al, J.Org. Chem. **56**, (1991), 4929-4932

(10) EP-A-0 137 445

IV. At the oral proceedings before the first instance, the Opponent abandoned his objection based on Article 100(c) EPC (see point 9 of the summary of facts and submissions of the decision of the opposition Division).

Regarding the objection under Article 100(b) EPC, the Opposition held that the feature "without protecting and deprotecting the two hydroxy groups of the open pyranone ring" had to be taken in its broadest sense, namely that a protecting group is a group which renders a functional group not reactive towards a specific reaction and/or reagent and which can be removed to restore the said functional group without any modification and/or influence on the other functional groups of a molecule as taught by document (1). In view of documents (6), (5) and (10), it turned out that the addition of a lithiated base, i.e. lithium pyrrolidide, as used in the patent in suit, not only allowed the methylation to take place but also formed specific

species, i.e. "-O-Li", which thus rendered the hydroxy groups not reactive towards the methylation. This was corroborated by documents (3) and (4) which taught that the ion pair "$-O^{-+}Li$" was relatively "tight" in a solvent like THF which restrained formation of ether when an alkylating agent was present. The process described in the patent in suit involved, therefore, a step of protection and deprotection of the hydroxy groups. Hence the person skilled in the art would not have found any teaching in the description of the patent in suit which would have allowed him to reproduce the claimed process which required that neither a protecting step, nor a deprotecting step be involved therein.

Thus, the patent in suit was insufficiently disclosed and gave rise to objection in the sense of Article 100(b) EPC. The decision was silent regarding the objection under Article 100(a) EPC.

V. With the communication accompanying the summons to oral proceedings, the Board had, first, noted that the ground of opposition based on Article 100(c) EPC was withdrawn. The parties were, furthermore, informed that Article 100(b) EPC would be discussed at the oral proceedings and, since the decision under appeal was silent regarding the inventive step issue (Article 100(a) EPC), it was the normal practice of the Boards of Appeal to remit the case to the first instance for further prosecution, should the Board accept the Appellant's case under Article 100(b) EPC.

VI. Oral proceedings took place on 1 February 2007. The Board was informed by a letter received on 2 January 2006 that the Appellant would not be represented at these oral proceedings. The oral proceedings were thus held in the absence of the duly summoned Appellant in accordance with Rule 71(2) EPC. With the letter of 2 January 2007, the Appellant also filed two auxiliary requests.

VII. The Appellant submitted with the statement of grounds of appeal further evidence:

(12) Declaration of U. K. Pandit

(13) T. W. Greene and P. G. M. Wuts, "Protective Groups in Organic Synthesis", 3rd Ed, John Wiley and Sons, (1999), v-vi (Preface to the third edition), vii- viii (Preface to the second edition), xi (Contents), 17 to 23 (protection for the hydroxyl group, including 1,2- and 1,3-diols)

(14) R. K. Thaper et al, Org. Proc. Res and Dev (1999), **3**, 476-479.

VIII. The Appellant submitted the following arguments in the written proceedings:

The use of lithium pyrrolidide was a neutralization process that could not be equated with a protection-deprotection step. As explained by U. K. Pandit in his declaration (12), the lithium pyrrolidide formed a polylithium salt intermediate which consisted of a fluxional equilibrium mixture of undefined composition which did not correspond to the notion of protection as

understood by the person skilled in the art. There was, furthermore, no counter part in the patent in suit to a deprotection step.

Contrary to the view of the Opposition Division, document (1) did not contain any definition of protection-deprotection but just set some properties of protective groups. Document (13), another extract of document (1), showed in that respect that lithium salts were not listed amongst the numerous protecting groups identified therein. Protection and deprotection was, by contrast, illustrated by documents (8) and (9) which disclosed the silylation and desilylation of hydroxy groups. Moreover, the documents (3), (6), (5) and (10) were cited by the Opposition Division on the assumption that these documents disclosed analogous situations and conditions to those in the patent in suit and hence that a presumed mechanism for of a possible action of lithium pyrrolidide could be deduced. This approach was speculative. Document (10), in particular, mentioned protection-deprotection in its prior art discussion and described a process which used lithium pyrrolidide without protection and deprotection of the hydroxy groups.

It followed that lithium salt formation was not recognized as a form of protection-deprotection. The patent in suit described in its description a process wherein the steps (ii) and (iii) did not involve a protection-deprotection step. Hence, the description of the patent in suit gave sufficient information to the person skilled in the art to reproduce the claimed process.

