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D E C I S I O N
of 9 May 2003

Case Number: T 0043/00 - 3.3.2

Application Number: 92103963.2

Publication Number: 0503521

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:
Low dose dry pharmaceutical preparations

Patentee:
Akzo Nobel N.V.

Opponents:
Jenapharm GmbH & Co. KG
Meggle GmbH
Schering AG

Headword:
"Pharmaceutical preparations/AKZO

Relevant legal provisions:
EPC Art. 52, 54, 84, 111(1), 123(2)(3)
EPC R. 57a, 71(2)

Keyword:
"Main request: novelty (no) - prior use adequately substantiated by evidence: prejudicial to the novelty of claim 5 as granted"
"First and second auxiliary requests: admissible and allowable"
"Remittal to the first instance for further prosecution: prior use represents highly relevant state of the art not considered by the first instance - case different from that on which the first instance's decision was based"

Decisions cited:
T 0472/92, T 0558/95

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0043/00 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 9 May 2003

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 20 December 1999 rejecting the oppositions filed against European patent No. 0 503 521 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: G. F. E. Rampold
S. U. Hoffmann

Summary of Facts and Submissions

I. The respondent is proprietor of European patent No. 0 503 521 ("the Patent") which was granted with 10 claims on the basis of European patent application No. 92 103 963.2. The claims as granted read as follows:

"1. A process of making pharmaceutical dosage units containing at least one micronized steroidal medicinal agent present in an amount varying from 0.005 to 0.5 percent by weight of each pharmaceutical dosage unit comprising: dry mixing 1 to 100 parts, by weight, of said steroidal medicinal agent with 2000 to 20,000 parts, by weight, of an excipient capable of binding said steroidal medicinal agent to an extent greater than 80% and a demixing potential of less than 10% for said steroidal medicinal agent, selected from the group consisting of a spray-dried polyalcohol, granulated alpha-lactose monohydrate, or mixtures thereof.

2. The process according to claim 1 further comprising: adding further excipients, in an amount of up to nine times the weight of the medicinal agent/lactose mixture to form an admixture containing 0.005 to 0.5 % medicinal agent by weight.

3. The process of claim 1 further comprising: compressing the admixture into tablets containing less than 0.5 percent medicinal agent by weight.

4. The process of claim 2 further comprising: compressing the admixture into tablets containing less than 0.5 percent medicinal agent by weight.

5. A dry mix consisting essentially of 1 to 100 parts, by weight, of at least one steroidal medicinal agent uniformly distributed throughout 2000 to 20,000 parts, by weight, of an excipient capable of binding said steroidal medicinal agent to an extent greater than 80% and a demixing potential of less than 10% for said steroidal medicinal agent, selected from the group consisting of a spray-dried polyalcohol, granulated alpha-lactose monohydrate, or mixtures thereof.

6. A process of making a pharmaceutical dosage unit comprising: forming the dry mix of claim 5 into a dosage unit selected from the group consisting of tablets, capsules, powders, and slugged granulates.

7. The process of claim 1 wherein said medicinal agent is selected from the group consisting of desogestrel, 3-ketodesogestrel, ethinylestradiol, gestodene, and mixtures thereof.

8. The process of claim 6 wherein said medicinal agent is selected from the group consisting of desogestrel, 3-ketodesogestrel, ethinylestradiol, gestodene, and mixtures thereof.

9. A process of manufacturing tablets characterized in that the resulting tablets have an amount of steroidal medicinal agent which is within 4 percent relative standard deviation of all the tablets produced by that process comprising: dry mixing 1 to 100 parts, by weight, of said steroidal medicinal agent with 2000 to 20,000 parts, by weight, of an excipient capable of binding said steroidal medicinal agent to an extent greater than 80% and a demixing potential

of less than 10% for said steroidal medicinal agent, selected from the group consisting of a spray-dried polyalcohol, granulated alpha-lactose monohydrate, or mixtures thereof, adding further excipients, in an amount of up to nine times the weight of the medicinal agent/ lactose mixture to form an admixture containing 0.005 to 0.5 % medicinal agent by weight, and compressing the admixture into tablets containing less than 0.5 percent medicinal agent by weight.

