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Datasheet for the decision of 17 June 2009

Case Number: T 0463/06 - 3.3.02

Application Number: 96921353.7

Publication Number: 0836506

IPC: A61M 37/00

Language of the proceedings: EN

Title of invention:
Transdermal patch for administering 17-deacetyl norgestimate alone or in combination with an estrogen

Patentee:
Ortho-McNeil Pharmaceutical, Inc.

Opponent:
Hexal AG

Headword:
Transdermal patch for 17-deacetyl norgestimate/ORTHO-MCNEIL PHARMACEUTICAL

Relevant legal provisions:
EPC Art. 100(c), 123(2), 83, 56

Relevant legal provisions (EPC 1973):
EPC R. 78(2)

Keyword:
"Article 83 is within the framework of appeal"
"Main request: sufficiency of disclosure (yes); inventive step (no)"
"First auxiliary request: admissibility (yes); remittal"

Decisions cited:
T 0389/86, G 0009/91, G 0010/91, G 0001/95, G 0007/95, T 0520/01, T 0074/03

Catchword:
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Case Number: T 0463/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 June 2009

Appellant: (Patent Proprietor)	Ortho-McNeil Pharmaceutical, Inc. U.S. Route No. 202 Raritan, NJ 08869-0606 (US)
Representative:	Warner, James Alexander Carpmaels & Ransford 43-45 Bloomsbury Square London WC1A 2RA (GB)
Respondent: (Opponent)	Hexal AG Industriestrasse 25 D-83607 Holzkirchen (DE)
Representative:	Boeters, Hans Dietrich BOETERS & LIECK Oberanger 32 D-80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 31 March 2006 revoking European patent No. 0836506 pursuant to Article 102(1)(3) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 836 506, which was filed as application number 96 921 353.7, based on international application WO 96/40355, was granted on the basis of seventeen claims. Claims 1 and 6 as granted were two independent product claims and claims 16 and 17 were two independent use claims in the "Swiss-type" form.

Claim 1 as granted read as follows:

"1. A transdermal patch for preventing ovulation in a woman comprising:

(a) a backing layer: and
(b) a matrix layer underlying the backing layer, the matrix layer comprising a mixture of 17-deacetyl norgestimate, a permeation enhancer and a pressure-sensitive adhesive comprising at least one of a silicone and polyisobutylene, and being adapted to be in diffusional communication with the skin of the woman and to administer to the woman an ovulation-inhibiting amount 17-deacetyl norgestimate."

Independent claim 6 as granted read as follows:

"6. A transdermal patch for providing hormone replacement therapy in a woman comprising:

(a) a backing layer; and
(b) a matrix layer underlying the backing layer, the matrix layer comprising a mixture of 17-deacetyl norgestimate, an estrogen and a pressure-sensitive adhesive comprising at least one of a silicone and

polyisobutylene, and being adapted to be in diffusional communication with the skin of the woman and to co-administer to the woman a therapeutic amount of 17-deacetyl norgestimate and estrogen."

Independent claims 16 and 17 as granted read as follows:

"16. Use of 17-deacetyl norgestimate in the manufacture of a transdermal patch as defined by claim 1 or any one of the preceding claims when dependent thereon for preventing ovulation in a woman."

"17. Use of 17-deacetyl norgestimate in the manufacture of a transdermal patch as defined by claim 6 or any one of the preceding claims when dependent thereon for hormone replacement therapy."

II. The following documents and exhibits cited during the proceedings are relevant for the present decision:

(1) WO 94/14450

(2) EP-A-0 275 716

(4) WO 95/18603

(5) EP-A-0 464 150

(8) Declaration of Mr Bret Berner with annexed technical data, filed by the patentee during the opposition proceedings (mentioned for the first time in patentee's letter dated 14 June 2004)

(10) "Prescribing Information of ORTHO EVRA^{R}" (post-published)

(11) Declaration of Ms Jane Stepic dated 8 August 2006, with several annexes concerning additional technical data.

(31) John L. McGuire et al, Am. J. Obstet. Gynecol., 2127-2131, 1990.

III. The date of publication and mention of the grant of the patent in Bulletin 2002/51 is 18 December 2002.

IV. Opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC 1973 for lack of inventive step and Article 100(c) EPC 1973 for added matter (grounds of opposition filed on 2 September 2006). These grounds of opposition were supplemented with the ground of lack of novelty (Articles 52 and 54(2) EPC 1973) with the opponent's letter of 17 September 2006 (received on 18 September 2006), i.e. before the 9-month period for opposition expired.

Article 83 EPC was late-filed as a ground of opposition since it was not mentioned either in the grounds of opposition (2 September 2003) or in the opponent's letter dated 17 September 2006. In fact, the opponent filed objections pursuant to Article 83 EPC for the first time with its letter of 7 October 2004 (i.e. after the expiry of the 9-months period for opposition).

Additionally, with its letter of 14 December 2005 the opponent drew the opposition division's attention to

sufficiency of disclosure (Article 83 EPC) in view of the absence of comments in relation to this issue in the division's communication sent on 11 August 2005, as an annex to the summons to the oral proceedings before it.

V. The appeal lies from a decision of the opposition division revoking the patent (Articles 102(1),(3) EPC 1973) for lack of inventive step (Article 56 EPC).

VI. It can be seen from the minutes of the oral proceedings before the opposition division that the division considered the lateness of Article 83 EPC and the fact that it was not "a ground prima facie relevant for the proceedings", and decided at the beginning of the oral proceedings not to allow the introduction of this ground of opposition into the procedure (Article 114(1) EPC) as being late-filed under Article 114(2) EPC.

VII. The written decision of the opposition division does not contain under the heading "Reasons for the decision" any reasoning in respect of the non-admissibility of Article 83 EPC as an opposition ground. However, in point 8 of the "Facts and submissions" of the opposition division's decision, it is stated: "Oral Proceedings were held on 14 February 2006. The Opposition Division **declared** that the objection under Article 83 EPC raised by the Opponent **was not allowed into the procedure because it was filed after the expiry of the opposition period, i.e. too late, and was not considered *prima facie* relevant**. The discussion was focussed upon added matter, novelty and inventive step" (emphasis added).

In relation to the main request (which was filed with letter of 14 February 2006), the opposition division considered that the amendments were allowable within the meaning of Article 123(2) EPC.

As regards novelty of the subject-matter claimed in the main request, the opposition division was of the opinion that none of the cited prior art documents "explicitly" disclosed a patch comprising 17-diacetyl-norgestimate (NGMN).