IX. The Respondent submitted in the written proceedings and during the oral proceedings the following arguments:

The definition of protection and deprotection provided by U. K. Pandit involved (i) the protection or inactivation of all sites except the one desired to undergo chemical transformation; (ii) the execution of the desired specific transformation ; and (iii) removal of the protecting groups on the remaining sites. This definition was to be approved since it was essentially the same as the one submitted with the notice of opposition.

While it was true that dedicated protecting group reagents, such as trimethylsilyl halides or more generally those listed in document (13), could be used for the step (i), this was by no means the only way to achieve the required effect. Selective inactivation of OH groups towards alkylation might readily be achieved by manipulation of the reaction conditions. Documents (3) and (4) explained the theoretical basis for this selective inactivation and document (5), (6) and (7) showed examples of it in operation. Stated briefly, conversion of OH groups to lithium alkoxides at low temperature in a non polar solvent such as THF rendered such groups resistant to alkylation and constituted "inactivation" for the purposes of step (i). Furthermore, this conversion did not prevent reaction taking place elsewhere in the molecule, and was readily reversed to regenerate the OH groups (cf. steps (ii) and (iii)). Thus, the protocol followed in the worked examples of the patent in suit involved protection and deprotection.

Furthermore, this interpretation was in line with the description of the patent in suit which stated on page 5, [0011], lines 5-6: "Heretofore, the methods described in the prior art required the protection and deprotection of the hydroxy groups as essential steps for the preparation of simvastatin". However, in the part "Background of the invention", on page 3, [008], US patent No. 4 852 915 corresponding to the European patent application No. 137 445, i.e. document (10) was referred to. This document disclosed the C-methylation step of the natural 2-(S)-methylbutyryloxy side chain of mevilonin in the presence of lithium pyrrolidide to inactivate the hydroxy groups. It derived therefrom that that type of inactivation was also within the strategy of protection and deprotection in the sense of the patent in suit.

Since the claimed process defined a route to simvastatin that did not require any form of protection and deprotection of the relevant OH groups, and since the description of the patent provided a route to simvastatin **involving protection and deprotection** of the hydroxy groups, the patent in suit failed to teach the person skilled in the art a way to achieve the claimed process, in contravention to Article 83 EPC.

The patent in suit also gave rise to objections under Article 100(b) EPC for two further reasons already set out in the notice of opposition.

First, the patent in suit failed to teach the skilled person how to achieve the claimed process for starting material other than lovastatin. In particular, it was not credible in view of document (10), on pages 4 and 5,

that the procedure of Example 1 would succeed if the corresponding mevinolinic acid sodium or potassium salt were to be used in place of the ammonium salt.

Secondly, the claimed process failed to teach the skilled person how to achieve the claimed process with reagents other than those defined in Claims 10 and 11, namely the use of a methyl halide as methylating agent and lithium pyrrolidide as base.

X. The Appellant requested in writing that the decision under appeal be set aside and the case be remitted to the first instance for further prosecution on the basis of the main request (patent as granted) or on the basis of the first or second auxiliary request filed with the letter of 2 January 2007.

The Respondent requested that the appeal be dismissed.

XI. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

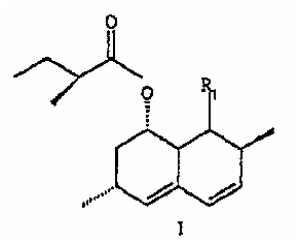
1. The appeal is admissible.

Main request

2. *Article 100(b) EPC*

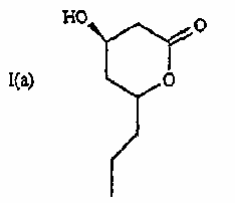
2.1 The patent in suit describes a multiple step process to prepare **simvastatin** of formula IIa (see point II above).

2.1.1 The first step consists in the amidification, with an n-alkylamine or a cycloalkylamine of formula R_3-NH_2, in particular n-butylamine or cyclopropylamine, of a compound of formula (I)



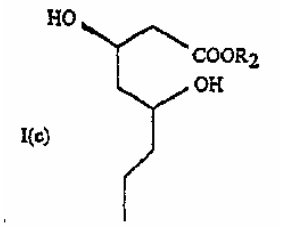
I

which is **lovastatin** of formula (Ia) when R_1 is a radical of formula



I(a)

and which is the **mevinolinic acid salt** of formula (Ic) when R_1 is the radical of formula