II. Oppositions to the patent were filed by three parties - opponent 01 (party to the appeal proceedings as of right under Article 107, second sentence, EPC) which sought revocation on the grounds of lack of novelty and inventive step (Articles 54, 56 and 100(a) EPC); opponent 02 (party to the appeal proceedings as of right under Article 107, second sentence, EPC) which sought revocation on the grounds of lack of inventive step (Articles 56 and 100(a) EPC); and opponent 03 (appellant) which sought revocation on the grounds of lack of novelty and inventive step (Articles 54, 56 and 100(a) EPC) and also on the ground of insufficient disclosure (Articles 83 and 100(b) EPC). The latter ground of opposition was, however, neither substantiated in the notice of opposition filed by opponent 03 nor introduced into the proceedings by the opposition division.

III. Of the numerous documents cited during the first-instance opposition and subsequent appeal proceedings, the following are relevant to the present decision:

(5) "Pharmatose Leading in Lactose", edited by HANS HILDEBRAND Handelsgesellschaft mbH, Hamburg;

(8) "Rote Liste 1991; Verzeichnis von Fertigarzneimitteln der Mitglieder des Bundesverbandes der Pharmazeutischen Industrie e. V.", Editio Cantor, Aulendorf/Württemberg, 1991;

(9) "Schering AG Präparateverzeichnis" page 130 of a computer print-out dated 14 February 1995;

(34) HNO, Springer Verlag Berlin Heidelberg New York London Paris Hong Kong Barcelona, 38. Band, Heft 10, October 1990, pages A 26, A 27;

(38) Invoices to wholesale distributors for LENEN®, all dated 15 October 1990;

(39) DPM, Der Pharmazeutische Markt Deutschland, The Pharmaceutical Market - Germany, Statistik über den Apothekenumsatz pharmazeutischer Spezialitäten, IMS HEALTH, Dezember 1990, page 96; Dezember 1991, pages 119-120;

(40) VIP, Verschreibungs-Index Pharmazeutika. 1990, page 3254;

(41) Leaflet accompanying the marketed medicament LENEN®, no publication date indicated;

(42) photographs dated 6 April 2000 of microscopic examinations of LENEN®;

(43) colour photographs dated 6 April 2000 of microscopic examinations of LENEN®;

(44) Statutory Declaration ("eidesstattliche Versicherung") by Jürgen Hilmann;

(45) Statutory Declaration ("eidesstattliche Versicherung") by Dr Helmar Dobinsky.

IV. In its decision posted on 20 December 1999, the opposition division rejected the oppositions pursuant to Article 102(2) EPC. The essence of the reasoning given in the opposition division's decision was as follows:

Having regard to the statutory declarations ("eidesstattliche Erklärungen") by Mr Ipsen and Dr Bolhuis, both filed during the proceedings before the opposition division with the letter of opponent 03 (appellant) dated 23 July 1998, the opposition division accepted that citation (5), which bears no date of publication, had to be considered as comprised in the state of the art under Article 54(2) EPC. It was further noted in the opposition division's decision that the proprietor of the patent (respondent) did not challenge this finding.

Although (5) disclosed in Table 12 on page 60 tablets comprising 2.5% by weight micronized prednisone, i.e. a steroidal medicinal agent, and 72% by weight α-lactose monohydrate-100 mesh, the opposition division found that the designation "α-lactose monohydrate-100 mesh" used in (5) related undoubtedly to an excipient which was a *crystalline* lactose product, whereas claim 5 of the patent stipulated the use of *spray-dried or granulated* α-lactose monohydrate (see I above) as the excipient. It concluded that this was a distinguishing feature which conferred novelty on the subject-matter of claim 5 over the prior art of citation (5).

As regards the attack against claim 5 on the ground of lack of novelty on the basis of an alleged prior use by the public availability of a medicament brought onto the market by the appellant (opponent 03) company under the trade name LENEN®, the opposition division considered the combined evidence of documents (8), (9) and (34) sufficient to establish that a medicament

LENEN® in powder form containing fluocortinbutyl as the active ingredient was introduced on the market prior to the priority date of the patent without any explicit or implicit secrecy proviso and was thus made available to the public by use within the meaning of Article 54(2) EPC. However, in the opposition division's judgment, the documents on file had insufficient weight as evidence to support a finding that the medicament LENEN® in the form as it was in the public domain before the priority date had a composition in accordance with claim 5 of the patent in suit.

Concerning inventive step, the opposition division found that none of the citations available in the proceedings before it suggested to a person skilled in the art that the use of spray-dried lactose or granulated α-lactose monohydrate as the excipient in accordance with the claimed invention would be responsible for the advantageous properties of low dose dry pharmaceutical preparations comprising a steroidal medicinal agent in combination with one of the above-mentioned excipients or a mixture thereof. In the view of the opposition division, these unexpectedly advantageous properties, such as the superior stability of the preparations and the improved homogeneous and more uniform distribution of the active ingredient in the dry compositions, were appropriately demonstrated in experiments c) and d) in the Table on page 8 and in Figure 6 and of the patent specification in comparison with preparations containing β-lactose or crystalline α-lactose monohydrate as the excipient (see experiments j) and l) in the Table on page 8 and Figure 6 of the patent specification). Inventive step was, thus, acknowledged.