In relation to the inventive step issue the opposition division considered that the closest prior art was Example 7 of document (2), which specifically disclosed a patch comprising 17-beta-estradiol, norgestimate and polydimethylsiloxane adhesive. In the opposition division's view the problem underlying the patent in suit was "the provision of a patch for the transdermal delivery of at least a progestin" and the solution suggested in claim 1 was a patch wherein 17-deacetyl-norgestimate was used as progestin.

The opposition division considered that the proposed solution was obvious in the light of document (1). In the opposition division's view, both documents ((1) and (2)) concerned the provision of transdermal patches comprising a progestin, and document (1) taught that norgestimate (NGM) and 17-deacetyl norgestimate (NGMN) were interchangeable. Furthermore, the opposition division did not endorse the patentee's submission that the opposed patent was the first to show skin flux data for such hormone patches. In this respect the opposition division pointed to the permeation rates of

ethinyl estradiol and norethindrone shown in document (2), Tables 1 to 3 on pages 13 to 15.

The opposition division considered that the first auxiliary request before it failed for lack of inventive step owing to the fact that claim 1 was identical to claim 1 of the main request.

As regards the second auxiliary request before it, the opposition division considered that the additional presence of an estrogen, which was mandatory according to amended claim 1, did not involve an inventive step since estrogens were also disclosed as components of the patches described in Example 7 of document (2).

VIII. The patent proprietor (appellant) filed an appeal against said decision and filed grounds of appeal. It also filed a main request (identical to the main request before the opposition division) and three auxiliary requests. It also filed a post-published document (10), entitled "Prescribing Information of ORTHO EVRA^{R}" and a declaration by Jane Stepic and additional experimental data (exhibit (11)).

Claim 1 of the main request read as follows:

"1. A transdermal patch for preventing ovulation in a woman comprising:
(a) a backing layer; and
(b) a matrix layer underlying the backing layer, the matrix layer comprising a mixture of 17-deacetyl norgestimate, a permeation enhancer and a pressure-sensitive adhesive, and being adapted to be in diffusional communication with the skin of the woman

and to administer to the woman an ovulation-inhibiting amount of 17-deacetyl norgestimate, wherein the pressure-sensitive adhesive is silicone adhesive or a polyisobutylene adhesive."

Independent claim 6 of the main request read as follows:

"6. A transdermal patch for providing hormone replacement therapy in a woman comprising:

(a) a backing layer; and
(b) a matrix layer underlying the backing layer, the matrix layer comprising a mixture of 17-deacetyl norgestimate, an estrogen and a pressure-sensitive adhesive, and being adapted to be in diffusional communication with the skin of the woman and to co-administer to the woman a therapeutic amount of 17-deacetyl norgestimate and estrogen, wherein in the pressure-sensitive adhesive is a silicone adhesive or a polyisobutylene adhesive."

The wording of claims 16 and 17 of the main request was identical to that of claims 16 and 17 as granted.

IX. The respondent (opponent) filed counter-arguments thereto and additional experimental data.

X. A communication expressing the preliminary opinion of the board (in particular in relation to the admissibility of the appeal) was sent to the parties as an annex to the summons to oral proceedings.

XI. Oral proceedings took place on 17 June 2009.

During the oral proceedings the appellant filed a new main request to replace the previous main request and a new auxiliary request to replace the previous first auxiliary request filed with the grounds of appeal. The only difference between the new main request and the previous main request was the deletion of use claims 16 and 17.

The new auxiliary request 1 contained only twelve claims. In this amended request the use claims had also been deleted.

Claim 1 of the first auxiliary request differed from claim 1 of the main request in that ", polyvinyl pyrrolidone" was added after "permeation enhancer" and before the expression "and a pressure-sensitive adhesive".

Independent claim 5 of the first auxiliary request differed from claim 6 of the main request in that the expression ", polyvinyl pyrrolidone" was added after "an estrogen" and before the expression "and a pressure-sensitive adhesive".

XII. The appellant's arguments submitted during the oral proceedings and in writing with the grounds of appeal may be summarised as follows:

Document (31) should not be admitted into the proceedings. The admissibility of document (31) had been contested at the oral proceedings before the opposition division by the patentee in view of the fact that said document was late-filed in relation to the time limit (Rule 71 EPC 1973) set out in the summons to

oral proceedings issued by the opposition division. However, the opposition division did not take a decision in this respect. Therefore, it was rather doubtful that said document could be considered as forming part of the proceedings. Moreover, although the opponent mentioned document (31) in its reply to the patentee's appeal, a copy of said document had not been submitted and the appellant did not have any copy of it. Thus, this situation was contrary to the provisions set out in Article 12 RPBA.

The appellant submitted that no objections in relation to Article 83 EPC had been raised with the grounds of opposition. Moreover, paragraph 8 of the opposition division's decision made it clear that this late-filed ground of opposition had not been admitted into the procedure (Article 114(1) and (2) EPC 1973).

The appellant further submitted that, according to the principles set out in the decisions of the Enlarged Board of Appeal G 10/91 (OJ EPO, 1993, 420) and G 9/91 (OJ EPO, 1993, 408), only those grounds of opposition that had been considered in opposition proceedings could be dealt with in appeal proceedings. The ground of opposition pursuant to Article 83 EPC was a fresh ground which could be considered in appeal proceedings only with the consent of the patentee, and the patentee did not give its consent.

Therefore, in the appellant's view the board had no power to examine this fresh ground for opposition and had to follow the principles set out in Enlarged Board of Appeal decisions G 1/95 (OJ EPO, 1996, 615) and G 7/95 (OJ EPO, 1996, 626).

Additionally, the opposition division was correct not to admit Article 83 EPC into the proceedings since the crux of the objection by the opponent was directed to features already present in the granted claims. Hence, there was no justification for a late filing of this ground for opposition. Furthermore, said ground was not *prima facie* relevant. If the opponent (respondent) considered that it had failed to make a complete case then it should go to the national courts. Patent proprietors need legal certainty in appeal procedures and it is not the boards' function to fill the gaps of presumably incomplete oppositions.

The appellant said that it was not contesting the fact that the requirements of Article 83 EPC were important. However, the board had no power to correct the framework of opposition which had been defined by the opponent in its own way. In the present case, the opponent had chosen not to challenge the granted patent under Article 83 EPC within the nine-month opposition period.

The appellant submitted that it did not believe that Article 83 EPC was within the framework of the appeal (G 9/91 and G 10/91) and that it did not wish for a remittal to the department of first instance. However, as an auxiliary request the appellant requested remittal to the department of first instance in the event that the board decided to examine sufficiency of disclosure.