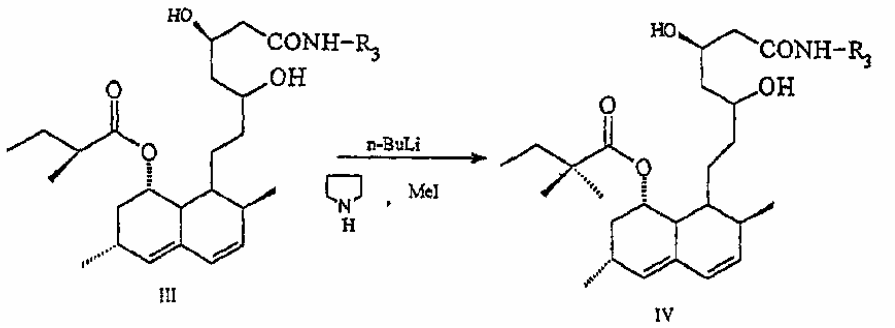


I(c)

wherein R_2 is Na, K, NH_4 (see reaction scheme, page 4 and [0015], page 5). The intermediate of formula (III) (see point II above) is obtained.

2.1.2 The second step consists essentially in the C-methylation of the intermediate of formula (III) in tetrahydrofuran (THF) by the addition of a solution in

THF of n-BuLi and pyrrolidine, which form *in situ* lithium pyrrolidide, then addition of methyl halide, preferably methyl iodide to yield the intermediate of formula IV according to the following reaction scheme



(see scheme, page 4 and [0016], page 5)

2.1.3 The third step consists in the lactonisation of the intermediate (IV) to obtain **simvastatin** (see scheme, page 4 and paragraphs [0017] and [0018], page 5).

2.1.4 Example I discloses the preparation of **simvastatin** from **mevinolic acid ammonium salt** using cyclopropylamine. Example II discloses the preparation of **simvastatin** from **lovastatin** using cyclopropylamine and examples III and IV disclose the preparation of **simvastatin** from **lovastatin** and **mevinolinic acid ammonium salt** using n-butylamine (see paragraphs [0021] to [0030], pages 4 and 5).

2.2 In the present case, the objection under Article 100(b) raises three different issues which are to be dealt with separately.

2.3 The first issue is whether the patent in suit as a whole discloses sufficiently and completely the technical conditions by which the person skilled in the

art, to whom the relevant common general knowledge is imputed, can reliably and effectively perform the claimed process "wherein step (ii) and step (iii) are performed without protecting and deprotecting the two hydroxy groups of the open pyranone ring of said compounds of structural formulae III and IV" as required by Claim 1 (see point II above).

2.4 The Appellant argued that the process described in the patent specification, in particular the examples, did **not** involve the steps of protection and deprotection of hydroxy groups and, therefore, enabled the person skilled in the art to achieve the claimed process. The Respondent argued, by contrast, that the process described in the patent specification **involved** the steps of protection and deprotection of hydroxy groups, which rendered the claimed process non enabling for the skilled person since he could not find in this patent the relevant information to achieve the claimed process.

2.5 According to the Jurisprudence of the Boards of Appeal, each of the parties to the proceedings carries the burden of proof for the facts it alleges (see e.g. decision T 270/90, OJ EPO 1993, 725, point 2.1). In order to establish insufficiency, the burden of proof is upon the Opponent (now Respondent) to establish that a skilled reader would not be able to carry out the invention (see e.g. T 182/89, OJ EPO 1991, point 2, third paragraph).

2.6 Since the patent specification does not explicitly say whether or not a step of protection and a step of deprotection of the hydroxy groups occur, and since none of the parties have submitted experimental results

to support their views, the Board can only rely on the common general knowledge of the person skilled in the art to decide whether or not the process as disclosed in the patent in suit as a whole implies a step of protection and deprotection of the hydroxy groups.

2.7 According to the jurisprudence of the Boards of Appeal, textbooks and general technical literature form part of the common general knowledge. Patent specifications and scientific publications cannot form part of common general knowledge except for some particular cases not relevant in the present situation (see Case Law of the Boards of Appeal 4th Ed. 2001, II.A.2.(a), page 145).

2.7.1 Therefore, the Board holds that documents (1), (2), (3) and (13) which are extracts of textbooks can be considered as forming part of the common general knowledge. The content of document (4), although being a scientific publication, can nevertheless be regarded as forming part of the common general knowledge given that document (3) refers explicitly to document (4) on page 325 (see reference No. 364) which is evidence not merely that the information contained in document (4) belongs to the state of the art but that it represents common general knowledge.