As regards the process of making pharmaceutical dosage units according to claim 1 (see I above) and the process of manufacturing tablets according to claim 9

(see I above), it was briefly mentioned in paragraph 4.7 of the opposition division's decision that the dose of the medicinal steroidal agent present in the pharmaceutical dosage units or tablets manufactured in accordance with the processes of claims 1 and 9 was reduced to the very low amount varying from 0.005 to 0.5 percent. The opposition division concluded that processes for the manufacture of such low dose pharmaceutical preparations with a homogeneous and uniform distribution of said steroidal medicinal agent in these preparations were not obviously derivable from the cited state of the art and, accordingly, fulfilled the requirements of inventive step.

V. Opponent 03 (appellant) filed a notice of appeal on 11 November 1999 and paid the appeal fee on the same date and filed a statement of grounds of appeal on 18 April 2000 enclosing documents (38) to (45). The respondent filed arguments supporting its requests for the appeal to be dismissed with its reply of 23 August 2000 to the appeal statement.

VI. In a facsimile letter dated 22 April 2003, the respondent's representative indicated certain difficulties in coping with the representation of the respondent at the oral proceedings, fixed for 9 May 2003, due to the maternity leave of two patent attorneys in the respondent's patent department, and requested an adjournment of the oral proceedings. In reply, by facsimile letter of 23 April 2003, the board referred to the notice of the Vice-Presidents, Directorates-General 2 and 3 dated 1 September 2000 (OJ EPO 10/2000), and informed the respondent that the grounds indicated in its letter of 22 April 2003 were considered insufficient to justify the fixing of a new date for the oral proceedings and that the board would accordingly not accede to the respondent's request for adjournment.

VII. By its letter dated 29 April 2003 the appellant informed the board that it would not attend the hearing and requested that a decision be taken on the basis of the documents in the file. Oral proceedings were held on 9 May 2003 in the absence of the appellant, as provided for in Rule 71(2) EPC. During the oral proceedings, the respondent filed two auxiliary requests.

The **first auxiliary request** consists of claims 1 to 9 as granted (see I above), with the following additions at the end of claim 5 indicated in bold italic letters below:

5. "A dry mix consisting essentially of 1 to 100 parts, by weight, of at least one steroidal medicinal agent uniformly distributed throughout 2000 to 20,000 parts, by weight, of an excipient capable of binding said steroidal medicinal agent to an extent greater than 80% and a demixing potential of less than 10% for said steroidal medicinal agent, selected from the group consisting of a spray-dried polyalcohol, granulated alpha-lactose monohydrate, or mixtures thereof, ***wherein the dry mix contains from 0.005 to 0.5 percent steroid by weight.***"

The **second auxiliary request** consists of claims 1 to 4, 7 (renumbered claim 5) and 9 (renumbered claim 6) as granted (see I above). Product claim 5 as granted, and process claims 6 and 8 as granted have been deleted from the set of claims forming the second auxiliary request.

VIII. The appellant's arguments, submitted in its statement of the grounds of appeal as regards the issues which are relevant to the present decision, can be summarised as follows:

Since the appellant's claims of public prior use had already been sufficiently substantiated in the proceedings before the first instance, the opposition division had wrongly concluded in the decision under appeal that the subject-matter of claim 5 as granted met the requirement of novelty.

The combined evidence of documents (8), (9) and (34) was, in the appellant's opinion, appropriate and sufficient to prove beyond all reasonable doubt that the medicament LENEN® (hereinafter in this decision abbreviated LENEN®) in the form as it was introduced on the market by the appellant company prior to the priority date of the patent fulfilled all technical features of claim 5. In particular, document (8) made it unambiguously clear that LENEN® was in the public domain prior to the priority date and the disclosure of the composition of LENEN® before the priority date in document (9) left no doubt that the known medicament LENEN® referred to in (8) had a composition in accordance with claim 5. Moreover, the skilled person would have been able to ascertain the composition of LENEN® by means of simple, known analytical techniques.