Furthermore, the appellant was of the opinion that the situation in the present case concerned a very

important point of procedural law and requested referral of the following question to the Enlarged Board of Appeal:

"In the case where a ground of opposition is not raised in the notice of opposition and is only raised later in the opposition proceedings but is not admitted into the proceedings under Article 114(1) EPC, as discussed in G 10/91, does the Board of Appeal have the power to remit the case to the first instance for discussion of the late-filed ground?"

Further to the issue of Article 83 EPC, the appellant stated that the inter-relationship between Article 83 EPC and Article 56 EPC had not been dealt with in written and hence it was unfair to the patentee to deal with it in these oral proceedings. The appellant's expectations with regard to the written file were that Article 83 EPC was not part of the appeal proceedings and hence there had never been a real chance to develop arguments in writing.

The appellant further stressed that it could not be seen from the decision of the opposition division that the division had dealt with the ground for opposition pursuant to Article 83 EPC. Hence, this ground for opposition was a fresh ground which was not within the framework of the appeal, since the patentee did not give its consent (G 1/95). The appellant was of the opinion that its arguments were reflected in the case law of the boards of appeal and cited non-published decision T 520/01 (date of decision 29 October 2003) in support of its view. The appellant added that the

framework of opposition and the framework of appeal were two different things.

After the Chairman announced at the oral proceedings that Article 83 EPC was within the framework of the present appeal, the appellant argued the following in relation to the main request:

The patent in suit was very important for the appellant since it encompassed a very successful commercial product (ORTHO EVRA^{R}).

The appellant explained that, although claims 1 and 6 were two independent product claims, its submissions would be the same for both claims.

The contribution to the art made by the patent in suit was the provision of a specific combination of a drug (NGMN) and a particular tissue which was neither disclosed nor foreseen in the prior art. Moreover, this specific combination permitted the production of transdermal patches which could be used either for preventing ovulation or for hormone replacement therapy.

The appellant argued that the description in the patent in suit provided sufficient information to produce such patches. The appellant further submitted that the moment the skilled person knew about the specific combination of drug and tissue as suitable for delivering the drug through the skin, then it was not an undue burden for him to find out the specific patches.

The appellant further stated that the patent in suit contained many examples showing variations, *inter alia* in relation to different loadings. The patent in suit taught how to make patches within the scope of the claims. Moreover, the appellant submitted that it had been plausibly shown that the technical effects stated in the claims were achieved by the exemplified patches. This had been shown by means of the flux data for progestin NGMN and for estrogen compound ethinyl estradiol (EE) in Tables 1 to 5 in the patent in suit. These data were backed up by an important amount of experimental work using a standard model on human cadaver skin described in US 5 252 334, which was referred to in example 1.

The appellant stressed that the patent in suit disclosed that the combination of the particular drug (NGMN) and tissue was able to transmit the drug to the patient in an appropriate flux and that there was sufficiency of disclosure as regards how to construct such a patch.

The appellant also stated that the patches of the examples were capable of being used either as contraceptive devices or as hormone replacement devices. The most important step was to get transport access through the skin. At the priority date of the patent in suit it had not been self-evident that penetration through the skin was possible. The patent in suit provided patches capable of transporting the drug through the skin. The appellant also submitted that there was no evidence on file that the patches of the contested patent were not capable of achieving the mentioned effects. The appellant argued that the tests

used in the patent in suit for determining the flux rates were routine tests. Moreover, these skin-flux tests were standard in the field and were generally accepted as supportive for the effects claimed. Additionally, they had been also used in document (2). The appellant added that, in the light of the results of the tests, it was not reasonable to doubt the penetration of the drug through the skin. There was no evidence to the contrary. The patches were capable of being used as a contraceptive, as the success of the commercial product based on the patent in suit testified.

The appellant also stated that some of the arguments submitted by the respondent under the issue of Article 83 EPC had nothing to do with sufficiency of disclosure.

As regards the issue of inventive step the appellant maintained the written arguments it submitted with the grounds of appeal. It also referred to the declaration of Ms Stepic (exhibit (11)) and the additional data annexed thereto, which showed an improved flux for the patches of the contested patent. This further technical information had been filed as a response to the comment in the opposition division's decision that "an unexpected effect had not been shown for the patches of the patent". Thus, it was now credibly shown that document (2) did not render "*prima facie*" obvious the claimed patches.

The appellant submitted that the "invention" overcame a number of problems associated with transdermal delivery, namely the problems of drug crystallisation and

providing sufficient hormone flux throughout the 7 days on which the patch was worn. The opposition division's conclusions were not correct since the requirement for a reasonable expectation of success had not been met in the light of the prior art knowledge.

The appellant further submitted that the development of an effective transdermal patch for HRT (hormone replacement therapy) or preventing ovulation was largely empirical. It was difficult to predict the impact of changing the active drug on flux and solubility and also on drug compatibility with adhesives and other components of the transdermal patch. The need to overcome these numerous problems simultaneously was summarised in paragraph 4 of Mr Berner's declaration (Exhibit (8)).

Moreover, the appellant cited document (4), which was published on 13 July 1995 (i.e. after the first priority date 7 June 1995 of the contested patent) and which had been filed on 9 January 1995, i.e. shortly before the first priority of the contested patent. In the appellant's view, document (4) showed the difficulties in relation to drug solubility and drug flux the skilled person faced at the time when providing transdermal delivery. The appellant stressed that a correct combination of drug and adhesive was needed for the active drug to penetrate the skin in an adequate flux and for crystallisation to be avoided.

The appellant also pointed to document (5), published in 1990, which discussed the significant problems of skin permeability of the active drug and how difficult it was to transport drugs through the skin. The

appellant also referred in this context to Mr Berner's declaration (Exhibit (8)) and stated that a particular drug/adhesive combination could not be translated into another drug/adhesive combination because it could not be predicted whether it would be capable of transport through the skin and whether the drug would crystallise.

The appellant further argued that document (2) disclosed transdermal patches comprising an estrogen and a progestin provided in different layers. However, document (2) did not mention NGMN in any way. The actual concrete technical disclosure of document (2) was shown in examples 1, 2, 3 and 8, relating to patches which were tested in relation to skin flux. These examples related to a different drug (norethindrone as progestin, which was used with ethinyl estradiol as an estrogen) and to different adhesives from those claimed in claims 1 and 6 of the main request.

The appellant also submitted that examples 4, 5, 6 and 7 of document (2) were hypothetical examples. Example 5 referred to norgestimate as the progestin and example 7 referred to polydimethylsiloxane as the adhesive.