2.7.2 By contrast, documents (5), (6), (7), (9), and (14) which are scientific publications and documents (8) and (10) which are patent applications do not form part of the common general knowledge and, therefore, are not relevant to the assessment of the sufficiency of disclosure of the patent in suit.

2.7.3 The declaration of U.K Pandit submitted by the Appellant as expert opinion, i.e. document (12), contains general considerations that the Board cannot consider as representing common general knowledge in the absence of supporting evidence. Furthermore, the fact that this expert concludes that the detailed role of lithium pyrrolidide in the transformation of [I] to [III] (see scheme on page 4 of the declaration) is mechanistically complex and undefined (see last page, last sentence of the declaration) tends to reduce the relevance of the whole declaration for defining the common general knowledge of the skilled person at the filing date.

In the Board's judgment, an expert's declaration which is not supported by verifiable facts but which merely constructs some hypotheses, cannot reflect the common general knowledge to be considered for assessing the sufficiency of disclosure in the sense of Articles 100(b) and 83 EPC. For this reason, document (12) does not form part of the common general knowledge.

2.8 In view of documents (1) and (13), the skilled person is aware that:

"When a chemical reaction is to be carried out selectively at one reactive site in a multifunctional compound, other reactive sites must be temporarily blocked. Many protective groups have been, and are being, developed for this purpose. A protective group must fulfil a number of requirements. It must react selectively in good yield to give a protected substrate that is stable to the projected reactions. The protective group must be selectively removed in good

yield by readily available, preferably non-toxic reagents that do not attack the regenerated functional group." (see page 1 of document (1), first seven lines).

Amongst the numerous groups identified in the list of the protecting groups for the hydroxy group, lithium salts are not mentioned (see pages 17 to 23 of document (13)). Document (13) is later than the priority date, it dates from 1999. Therefore, if lithium salts were not known as protective groups in 1999, they were also not known in 1991 since the Preface of the third edition, page v, states that said edition adds 348 new protective groups to the second edition (1991).

It can only be concluded that in the common general knowledge of the person skilled in the art in organic synthesis, the notion of protecting and deprotecting had a clear meaning and that lithium pyrrolidide is not a protecting group in the sense of documents (1) and (13).

2.9 The Respondent argued, in particular, that the reaction disclosed in documents (1) and (13) was only a particular way for achieving protection and deprotection. Protection and deprotection was to be viewed as a strategy which could be implemented by other ways such as manipulating solvent, temperature, polarity and so on as, for instance, taught by documents (3) and (4).

2.9.1 Document (3) examines the way a nucleophile attacks an atom. It is, in particular, pointed out that the solvent influences the position of the attack. In that context, this document cites the attack by sodium β-

naphtoxide on benzyl bromide by reference to document (4). In view of document (4), depending on the solvent used, O-alkylation **or** C-alkylation occurs (see page 1148, right-hand column). However, neither in document (3) nor in document (4) is such an orientation in the reaction described as a reaction of protection and deprotection. Therefore, the Respondent's submission that protection and deprotection had to be seen as a strategy going beyond the definition given in documents (1) and (13) is not substantiated.

2.9.2 Furthermore, accepting the Respondent's submission would be at variance with the teaching of documents (1) and (13) which require a subsequent removal step that is not present in the reactions described in documents (3) and (4). That would render the notion of protection and deprotection indefinite and meaningless. Document (2) merely relating to a list of pK_a values for many types of acids, in particular RCH_2OH, is irrelevant for rebutting that finding.

2.10 The Appellant also pointed out that the description of the patent in suit confirmed that the protection and deprotection of hydroxy groups occurred when lithium pyrrolidide was used in a process involving the C-methylation step of 2-(S)-methylbutyryloxy side chain of mevilonin to yield simvastatin. Reference was made in that respect to document US-A-4 582 915, namely the American counter-part of the European application No. 137 445, i.e document (10), (see "background of the invention", paragraph [0008], page 3) in conjunction with the subsequent phrase "Heretofore, the methods described in the prior art required the protection and deprotection of the hydroxy groups as essential steps

for the preparation of simvastatin" (see "Summary of the invention", paragraph [0011], (b), page 5).

However, neither the above referred to passage of the patent in suit concerning US patent 4 582 915, nor the content of document (10) mention such protection and deprotection steps. Furthermore, the phrase "Heretofore…." is drawn from another context and does not refer explicitly to this document but only refers to "the prior art".