The common designation LENEN® for both the marketed medicament referred to in (8) and the product disclosed in (9) was proof of the identity as far as the composition of these two products was concerned and, accordingly, of the composition of LENEN® before the date of priority. The fact that the composition of LENEN® disclosed in (9) was also identical with that of LENEN® currently offered for sale provided further proof that the composition of LENEN® remained unchanged

since its introduction on the market before the priority date. Contrary to the opinion of the opposition division in the impugned decision, the regulations of the German Medical Preparations Act (AMG) made it almost impossible to modify the composition of a registered medicament without indicating this modification by a simultaneous change of the medicament's name or designation.

Documents (38) to (45) filed together with the statement of the grounds of appeal were cited as additional evidence to further substantiate the appellant's claims of public prior use. Documents (38) to (41) provided further evidence of the public availability of LENEN® before the priority date. Comparison of photographs (42) and (43) of the appellant's microscopic examinations of LENEN® with the photographs on pages 18 and 31 of (5) provided appropriate evidence that the excipient in LENEN® was spray-dried Lactose DC 11. The statutory declarations (44) and (45) were the ultimate proof that the composition of LENEN® had remained unchanged since its introduction on the market.

IX. As regards the issues which are relevant to the present decision, the respondent argued, in writing and at the oral proceedings, essentially as follows:

The opposition division was in the impugned decision entirely correct in its opinion that the appellant's allegation of public prior use was without foundation and that, consequently, the novelty requirement was satisfied as regards the subject-matter of all claims, including claim 5, as granted.

Even if one accepted the appellant's submission that LENEN® was made available to the public prior to the priority date of the patent, the combination of

documents (8) and (9) would have insufficient weight as evidence to support the appellant's mere allegation that the medicament LENEN® in the form it was in the public domain before the priority date had a composition in accordance with claim 5 of the patent in suit. In the context of the composition of LENEN®, document (9) referred to three different dates, including one after the priority date. Consequently, besides the uncertainty as regards the precise composition of LENEN® in the form as placed on the market by the appellant company before the priority date, the common designation LENEN® for both the product disclosed in (8) and the product referred to in (9) was, contrary to the appellant's assertions, not proof of identity as far as their composition was concerned, nor therefore of the continuity of the chain of evidence furnished by the appellant.

Documents (38) to (40) which were filed together with the statement of the grounds of appeal merely confirmed that LENEN® had been introduced on the market prior to the priority date but did not add anything new to the evidence already on file in the proceedings before the first instance. Documents (41) and (42) were photographs of microscopic examinations of LENEN®, "Lactose DC 11" and "Lactose DIN 30", all dated 6 April 2000, and as such without any probative value as to the composition of LENEN® before the priority date.

The statutory declarations ("eidesstattliche Versicherungen") (44) and (45) were apparently filed on behalf of the appellant with the intention of giving the reader the impression that the composition of LENEN® had not been changed since its introduction on the market. However, these conclusions could simply not be drawn from the statements in these declarations. In both declarations it was only said that the method of preparing LENEN® ["Herstellverfahren"- see (44) or

"Herstellungsweg" - see(45)] had not been changed. A clear statement that the composition of LENEN® had not been changed was thus missing.

X. The appellant requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained either as granted or in amended form on the basis of the first or second auxiliary request, both filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request; public prior use; novelty

2. In its statement setting out the grounds of appeal the appellant maintained its objection of lack of novelty of the subject-matter of claim 5 (see I above) on account of public prior use. Together with the appeal statement the appellant produced further evidence in support of its submissions

(i) that a medicament which was brought onto the market by the appellant company under the trade name LENEN® was made available to the public by use prior to the claimed priority date of the patent and thus forms part of the state of the art under Article 54(2) EPC and

(ii) that LENEN® in the form made available to the public prior to the priority date of the patent had a composition in accordance with claim 5 as granted and is thus prejudicial to the novelty of claim 5.

2.1 The first question to be decided is therefore whether or not the appellant's claims of alleged public prior use prejudice the maintenance of the opposed patent. According to the case law of the boards of appeal (see Case Law of the Boards of Appeal, 4th edition 2001, VII.C.8.6, pages 473-474), if an opponent wishes to rely upon prior use as being part of the state of the art for the purpose of Article 54(2) EPC and as part of the legal and factual framework within which substantive examination of the opposition is to be conducted, the following circumstances have to be clarified:

(a) when the act of prior use occurred

(b) what was made available to the public through that use

(c) the circumstances of the act of use, ie where, how and by whom the subject-matter was made public through that use.