The appellant argued that the skilled person would have taken as a more promising starting point those examples which had been shown to work, i.e. examples 1, 2, 3 and 8, all of which related to a polyacrylate adhesive.

Hence, in the appellant's view, the problem to be solved was to provide a transdermal patch for preventing ovulation (claim 1 of the main request) or for hormone replacement therapy (claim 6 of the main

request). The solution was to use a different drug (NGMN) and a different adhesive.

The appellant also submitted that document (1) was the only document of the state of the art which proposed NGMN in transdermal patches. However, NGMN was listed as an option for a progestin among several others. The content of document (1) did not fill the gap of document (2) since it did not teach that NGMN could cross through the skin. Moreover, there was no teaching in document (1) suggesting the use of polysiloxane or polyisobutylene (PIB) adhesives as a matrix. The constituents of the patches disclosed in document (1) were quite different.
The appellant argued that there was no teaching in the prior art to combine NGMN and PIB or silicone adhesives as a matrix to be able to release the drug through the skin. The only flux shown in the prior art concerned norerthindrone and polyacrylate patch in document (2). There was a big step to be made from that specific disclosure in order to arrive at the proposed solution. Thus, the patches claimed in claim 1 involved an inventive step. The appellant also added that the same arguments applied by analogy to the patches of claim 6 of the main request.

As regards document (31), it did not tell anything about how NGMN would behave in a transdermal patch. The patent in suit acknowledges the teaching of document (31), namely that NGMN was a metabolite of NGM. However, document (31) did not represent common general knowledge. There was no evidence that the teaching of document (31) in relation to the pharmacokinetic of NGMN could be applied to transdermal delivery.

The appellant further stressed that it had not been an easy task to find the right drug and the right adhesive material for the patch and that the evidence about the ability of a certain drug to go through the skin or not was difficult to achieve. The state of the art did not contain any hint in this respect.

As the respondent raised during the discussion of the auxiliary request an objection pursuant to Article 100(c) EPC in relation to claim 6 of the main request, the appellant stated that the respondent's way of proceeding was quite irregular. In particular, such an objection had not been raised in the written appeal procedure and the discussion of the main request had finished. Thus, this respondent's objection should be rejected as too late-filed.

As the Chairman allowed the discussion re Article 100(c) EPC for the main request, the appellant argued that the objection had no basis since the objected expression was a self-explanatory feature. The claim was directed to a transdermal patch for hormone replacement therapy and hence it had to have a therapeutic amount of the active drugs. Hence, the contested expression did not add any new matter to that claim.

As regards the amended first auxiliary request the appellant stated that claims 1 to 12 were entitled to the first priority. Therefore, document (4) was not part of the state of the art within the meaning of Article 54(2) EPC and could not be used for the assessment of Article 56 EPC.

XIII. The respondent's arguments may be summarised as follows:

At the beginning of the oral proceedings before the board the respondent confirmed its request that the appeal be found inadmissible and referred to the written arguments filed with its reply to the appellant's grounds of appeal. In this written reply, the respondent stated that the appeal should be found not admissible since the time limits set out in Article 108 EPC 1973 had not been observed.

The respondent did not contest the admissibility of the new main request and of the new auxiliary request 1, both filed at the oral proceedings before the board.

Document (31) was part of the proceedings since it had been filed on 8 February 2006, shortly before the date of the oral proceedings before the opposition division. Moreover, it had been cited in the respondent's reply to the grounds of appeal. Additionally, document (31) was cited on page 1 of the application (i.e. WO 96/40355) corresponding to the contested patent. Hence, the appellant had to be aware of its content and the document should be admitted into the procedure.

The only comments made by the respondent in relation to the issue of admissibility of Article 83 EPC as a ground for opposition, and to the issue of the framework of the appeal, were the following: Its objections concerning Article 83 EPC were fully contained in the written appeal file and a complete case against sufficiency of disclosure was made in the respondent's reply to the grounds of appeal. Hence, in

the respondent’s view there was no surprise that this was an issue to deal with at the appeal proceedings.

As regards the main request the respondent submitted that the requirements of Article 83 EPC had not been met since the flux data in the tables of the patent in suit related to the examples but did not necessarily support the effects of anti-ovulation and hormone replacement therapy appearing in the claims. Moreover, in order to be suitable as contraceptive the patch was required to provide the anti-ovulation effect with a low rate of error. In this context the respondent referred to its written arguments in its reply to the grounds of appeal. In the respondent's opinion it was unclear as to how far the patches claimed in claim 1 met the safety and reliability requirements for an effective contraceptive.

The respondent referred to paragraph 5.32 of the grounds of appeal in which it was stated that "the skilled person would consider it inherently implausible that NGMN and NGM would have the same properties in a silicone or PIB patch". However, in the respondent's opinion it could have been expected from the prior art that NGMN would penetrate the skin using the tissue components disclosed in document (2) since document (2) referred to "a progestin" as the generic term for the drug in the tissue and to NGM and norethindrone in particular. NGMN was a metabolite of NGM and differed from NGM only in that the hydroxyl group at position 17 was de-acetylated, but this was also the case with norethindrone, which was explicitly disclosed in the patches in document (2). In fact, norethindrone (which had not derivatised the keto group at position 3) was

structurally quite similar to another metabolite of NGM, levonogestrel (difference: a methyl group instead of an ethyl group at position 18), which was also mentioned in document (2) (page 11), although not employed in the examples.

The respondent pointed to document (31), which related to the pharmacokinetic characteristics of norgestimate and its metabolites. Document (31) teaches that NGMN, 3-keto norgestimate and levonogestrel are active metabolites of NGM. Moreover, document (31) further teaches that the pharmacokinetic profile of NGMN is similar to that of NGM and shows that NGMN was the most important contributing metabolite. The respondent also pointed to Fig 3 of document (31) which depicted mean serum levels of NGM and NGMN after oral administration. Whereas NGM showed a rapid decline, NGMN serum levels were maintained longer than one day after administration.

Although document (2) did not explicitly mention NGMN within the options for the progestin component on page 11, levonorgestrel and norgestrel were listed among them (both levonorgestrel and norgestrel were 17-deacetyl derivatives of norgestimate). Therefore, document (2) explicitly taught that the non-hydrolysed NGM and its fully hydrolysed metabolite levonorgestel were both suitable for transdermal delivery by means of transdermal patches in which the matrix was built up of a silicone adhesive. Thus, there was no objective reason to doubt the suitability of the mono-hydrolysed metabolite NGMN (intermediate metabolite from the transformation of norgestimate to levonorgestrel).