The Board cannot, therefore, consider the combination of those separate statements as an evidence that protection and deprotection of hydroxy groups occur in the process disclosed in US patent 4 582 915.

2.11 In conclusion

(a) The sole meaning that the skilled person can give to the reaction of protection or deprotection of hydroxy groups is that set out in documents (1) and (13), namely the reaction of a particular reagent, **not including lithium pyrrolidide**, and subsequently removal of that protecting group (see point 2.8 above). No other interpretation is realistic. It derives therefrom that the second and third steps of the process disclosed in the patent in suit (see points 2.1.2 and 2.1.3) along with the examples (see point 2.1.4) which are carried out in the presence of lithium pyrrolidide **do not** involve the steps of protection and deprotection of the hydroxy groups.

(b) The subject-matter of Claim 1 defines a process for producing simvastatin "wherein step (ii) and step (iii)

are performed without protecting and deprotecting the two hydroxy groups of the open pyranone ring of said compounds of structural formulae III and IV " (see point II above).

(c) The patent in suit thus provides the person skilled in the art with the relevant information to achieve a process for preparing simvastatin as defined in Claim 1 in a way whereby step (ii) and step (iii) are performed without protecting and deprotecting the two hydroxy groups of the open pyranone ring of said compounds of structural formulae III and IV.

(d) The Respondent's first line of argument is, therefore, not properly substantiated and is to be rejected.

2.12 As a second line of attack under Article 100(b) EPC, the Respondent argued that it was not credible in view of the teaching of document (10), on pages 4 and 5, that the procedure of Example 1 of the patent in suit would also succeed if the corresponding sodium or potassium salt were to be used in place of the ammonium salt. Furthermore the patent in suit failed to teach the skilled person how to achieve the claimed process with a starting material other than lovastatin.

2.12.1 Although the Board found that document (10) did not form part of the common general knowledge (it is a patent, see point 2.7.2 above), a party may present any facts or evidence he finds appropriate to bring the proof of what he alleges. Document (10) is, in that context, taken as a piece of evidence.

2.12.2 The first question is, therefore, whether document (10) renders credible the Respondent's assertion that the procedure of Example 1 of the patent in suit would not succeed if the corresponding sodium or potassium salt were to be used in place of the ammonium salt.

2.12.3 This document relates, in particular, to a process of C-methylation of lovastatin to form simvastatin. This process involves, as a first step, the conversion of the lactone to its alkali metal salt, followed by C-methylation in the presence of, e.g. lithium pyrrolidide. This process however does not reflect the experimental conditions of Example 1 of the patent in suit which requires the amidification of the salt prior to the C-methylation. Such a document cannot, therefore, be considered as an evidence liable to reverse the burden of proof which still remains upon the Respondent and which he has not discharged (see point 2.5 above).

2.12.4 Furthermore, the more general argument concerning the alleged lack of sufficiency of disclosure regarding the processes involving starting material other than lovastatin is at variance with the fact that Example I discloses the preparation of **simvastatin** from **mevinolic acid ammonium salt** (see point 2.1.4 above). This line of attack remains unsubstantiated in the absence of evidence to the contrary.

2.13 As a third argument with respect to the objection under Article 100(b) EPC, the Respondent submitted that the patent in suit failed to teach the person skilled in the art processes for preparing simvastatin for conditions other than those recited in Claims 8, 10 and 11 (see point II above). However in the absence of

evidence in support of his contention, this argument is unsubstantiated and is also to be rejected.

2.14 Since none of the three attacks raised by the Respondent against the sufficiency of disclosure of the patent in suit can succeed, the objection under Article 100(b) EPC is to be rejected.

3. *Remittal to the first instance*

3.1 The Board has come to the conclusion that the patent in suit did not give rise to objection under Article 100(b) EPC, overcoming, therefore, the sole reason for revoking the European patent as granted. Having so decided, the Board has not taken a decision on the complete case.

3.2 Indeed, with its opposition the Respondent also sought revocation of the patent in suit on the ground that its subject-matter did not involve an inventive step (see point III above). The decision of the Opposition Division is silent regarding this issue.

3.3 Given that the purpose of the appeal proceedings *inter partes* is primarily to give the losing party the possibility of challenging the decision of the Opposition Division (see G 9/91, OJ EPO 1993, 408, point 18), the Board finds appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the first instance in order not to deprive the parties of the possibility of being heard by two instances with regard to the other issue raised in the opposition proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of the main request.

The Registrar: The Chairman:

N. Maslin A. Nuss