2.2 In the present case, there is no longer any dispute concerning the fact that the evidence, which was presented in the proceedings before the opposition division and completed by the submission of further documents in the subsequent opposition appeal proceedings, is appropriate and sufficient to clarify and prove the following facts and circumstances:

- LENEN® containing fluocortinbutyl as the active steroidal medicinal agent was introduced on the market in Germany by the appellant company without any explicit or implicit secrecy proviso prior to the priority date (12 March 1991);

- LENEN® was offered for sale and actually sold in drug stores ("Apotheken") in the Federal Republic of Germany prior to the priority date of the patent;

- LENEN® was thus made available to the public by use before the priority date of the patent and is accordingly comprised in the state of the art under Article 54(2) EPC.

2.3 These circumstances and facts are already clear from document (8) alone, i.e **"Rote Liste 1991;** Verzeichnis von Fertigarzneimitteln der Mitglieder des Bundesverbandes der Pharmazeutischen Industrie e. V."; the document "Rote Liste 1991" (8) includes pharmaceutical preparations ("Fertigarzneimittel") made available to the public in the Federal Republic of Germany before the end of October 1990 - see especially "Vorwort", page 5, last sentence of the text and entry 71 032 **LENEN®.**

The above-mentioned facts and circumstances have further been confirmed and clarified in the proceedings before the opposition division by document (34) and at the appeal stage by the submission of the additional documents (38) (i.e. six invoices to wholesale distributors for LENEN®, all dated 15 October 1990); (39) (i.e. Statistics relating to sales of pharmaceutical specialities, including LENEN®, in drug stores ("Apotheken"), 1990, 1991 - "Statistik über den Apothekenumsatz pharmazeutischer Spezialitäten"); and

(40) (ie Prescription index of pharmaceutical preparations, including LENEN®, 1990, 1991 - "VIP, Verschreibungsindex Pharmazeutika").

2.4 The board, in agreement with the finding of the opposition division in the impugned decision, is thus satisfied that circumstances (a) and (c) set forth in point 2.1 above have been clarified to a degree of certainty which is beyond all reasonable doubt. Since this was not contested by the respondent, it is not necessary to go into further detail on this point.

2.5 It is not disputed either that LENEN® in the form in which it was offered for sale and sold in drugstores ("Apotheken") at the time the notice of opposition was filed (19 April 1996) by the appellant (opponent 03) and in which it is currently on the market and offered for sale has the composition fluocortinbutyl 2.5 percent by weight and spray-dried Lactose DC 11 97.5 percent by weight.

2.6 There is dispute, however, as to whether or not the evidence available in the proceedings is sufficient to prove the appellant's assertions that the composition of the medicament LENEN®, as already listed in document (8), **"Rote Liste 1991"**, has not been changed since its introduction on the market in Germany prior to the priority date or, differently expressed, that the composition of LENEN® in the form in which it was made available to the public prior the priority date of the patent was identical with the composition of LENEN® currently offered for sale. This means that the controversial point here is whether also circumstances (b) set forth in point 2.1 above ("what was made available to the public through that use") have been proven and clarified to a degree of certainty which is beyond all reasonable doubt.

2.7 In order to prove and clarify the composition of LENEN® prior to the priority date, the appellant submitted document (9) as evidence. This document (9) gives, in the board's judgment, an appropriate indication of the composition of LENEN®, before and shortly after the priority date of the patent. Document (9) is page 130 of a computer print-out headed "Schering AG Präparateverzeichnis" and dated 14 February 1995, ie about four years after the priority date of the patent (12 March 1991). The following facts and circumstances can reasonably be derived from the disclosure of document (9):

- LENEN® [see (9), right-hand vertical column: "Warenzeichen im Land DEUTSCHLAND LENEN"] was produced and tested by the appellant company [see (9), first vertical column: "Schering AG, Präparateverzeichnis"] in Germany [see (9), right-hand vertical column: "Herst.-Land DEUTSCHLAND"];

- LENEN® had at all three dates indicated in (9) [see (9), third horizontal column: **"15.09.1983", "06.09.1991" and "26.07.90"**] the same composition [see (9), left-hand vertical column: **"Zusammensetzung pro 100 g - Fluocortinbutyl Micro 2.5 g, Lactosemonohydrat DC 11 97.5 g"** per 100 g of the preparation];

- LENEN® was produced and tested in (9) in powder form [see (9), last horizontal column: "FEINKRISTALLINES, FREIFLIESSENDES PULVER, WEISS" - fine crystalline, free flowing, white powder];

- the composition and physical state (appearance) reported for LENEN® in (9) is identical with the composition and physical state (appearance) of LENEN® currently on the market and offered for sale.