The respondent further argued that it had to be kept in mind that the adhesive materials used for the matrix in the patent in suit were commercially available and commonly used in transdermal patches at the priority date of the contested patent. The silicone adhesives were *inter alia* polydimethylsiloxane derivatives such as those disclosed in document (2) and were accessible from the same manufacturer as that mentioned in document (2). This was acknowledged in paragraph [0017] of the patent in suit, where document US 4 906 169 (a family document of document (2)) is cited.

Additionally, the respondent argued that in the application as filed Duro-Tak (i.e. a polyacrylate adhesive) had been also used as an option comparable to silicone and PIB adhesives, and had then been abandoned in the granted patent.

Moreover, the expressions employed in the claims "silicone adhesive" and "polyisobutylene adhesive" were generic terms encompassing a very broad palette of possibilities.

The respondent submitted that document (31) provided a clear motivation for the skilled person to try NGMN as an alternative to NGM. Moreover, since the basics behind transdermal therapy were to circumvent liver-passage then the solution was to try the active body metabolite of NGM, namely NGMN.

After the discussion of the main request had finished the respondent stated that it had forgotten to mention an objection pursuant to Article 100(c) EPC against the expression "therapeutic amount" in claim 6 of the main

request. There was no basis in the application as filed for this expression.

The respondent did not comment on the validity of the first priority for the subject-matter of the amended first auxiliary request filed at the oral proceedings before the board, stating only that claim 6 was not entitled to the first priority in view of the expression "therapeutic amount".

XIV. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main or auxiliary request filed at the oral proceedings or on the basis of the second or third auxiliary request filed with the grounds of appeal. Furthermore, it requested referral of a question to the Enlarged of Appeal.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. *Admissibility*

1.1 *Admissibility of the appeal*

The patent proprietor filed an appeal against the opposition division's decision revoking the patent, announced at the end of the oral proceedings before the opposition division.

The oral proceedings before the opposition division took place on 14 February 2006. The notice of appeal was filed with the letter of 8 March 2006 and the appeal fees were also paid. Thus, the notice of appeal was filed after the opposition division announced the decision at the oral proceedings of 14 February 2006, but before the written decision of the opposition division was sent to the parties (i.e. 31 March 2006). The grounds of appeal were filed on 9 August 2006, i.e. within four months of notification of the decision, in consideration of the tenth day following its posting, as expressed in Rule 78(2) EPC 1973 (see also decision T 389/86, OJ EPO, 1988, 87).

Although the respondent maintained at the oral proceedings its request that the appeal be found not admissible, it did not counter-argue the above findings, which had already been expressed in the board's communication sent as an annex to the summons to the oral proceedings.

Hence, the appeal is admissible.

1.2 *Admissibility of the sets of claims filed at the oral proceedings before the board*

The two sets of claims filed at the oral proceedings before the board (amended main request and first auxiliary request) differed from the corresponding sets of claims (main request and first auxiliary request) previously on file only in that several claims had been deleted, as a reaction to the discussion which took place at the oral proceedings.

In particular, the deletion of the use claims was a direct response to the board's provisional opinion, expressed at the oral proceedings, that the second medical use claims did not meet the requirements of Article 56 EPC. Moreover, the other amendments to auxiliary request 1 were clear and easy to handle since they merely concerned deletion of further claims. Therefore, both amended sets of claims (main request and first auxiliary request) filed at the oral proceedings before the board are admissible.

The respondent did not object to their admissibility.

1.3 *Admissibility of document (31)*

Document (31) was cited on page 1 of the application corresponding to the contested patent. Moreover, it is also cited on page 1, paragraph [002] of the patent in suit.

Furthermore, document (31) was quoted as "Mc Guire et al. 1990" on page 3 of the respondent's reply to the grounds of appeal. Although document (31) was quoted in this abbreviated way in the list of documents on page 3, a complete citation appeared on page 12 of said respondent's reply to the grounds of appeal. Hence, the board assumed that the appellant was able to identify the reference as one of the documents cited on page 1 of the patent in suit (as well as on page 1 of the corresponding international application).

Document (31) served as a substantive support to the respondent's arguments in its reply to the appellant's grounds of appeal and it is a document cited from the

beginning in the application and the patent in suit. Thus, said document is admissible.

The appellant raised an objection against the admissibility of document (31) at the oral proceedings before the board in view of the fact that the opposition division had not concluded on its admissibility. He also stated that it did not have a copy of said document.

As regards the lack of a copy of document (31), the appellant had not asked for a copy of said document prior to the oral proceedings. The board was able to provide the appellant with a copy of document (31) at the oral proceedings, immediately after the appellant had stated that it did not have a copy of it.

The appellant did not ask at the oral proceedings before the board for an additional break to prepare its response in relation to document (31) and was able to counter-argue the respondent's submissions in relation to document (31) with a well-founded reasoning.

Furthermore, the lack of a decision by the opposition division in relation to the admissibility of document (31) in the opposition proceedings cannot deprive the board of the opportunity to examine the admissibility of document (31) in the appeal procedure. As mentioned above, document (31) was relied upon in the respondent's reply to the grounds of appeal and there is no objective reason not to admit it into the appeal procedure.

Moreover, it would have been desirable for the purposes of improving the efficiency of the further processing of the file that the opposition division have taken a decision in relation to the admissibility of the additional documents (*inter alia* document (31)) filed by the opponent shortly before the oral proceedings before the opposition division. However, the absence of such a decision does not constitute a substantial procedural violation by the opposition division. The reasons are that none of these additionally cited documents was taken into account for the substantiation of the opposition division's written decision. In fact, the only documents mentioned in the opposition division's decision are documents (1) and (2).

1.4 *Admissibility of the late-filed opposition ground*

It was within the discretionary power of the opposition division to decide whether or not to admit Article 83 EPC into the opposition procedure. The written decision of the opposition division (which includes the headings "Facts and submissions" and "Reasons for the decision") has to be taken as a unit. Thus, the items discussed under "Facts and submissions" also form part of the decision. The passage in point 8 of "Facts and submissions" (quoted *verbatim* in paragraph VII above) makes it clear that the opposition division did not admit insufficiency of disclosure as a late-filed ground for opposition because it considered that it was not *prima facie* relevant.

Therefore, in the present case the board has the power to examine the correctness of the conclusion not to admit said ground for opposition.