Although spray-dried lactose is referred to in the evidence available in the proceedings, see eg document (5), as "DC Lactose 11" or "Lactose DC 11", the board does not share, in the absence of any reasoned argument, the doubts expressed by the respondent during the oral proceedings that the designation "Lactosemonohydrat DC 11" used in (9) could possibly relate to anything other than spray-died lactose DC 11 and that a preparation with the composition disclosed in (9) would thus not fall within claim 5 of the patent.

2.8 In the context of the composition given in (9) for LENEN® (ie 2.5 g "Fluocortinbutyl Micro" and 97.5 g "Lactosemonohydrat DC 11" per 100 g of the preparation), document (9) refers back to three different dates as follows:

(i) manufacturing process pharmaceutical development ("Herstellvorschrift Pharmaz. Entwicklung"): 15 September 1983 (prior to the priority date);

(ii) manufacturing process Berlin plant ("Herstellvorschrift Berliner Betrieb"): 6 September 1991 (shortly after the priority date);

(iii) test (product examination) method ("Prüfvorschrift 0089 B"): 26 July 1990 (prior to the priority date).

2.9 Although the Board could find nothing in the entire proceedings to indicate or at least to suggest that the composition of LENEN® disclosed in (9) was possibly different from the composition of LENEN® in the form as was placed on the market and offered for sale before the priority date (see (8), **"Rote Liste 1991"**) and as currently offered for sale, the opposition division accepted in the decision under appeal the respondent's (proprietor's) unproven allegation that, in view of the three different dates referred to in (9), including one after the priority date of the patent (see (ii) above), the probative value of the combined evidence of documents (8), (9) and (34) was insufficient to prove that LENEN® in the form made available to the public prior to the priority date and referred to in documents (8), (9) and (34) had a composition in accordance with claim 5 and was thus prejudicial to the novelty of the claimed subject-matter in the patent.

2.10 The board cannot agree. In the absence of any evidence to the contrary and in accordance with commonly experienced facts of life, the board considers the probative value of the combined evidence of documents (8) and (9) (see 2.7 to 2.9 *supra*) as sufficient to prove at least *prima facie* that

(a) the composition of LENEN® in the form as introduced on the market and offered for sale prior to the priority date was identical with

(b) the composition disclosed in (9) for preparations of LENEN® available at different dates before (see (i) and (iii) above) and shortly after the priority date (se (ii) above), and was also identical with

(c) the composition of LENEN® offered for sale and sold at the time the opposition was filed and currently offered for sale in drug stores.

In the board's judgment, the above-mentioned facts and circumstances, coupled with

(d) the common designation LENEN® for (i) the marketed product disclosed in (8), (ii) the product referred to in document (9) and (iii) the product currently offered for sale,

(e) the identity of the composition of LENEN® disclosed in (9) in the composition of LENEN® currently on the market and offered for sale, and

(f) this continuity and identity of both the designation and composition of LENEN® which have been demonstrated over such a long period of time,

constitute in themselves sufficient *prima facie* evidence to support the appellant's assertions that the composition of LENEN® has not been changed in the period from its introduction on the market prior to the priority date up to now and that LENEN® had throughout this period the same composition of 2.5 g fluocortinbutyl and 97.5 g spray-dried Lactose DC 11" per 100 g of the preparation.

2.11 The facts are (i) that LENEN® was undoubtedly introduced on the market and listed in document (8) under its trade name prior to the priority date and (ii) that both the actual designation and composition of LENEN® are still identical with the composition and designation disclosed in (9). The respondent's mere assumptions that the composition of LENEN® might have been changed after the priority date without a simultaneous change of its name or designation and that

the medicament which is currently on the market and offered for sale might no longer be identical with the product LENEN® listed in "Rote Liste 1991" before the priority date must thus be considered as an untypical sequence of events for which no indication or hint, let alone real evidence, is to be found in the entire proceedings. The respondent, which carries the burden of proof in this respect, has not provided any evidence to refute the appellant's reasoned argument that the regulations of the German Medical Preparations Act (AMG) would normally not even allow minor modifications of the composition of a registered medicament without indicating this modification by a simultaneous change of the medicament's name or designation.

2.12 By *"prima facie* evidence" is meant evidence which, if not challenged, may be regarded as sufficient to establish the matter at issue. In the present case, the applicant submitted in its reply to the statement of the grounds of appeal and during the hearing before the board certain arguments to challenge the *prima facie* evidence mentioned above but did not succeed in providing any convincing counter-evidence to displace such *prima facie* evidence.