Enlarged Board of Appeal decision G 10/91 states in point 2 of the opinion:

"2. In principle, the Opposition Division shall examine only such grounds for opposition which have been properly submitted and substantiated in accordance with Article 99(1) in conjunction with Rule 55(c) EPC. Exceptionally, **the Opposition Division may in application of Article 114(1) EPC consider other grounds for opposition which, prima facie, in whole or in part would seem to prejudice the maintenance of the European patent**." (*emphasis added*)

In the present case the opponent first raised the objection re lack of sufficiency of disclosure in the opposition proceedings in its letter of 7 October 2004. This objection was raised as a response to the patentee's observations in its letter of 14 June 2006. The opponent reasoned lack of sufficiency as to be intertwined with the problem-solution approach in view of the different functional features appearing in independent claims 1 and 6. This late-filing was justified as a direct response to the patentee's observations in the letter dated 14 June 2004 in relation to Mr Berner's declaration and the additional data submitted therewith (see Exhibit (8)). These observations and additional technical data addressed a contraceptive patch for which the arguments relating to the functions linked to a high and continuous drug flux through the skin played suddenly an essential role for the maintenance of the patent.

The opponent further insisted on its arguments as to lack of sufficiency with its letter of 14 December 2005, noting that if the functional features were taken to define the "invention" in relation to an adequate "high" or "low" concentration (which meant that there were different skin-flux requirements for the two independent product claims 1 and 6) then there was a problem of lack of sufficiency of disclosure.

The opposition division considered at the oral proceedings which took place on 14 February 2006 that the arguments of lack of sufficiency were not "*prima facie*" relevant for the proceedings.

However, the board is of the opinion that in view of the independent claims' wording (i.e. owing to the presence of functional features in those claims), and in consideration of the arguments developed by the parties in writing during the opposition proceedings, it was essential to investigate whether the conditions set out in Article 83 EPC were met, before Article 56 EPC could properly be assessed. Therefore, the opposition division should have considered the discussion re sufficiency of disclosure to be "*prima facie*" relevant.

Furthermore, since the review of the first-instance decision as to its merits is one of the main duties of the board, the discussion about Article 83 EPC forms part of the framework of the present appeal. Moreover, for the reasons expressed above, Article 83 EPC is not a fresh ground for opposition introduced for the first time in the appeal procedure. In fact, Article 83 EPC was in the opposition proceedings and was an essential

part thereof. Moreover, the opponent did not withdraw its objections re Article 83 EPC at any time during the opposition written proceedings or at the oral proceedings before the opposition division.

Furthermore, in the appeal proceedings the respondent developed its arguments in full in its reply to the grounds of appeal.

Correspondingly, there is a fundamentally different situation from that depicted in decision T 520/01, where the ground for opposition (insufficiency) was not maintained in the opposition oral proceedings by the only party which had relied on the ground and the opposition division did not deal with the ground in its decision.

As regards the appellant's request for referral, the question addresses whether or not a board of appeal has the discretionary power to remit a case to the first instance for discussion of a late-filed ground of opposition. The board is convinced that it has the power to remit a case *ex officio* for further prosecution (Article 111(1) EPC) if it considers it appropriate for well-founded reasons (see, for instance, point 8 of the reasons in decision T 074/03-3.3.02, same board in another composition, unpublished in the OJ EPO, date of decision 10 May 2005). Apart from that, the board is not aware of any contradictory case law in this respect and hence does not consider that a referral is required in order to ensure uniform application of the law.

2. *Main request*

2.1 *Added matter*

In the present case Article 100(c) EPC is a ground for opposition. The respondent objected to the expression "a therapeutic amount" which is present in claim 6 of the main request, as well as in claim 6 as granted.

However, the board adheres to the appellant's position in that said term does not introduce added matter since it is a self-explanatory feature to be read within the context of the claim. There has been no objection on the basis that the patches of claim 6 find no support under Article 123(2) EPC in the application as originally filed. What has been objected to is the fact that the specific term mentioned above was not present *verbatim* in the application as filed. This argumentation is not sufficient under the present circumstances because the term objected to as used in the context of claim 6 is directly and unambiguously derivable from the content of the application as filed.

No other objections were raised in relation to Article 123(2) and (3) EPC for the main request and the board sees no reason to differ.

Hence, the main request meets the requirements of Article 123 EPC.

2.2 *Sufficiency of disclosure*

2.2.1 A European patent must disclose the invention in a manner sufficiently clear and complete for it to be

carried out by a person skilled in the art (Article 83 EPC).

It should be remembered that the content of the whole patent, i.e. the claims and the description (including the examples), has to be investigated by the skilled person in the light of the general common knowledge of the technical field involved.

Additionally, it is the claimed "invention" which has to be investigated. The set of claims of the main request is an amended set of claims with two independent product claims concerning transdermal patches. The latter contain the following functional features: "for preventing ovulation in a woman" in claim 1 and "for providing hormone replacement therapy" in claim 6.

As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on an assessment of the facts of each particular case, such as the character of the technical field, and the actual technical detail disclosed.

2.2.2 The board is satisfied that the patent in suit contains sufficient technical information for the skilled person to produce patches such as those claimed in claims 1 and 6 since the preparative examples illustrate different constitutions (matrix material, penetration enhancer) for the claimed patches. Moreover, the patent in suit also contains "in vitro" data in order to support the ability of the transdermal patches to effect transdermal delivery of the active drug(s) through the skin. The tests performed on cadaver skin

models are standard in the field and are the same kind of tests as those in document (2) for supporting the same pharmaceutical indications (namely contraception and HRT). Hence, it can be accepted that the skin-flux data obtained from the exemplified patches in the patent in suit make it plausible that the claimed patches are useful as transdermal delivery devices of the progestin NGMN (claim 1) and of the progestin NGMN and an estrogen (claim 6).

Moreover, as the facts on file stand, the appellant's argumentation that, the moment the skilled person knew about the specific combination of drug and tissue was suitable for delivering the drug through the skin, then it was not an undue burden for him to find out the specific patches, can be endorsed.

Consequently, the technical information in the patent in suit makes it plausible that transdermal patches which could be used either for preventing ovulation or for hormone replacement therapy are reproducible. Using his general technical knowledge in the field of transdermal patches, the skilled person would be in a position to provide for sufficient amounts of the drug(s) in the patch or for an adequate constitution of the patch (thickness, surface area, loading) to achieve the purposes set out in the claims.

2.2.3 As regards the respondent's arguments, they do not suffice, in the absence of any technical evidence, to cast reasonable doubt on reproducibility of the claimed "invention(s)".

2.2.4 Accordingly, the requirements of sufficiency of disclosure are met by the main request (Article 83 EPC).

2.3 *Inventive step*

2.3.1 Document (2), which discloses patches for the transdermal delivery of a progestin and an estrogen, represents the closest prior art. This has not been disputed by the parties.

2.3.2 The patches of document (2) are suitable for "administering the hormones (*a progestin and an estrogen*) transdermally to the subject to achieve fertility control or estrogen replacement" (passage bridging pages 4 and 5 of document (2)).

Document (2) teaches that the "transdermal estrogen/progestin dosage units ... comprise:

a) a backing layer which is substantially impervious to the estrogen and progestin to be delivered transdermally...
b) a polymer layer which is in contact with said backing layer and which has dissolved and/or microdispersed therein an effective amount of an estrogen..., said polymer layer providing a dosage amount of the estrogen to be delivered transdermally; and
c) an adhesive layer which can adhere the dosage unit in intimate contact with the skin of the subject being treated to permit the hormones to be absorbed transdermally, said adhesive layer being adhered to the polymer layer, and having dissolved and/or microdispersed therein an effective dosage amount of a

progestin...said **adhesive layer** being bioacceptable and **permitting said progestin and said estrogen to be transmitted for transdermal absorption**, said adhesive layer having an effective amount of a skin absorption enhancing agent". (page 3, lines 28-41) (*emphasis added*)

Document (2) discloses that the "progestin can be and presently preferable [*sic*] is norethindrone or norgestimate or combinations thereof. However, other suitable progestins can be used in place thereof or in combination therewith. For example, a progestin can be selected from **levonorgestrel**, norethynodrel, dydrogesterone,..., **norgestrel**, progesterone, and the like" (page 11, lines 23-27) (emphasis added).

Although 17-deacetyl norgestimate is not specifically mentioned in this list, document (2) explicitly motivates the skilled person to include other progestins in the transdermal patches: "It will be suggested to those skilled in the art to use other estrogens and progestins in forming the dosage units of the invention" (page 11, lines 28-29).

Document (2) further states: "The polymer layer which has the estrogen distributed therein can be made of a suitable **polymer adhesive**, such as a suitable polyacrylic or a **silicone adhesive**" (page 4, lines 7-9) (*emphasis added*).

This generic disclosure is further supplemented by the disclosure beginning at the end of page 5 and continuing through to page 8. Document (2) states: "The polymer layer can also be made, for example, from

silicon elastomers of the general polydimethylsiloxane structure,..." (end of page 5).

Among other exemplary materials for fabricating the polymer layer "polyisobutylene" is also explicitly mentioned (page 7, line 48).

Moreover, document (8) lists the specific options on page 8: **silicone adhesive, polyisobutylene adhesive** and polyacrylic adhesive, as the constituent for both the adhesive and the polymer layer, and teaches that "the preferred adhesive layer is pressure-sensitive" (page 8, lines 55-56).

It is apparent from reading paragraph [0017] of the patent in suit that the silicone adhesives employed are those described in document (2) for the transdermal patches.

Additionally, document (2) also discloses and illustrates in the examples those patches in which both polymer and adhesive layer are made of the same material (without any separation layer in between) (see, for instance, examples 1-7).

Moreover, document (2) also discloses the use of a penetration enhancer in the pressure-sensitive adhesive which is to be in intimate contact with the skin.

Examples 1 to 7 illustrate the preparation of patches containing different adhesive materials and several progestins and estrogens. Examples 1 and 2 in document (2) disclose in detail a method for preparing the patches, as well as a protocol of skin-flux tests

(using *inter alia* an *in vitro* cadaver-skin model). The specific skin-flux data for the patches of examples 1 and 2 are displayed in tables 1 to 3. The specific drugs contained in the patches of examples 1 and 2 are ethinyl estradiol (i.e. EE as estrogen) and norethindrone (as progestin) and the polymer layer and the adhesive layer are both constituted of the same material, which is a polyacrylate adhesive.

Examples 5 and 6 of document (2) teach that the preparation methods of examples 1 and 2 were repeated for norgestimate, instead of norethindrone, as the progestin, and either EE or 17-beta-estradiol as the estrogen. Moreover, example 7 of document (2) teaches that examples 5 and 6 were repeated using polydimethylsiloxane adhesive instead of polyacrylic adhesive as constituent of the patch.

There is no objective reason to doubt the general applicability of the preparative method disclosed in examples 1 and 2 to the adhesive material specified in example 7.

2.3.3 Therefore, the starting point for the skilled person is example 7, which relates to transdermal patches constituted of a polymer and an adhesive layer, both of the same material, namely a **polydimethyldiloxane adhesive,** and which contain **norgestimate** and either EE or 17-beta-estradiol.

2.3.4 Hence, in the light of the closest prior art the problem to be solved lies in the provision of alternative patches for transdermal delivery in contraception and HRT.

The solution defined in claims 1 and 6 lies in the choice of 17-deacetyl norgestimate (NGMN) as the progestin.

2.3.5 The problem has been plausibly solved in the light of the examples in the patent in suit. In particular, the examples illustrate the preparation of patches having different matrix constituents (pressure-sensitive adhesive, penetration enhancer, drug loading). The patent specification also contains skin-flux data for the exemplified patches tested using a cadaver-skin model.

It is perfectly usual for a patent not to exemplify and/or test every conceivable combination encompassed by generic claims. Although the pressure sensitive adhesive is broadly defined in independent claims 1 and 6 of the main request (as silicone adhesive or polyisobutylene adhesive), it is plausible that the claimed patches solve the stated problem.

2.3.6 It remains now to investigate whether the proposed solution is obvious in the light of the cited prior art.

The patch disclosed in example 7 of document (2) is constructed by application of polydimethylsiloxane adhesive comprising the progestin over a dried layer of (the same) polydimethylsiloxane adhesive comprising the estrogen (without a separation layer between the two layers). Whether or not such a transdermal patch can still be considered a monolithic transdermal system (in which the "bi-layer" construction of the matrix provides for different concentration gradients of the

estrogen and the progestin in the adhesive material) is not a decisive factor for reducing the value of the teaching of document (2). What counts is that the matrix in the patches of example 7 of document (2) is formed by a pressure-sensitive silicone adhesive which is in contact with the skin and which permits said progestin and estrogen to be transmitted for transdermal absorption. This is also the case for the transdermal patches in independent claims 1 and 6 of the main request.