2.13 The respondent essentially argued that the disclosure in document (9) concerning the composition of LENEN® prior to the priority date was not reliable in view of the three different dates indicated in that document. It also submitted that no objective or convincing evidence, let alone real proof, was made available by the appellant to show in an unequivocal manner that the composition of the medicament LENEN® had not been changed after the priority date and that the composition of LENEN® in the form made available to the public before the priority date was indeed identical with the composition at any time after the priority date, for example, with the composition of LENEN®

currently offered for sale. It concluded therefrom that there were missing links in the chain of evidence presented by the appellant. However, in view of the conclusions reached by the board in points 2.9 to 2.12 above, the board cannot recognise the alleged missing links in the chain of *the prima facie* evidence developed above.

2.14 By the submission of further pieces of evidence together with the statement setting out the grounds of appeal, the appellant succeeded in furnishing any alleged missing links in the chain of evidence relating to the exact composition of LENEN® prior to the priority date and in clearing any remaining doubts in this respect, if such doubts really existed. To this end, the appellant submitted, *inter alia,* document (45) which is a statutory declaration ("eidesstattliche Versicherung") signed on 6 April 2000 by the Declarant, Dr Helmar Dobinsky, who is an employee of the appellant (opponent 03).

2.15 Article 117(1) of the Convention provides, among other means of giving or obtaining evidence, for the production of sworn statements in writing. In decision T 558/95 of 10 February 1997 (not published in OJ EPO) the deciding board stated that a statutory declaration ("eidesstattliche Erklärung") was evidence within the meaning of Article 117(1) EPC and as such subject to free evaluation of evidence. It took the place of sworn statements in writing referred to in Article 117(1)(g) EPC which did not exist as evidence under German law. In the cited decision the board further held that the fact that the statutory declarations provided by the opponent were to some extent identical in wording and drawn up by employees of the opponent did not rule them out as admissible evidence. It was rather a question of the board's evaluation to see whether the evidence provided was sufficient.

2.16 In his statutory declaration (45), Dr Helmar Dobinsky states that

(a) he has been an employee of the appellant company located in D-13342 Berlin since 1974;

(b) he was head of the packaging department for solid and semi-solid pharmaceutical preparations in the appellant's final production unit ("Endfertigungsbetrieb") W III from 1986 until 1999;

(c) he has been head of production responsible for all pharmaceutical matters in the appellant's final production unit W III since 1999;

(d) within the scope of his activities as an employee of the appellant company, he was responsible for filling/packaging of LENEN® until the production of LENEN® was transferred to Weimar in 1999;

(e) the manufacturing process for LENEN® in powder form involves the step of dry mixing of the components fluocortinbutyl 2.5 percent by weight and spray-dried Lactose DC 11 97.5 percent by weight;

(f) the above manufacturing process was used without any modification from 1986 (production of LENEN® for clinical tests) until now;

(g) LENEN® was introduced onto the market on 1 October 1990;

(h) since this date LENEN® has been offered for sale exclusively in drug stores ("Apotheken");

(i) on the basis of his knowledge gained from his professional activities and duties as an employee of the appellant company responsible for the final stage in the production of LENEN®, he can categorically confirm that neither the manufacturing process for the medicament LENEN® nor the starting products ("Edukte") fluocortinbutyl 2.5 percent by weight and spray-dried lactose DC 11 97.5 percent by weight have ever been changed between June 1986 and now.

2.17 It is thus clear that Dr Dobinsky's statements in his statutory declaration (45) are fully consistent with all previously mentioned findings in this decision which were derived from the combined evidence of documents (8), (9), (34) and (38) to (40). Moreover, these statements are proof of the continuity of the chain of evidence furnished by the appellant and strongly confirm the board's conclusions drawn on the basis of the *prima facie* evidence mentioned above.

2.18 To summarise, free evaluation of the combined evidence available in these proceedings leads the board to the conclusion that the probative value of the various statutory declarations and documents produced by the appellant is sufficient to prove "up to the hilt" - see decision T 472/92 (OJ EPO 1998, 261) -

(i) that LENEN® was made available to the public by use prior to the priority date of the patent within the meaning of Article 54(2) EPC and

(ii) that LENEN® had before the priority date the composition fluocortinbutyl 2.5 percent by weight and spray-dried Lactose DC 11 97.5% percent by weight.

This means that circumstances (b) set forth in point 2.1 above have also been clarified with to degree of certainty which is beyond all reasonable doubt.