As regards the nature of the drug, it can be generally accepted that one of the constraints of transdermal delivery is skin penetration. However, a person skilled in the field of pharmaceutical technology and with a knowledge of transdermal therapeutic systems knows that the ability of drug molecules to follow this route of application is based on diffusion through the skin. This ability depends on the molecular weight and chemical structure of the drug molecule, and is related *inter alia* to the hydrophobic-hydrophilic partition coefficient and water solubility of the drug. In this context it has to be stressed that the notional person skilled in the art is expected to have the same qualifications as the skilled person referred to for the assessment of Article 83 EPC.

Thus, it is essential to bear in mind that the skilled person knows about the similitude in the chemical structure of the progestin derivatives relevant for the present decision. In fact, 17-deacetyl norgestimate, or NGMN, merely differs from norgestimate (NGM) in that the acetate group is hydrolysed leaving a free OH group at position 17. However, norgestrel and its (-)isomer

levonorgestrel possess at position 17 a free OH group, as is the case with NGMN. Additionally, it must be emphasised that norgestrel and levonorgestrel share the same polycyclic framework (namely, 1,2,3,4,6,7,8, 9,11,12,13,14,16,17-tetrahydro-15H-cyclopenta(a)-phenanthrene) and the same ethynyl group as substituent at position 17, with the other two progestins: NGM and NGMN. The structural difference lies in the fact that the keto group at position 3 of the progestin skeleton is free in norgestrel and levonorgestrel, and masked as an oxime in NGM and NGMN. Hence, the progestin derivatives specifically mentioned in document (2) generically cover the structural variations (masked/unmasked at positions 3 and 17) which characterise NGMN.

Hence, document (2) teaches in general that this type of progestin derivatives is in principle suitable for transdermal delivery. Moreover, it exemplifies specific transdermal patches containing norgestimate.

Therefore, there is nothing in the prior art to prevent the skilled person trying NGMN as an alternative drug for transdermal delivery with the expectation of success.

In fact, the skilled person has a motivation to try NGMN as the progestin, since 17-deacetyl norgestimate (NGMN) was already known to be an active metabolite of NGM at the priority date(s) of the patent in suit. For instance, document (31) (which discloses NGMN as the main metabolite of NGM) is one of the documents acknowledged on page 1 of the application on which the patent in suit is based.

Furthermore, the patent in suit is not the first to suggest NGMN for transdermal delivery. NGMN is explicitly mentioned among other progestins (*inter alia* norgestimate) in connexion with the generic disclosure of document (1) as a hormone component for transdermal patches (see top of page 10). The reasons why document (1) does not represent the closest prior art are that the transdermal patches disclosed therein are quite different from the claimed patches and that a patch containing NGMN is not specifically exemplified in said document.

2.3.7 In view of the above, the subject-matter of claims 1 and 6 of the main request lacks an inventive step (Article 56 EPC).

2.3.8 The appellant's view that examples 1 or 2 of document (2), and not example 7, were the correct starting point cannot be endorsed. The specification of examples 4 to 7 cannot be disqualified as being "hypothetical" simply because these examples refer to previous examples for the experimental details. The appellant's position in this respect amounts to considering the disclosure of document (2) as non-enabling for norgestimate, without giving any evidence or proof that that is the case.

Apart from that, the additional technical data submitted by both parties during the opposition and appeal proceedings confirms that norgestimate patches according to document (2) can be prepared.

Moreover, the teaching of some of the specific examples in document (2) cannot be put aside just because there

is no actual skin-flux data for every single patch specifically prepared. For a complete teaching it is sufficient, in the absence of any evidence to the contrary, for it to be plausible that the transdermal patches of example 7 are suitable for the transdermal delivery of the particular drug NGM (as well as for the estrogen also contained in the patches).

As regards the possible presence of an improved technical effect achieved by the patches claimed in claims 1 and 6 of the main request, it has to be said that the skin-flux data provided for the different patches with Exhibits (8) and (11) only serve to demonstrate that the fine-tuning (drug loading, choice of specific adhesive material, choice of specific penetration enhancer, presence or not of crystallisation inhibitor, etc.) is essential for achieving an optimisation of the effects to be attained by the transdermal patches. However, since these specifically mentioned aspects are not reflected in the claims' wording, the subject-matter claimed also covers obvious alternatives to the patches of document (2).

Finally, the fact that the actual realisation of a transdermal patch for a specific drug and a specific pharmaceutical indication may be very laborious (as reflected by the appellant's comments referring *inter alia* to documents (4) and (5)) is not denied. However, this does not necessarily mean that it is inventive.

Document (1) states on page 10: "The selection of hormones most suited for transdermal delivery may be determined by conventional tests used in the art to determine skin permeability. The most common is the In

Vitro Skin Permeation Chamber using hairless mouse skin or human cadaver skin". Document (1) therefore expressly teaches the skilled person how to check the suitability of NMGN for transdermal delivery and suggests it as an adequate component.

Finally, although the appellant argued about the specific choice of adhesive material to be regarded as essential for achieving skin permeation for a specific drug, the reality is that the adhesive material definition in claims 1 and 6 is very broad and encompasses the silicone adhesive material disclosed in document (2) and exemplified in example 7.

2.4 Consequently, the main request fails for lack of inventive step of the subject-matter of claims 1 and 6.

3. *Remittal to the department of first instance*

The grounds of opposition filed by the opponent before the expiry of the time limit for opposition did not contain sufficiency of disclosure.

The board has decided that sufficiency of disclosure is part of the present proceedings (see point 1.4 above). One of the appellant's auxiliary requests expressed at the oral proceedings was that in the event that Article 83 EPC was to be considered as part of the framework of the present appeal, remittal to the department of first instance for further prosecution should be considered in order not to deprive the appellant of an instance to defend sufficiency of disclosure.

As already said in point 2.2.1 above, it is the claimed "invention" which has to be investigated. The set of claims of the first auxiliary request was filed at the oral proceedings before the board, the subject-matter of these claims was never the subject of discussion before the opposition division. The two independent product claims (claims 1 and 5) contain an additional component (i.e. polyvinyl pyrrolidone) which fulfils a specific function in the transdermal patch, which has to be investigated.

Hence, although there is no absolute right to having two instances to deal with every aspect in a case, the board considers it appropriate under the present circumstances, where several essential issues were never fully developed in writing for this newly amended request (e.g. sufficiency of disclosure, validity of priority, assessment of further documents of the state of the art, inventive step), to exercise its discretionary power and remit the case to the department of first instance for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the first instance for further prosecution on the basis of auxiliary request 1 filed during the oral proceedings before the board of appeal.

The Registrar: The Chairman:

N. Maslin U. Oswald