It follows that LENEN® which forms part of the state of the art under Article 54(2) EPC destroys the novelty of claim 5 and prejudices the maintenance of the European patent as granted. The main request must therefore fail.

First and second auxiliary requests

Admissibility

3. Although both auxiliary requests were presented during the hearing before the board and were, accordingly, filed late, the board, exercising its discretionary power under Article 111(1) EPC, considers that they should be admitted into the proceedings. The respondent submitted that these requests were prompted by the discussion in the oral proceedings and were reinforced by the weight given by the board during the hearing to the statutory declaration (45) by Dr Dobinsky which was presented by the appellant for the first time during the appeal proceedings. These assertions appear, *prima facie*, correct. Although the board does not condone such lateness per se, the exact meaning and impact of the proposed small amendment in claim 5 of the first auxiliary request (see VII above) was immediately comprehensible to the board. It was likewise immediately clear to the board that product claim 5 and claims 6 and 8, which contained a reference to claim 5, were deleted in the second auxiliary request (see VII above) for the purpose of establishing novelty should the board decide to accept the appellant's claims of public prior use. Coupled with the fact that the case must be remitted to the first instance for further prosecution and the fact that the appellant, which was

absent from oral proceedings, is thus given the opportunity to present its comments on these requests, the board exercises its discretion in favour of the respondent.

3.1 The amendments to the claims in the first and second auxiliary requests can fairly be said to be occasioned by grounds for opposition specified in Article 100(a) EPC and to constitute a bona fide attempt on the part of the respondent to overcome the appellant's objections of lack of novelty and inventive step raised in the opposition and appeal statements. The proposed amendments to the granted patent are thus also admissible under the terms of Rule 57a EPC.

Allowability

3.2 The amendment to claim 5 in the first auxiliary request is adequately supported by the disclosure in lines 27 to 32 on page 5 of the application as originally filed.

The amendments in the second auxiliary request concern the renumbering of claims 7 and 9 as claims 5 and 6 respectively. This was necessary in view of the deletion of claims 5, 6 and 8 as granted.

The amendments to the claims in the auxiliary requests appear accordingly acceptable under Article 123(2) and (3) EPC.

3.3 Although an objection under Article 84 EPC cannot in itself be a ground of opposition under Article 100 EPC, the board accepts that such an objection can be raised during opposition or opposition appeal proceedings if amendments made in those proceedings reveal a problem of clarity. In this case, the subject-matter for which protection is sought is defined in the introductory portion of independent claim 5 as "a dry mix consisting

essentially of 1 to 100 parts, by weight, of at least one steroidal medicinal agent uniformly distributed throughout 2000 to 20,000 parts, by weight, of an excipient", while the newly added feature at the end of claim 5 of the first auxiliary request stipulates that "the dry mix contains from 0.005 to 0.5 percent steroid by weight". Although, the content of steroid defined in the newly added feature is outside the range defined in the introductory portion of claim 5 and, in the preliminary opinion of the board, a certain contradiction appears to exist between these two definitions given in one and the same claim, the claim is considered to be sufficiently clear that, for the skilled reader, this issue is not crucial to an understanding of the other issues to be examined in the present case.

Remittal to the first instance

4. Under Article 111(1) EPC, following initial examination of the appeal, the board has the discretionary power to remit the case to the first instance for further prosecution.

From the board's finding that LENEN® forms part of the state of the art under Article 54(2) EPC which destroys the novelty of claim 5, it is immediately clear that the impugned decision of the department of first instance cannot stand. Examination as to patentability of any amended claims which the respondent might wish to rely on during further prosecution of this case in order to take account of this newly established relevant state of the art, needs to be resumed on a new basis and with reference to the technical problem to be solved by the invention determined in the light of the claimed prior use as a relevant new piece of the state of the art. That is primarily the task of the department of first instance. Were the Board itself to

undertake this examination on the new basis and taking into account the relevant state of the art as newly established, this would necessarily have the effect of bypassing one level of jurisdiction, which in turn would be contrary to the principle of equity followed by the board. However, thus allowing the filing of amended claims at this stage could lead to abuses difficult to control. The board accepts that to allow the filing of amended claims necessarily means considerably lengthening the procedure and that certain limits must be set. In the board's opinion those limits were not exceeded in the present case, since the inconvenience resulting from the lengthened procedure is here offset by the board's finding that the claimed prior use forms part of the state of the art and destroys the novelty of the patent as granted. This raises a case entirely different from that on which the first instance's decision was based.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

A. Townend J. Riolo

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