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**Datasheet for the decision
of the Enlarged Board of Appeal
of 22 November 2012**

Case Number: R 0018/11

Appeal Number: T 0007/07 - 3.3.02

Application Number: 00953387.8

Publication Number: 1214076

IPC: A61K 31/565, A61K 31/585,
A61P 15/00

Language of the proceedings: EN

Title of invention:
Pharmaceutical combination of ethinylestradiol and
drospirenone for use as a contraceptive

Patent Proprietor:
Bayer Pharma Aktiengesellschaft

Opponent:
Hexal AG

Intervener:
Ladee Pharma Baltics UAB

Headword:
-

Relevant legal provisions:
EPC Art. 112a(2)(c), 112a(4), 113, 115
EPC R. 106, 109

Keyword:
"Petition clearly unallowable (yes)"

Decisions cited:
R 0001/08, T 0152/03, T 0906/01



Case Number: R 0018/11

D E C I S I O N
of the Enlarged Board of Appeal
of 22 November 2012

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Decision under review: **Decision of the Technical Board of Appeal
3.3.02 of the European Patent Office of
7 July 2011.**

Composition of the Board:

Chairman: W. van der Eijk
Members: M. J. Vogel
J. Riolo

Summary of Facts and Submissions

- I. This petition for review concerns decision T 7/07 dated 7 July 2011 of Technical Board of Appeal 3.3.02 setting aside the opposition division's decision of 23 October 2006 and revoking European patent No. 1 214 076 - entitled "Pharmaceutical combination of ethinylestradiol and drospirenone for use as a contraceptive" - under Article 54(2) EPC. The board's decision was posted on 10 November 2011, the petition filed on 25 November 2011 and the prescribed fee paid on the same day.
- II. In its decision the board held that the patent in suit was not new, because trials with contraceptives containing the composition claimed in the contested patent had taken place in the US prior to its priority date (31 August 1999), namely between December 1996 and July 1998. As the respondent (patent proprietor) had conceded during the oral proceedings, the drugs in question had been handed out to the trial participants without a confidentiality agreement and the participants had been informed about the active agents of the contraceptive but not that the drospirenone was in micronised form.
- On the basis of these uncontested facts and on what it had learnt about the trials from the judgement of the New Jersey District Court (US) dated 3 March 2008 the board came to the conclusion that, contrary to the respondent's assertion but in line with the established case law of the boards of appeal, the trials had indisputably not been carried out under confidentiality agreements with the participants and, referring to decision G 1/92, that it had been possible for the

skilled person to discover the composition of the internal structure of the drugs and to reproduce it without undue burden. For these reasons the drugs had been publicly available and the trials were novelty-destroying prior use.

The board emphasised that information was considered as being available within the meaning of Article 54(2) EPC if a single member of the public who was not under an obligation of confidentiality had the theoretical possibility to access it (Reasons 3.3, 2nd paragraph). As the tablets had been handed out to a large number of persons not bound by a confidentiality agreement and for use at home over a substantial period of time, the respondent had effectively lost control over them and made them publicly available.

III. The petitioner requested under Article 112a(2)(c) EPC that the decision under review be set aside and that proceedings before the boards of appeal be reopened. The main arguments submitted in support of its petition were as follows:

In its decision the board had stated, that it appeared that due to the trials the respondent had effectively lost control over the drugs as the participants were not barred in any way from disposing of the drugs as they wanted. That conclusion, however, implied a new standard of proof, at odds with the boards' established case law.

At the end of the oral proceedings the board had announced its finding of lack of novelty based on public prior use, without mentioning anything about the

proprietor having effectively lost control over the drugs. During the oral proceedings there had been no discussion of the possibility that a mere assumption of loss of control could substantiate an assertion of public prior use. As this legal issue had not been discussed either in writing or orally, the petitioner had become aware of it only on receipt of the written decision. It had therefore been unable within the meaning of Rule 106 EPC to raise objections during the oral proceedings.

Furthermore, the third-party observations dated 10 June 2011 concerning the issue of public prior use had been forwarded to its representative on 12 June 2011, i.e. only two weeks before the oral proceedings. The letter issuing them was in German, which was not the language of the proceedings. Therefore, in view of Enlarged Board of Appeal decision G 4/08 and further decisions of the boards of appeal, they had to be disregarded.

With respect to the allowability of its petition, the petitioner submitted that the board's assertion of a novelty-destroying public prior use was based only on an assumption, not on certainty. The expression "it appears" did not and could not mean that there was complete and utter certainty about public prior use, especially when the only evidence on which the board had relied on had been the facts and submissions set out in the decision of the US District Court. Hence, any confirmation of the board's assumption necessarily had to be found there. However, the US court, unlike the board, had concluded that the respondent in that case had failed to discharge its burden of showing,

clearly and convincingly, that the clinical trials had been public.

Under the boards' established case law (T 1399/04, T 464/94, T 750/94), a board could not decide on novelty on the basis of probability; it had to be sure, in the light of the proceedings and the evidence on file, that revoking the patent was justified. Thus, the petitioner had had legitimate expectations that the board would follow that case law, and would not change the standard of proof without giving the parties any hint of that intention. It had therefore had no opportunity to submit further evidence and arguments to counter an assumption made by the board solely on the basis of facts established by the US District Court. There was undoubtedly a causal link between that lack of opportunity and the board's decision revoking its patent on the grounds that it had lost control over the drugs and they had thereby become publicly available.

Lastly, the petitioner referred to the opposition proceedings against divisional patent EP 380 301, in which it had filed several documents (annexed to the petition as E2 to E10) proving conclusively that the US trials had been carried out in strict confidentiality.

IV. The Enlarged Board summoned to oral proceedings on 22 November 2012, in a three-member composition under Rule 109 EPC. In a non-binding communication annexed to the summons it expressed its provisional opinion regarding the obligation under Rule 106 EPC that a party object immediately if it thought that a fundamental procedural defect had occurred. It also expressed the opinion that it was doubtful that the

petitioner's right to be heard had been violated. The opinion further indicated that the interpretation of the term "it appears" by the petitioner might not correspond to the intention of the Board and this expression should be understood as meaning "it is apparent". According to the communication it was clear from the decision's overall context that the board had not intended to decide on public prior use only on the basis of probability. The misunderstanding seemed to also have been caused by the way the decisive paragraphs on pages 16 to 20 of the written decision were numbered.

- V. In response to that communication the petitioner filed a letter dated 22 October 2012 in which it strongly disagreed with the Enlarged Board's view. It stressed that it did not consider that it had received the third-party observations of 22 June 2011, on the grounds of a failure to use the language of the proceedings. Independently of that, these third-party observations were at odds with those dated 16 April 2008. They were based on a new concept - "loss of control"/"free disposal" - which however was not discussed clearly.

There had been no mention that the study participants being free to dispose of the drugs as they wanted might constitute prior use. As this new concept, which had been decisive for the board, had appeared for the first time in its written decision, the petitioner had not had any possibility to object to it during the oral proceedings. Citing R 12/09, the petitioner submitted that decisions had to be based solely on arguments submitted by the parties to the proceedings, not by

third parties. However, the appellant had not really contributed to the public prior use discussion.

Furthermore, there was no evidence unequivocally demonstrating that the patentee had lost control of the drugs. On the contrary, due to the assumption made in the board's decision, the patentee had not had any opportunity to counter the assertion of "loss of control"/"free disposal". Its right to be heard had therefore been violated. For the rest, the board had only summarised the case law on novelty; nothing in the decision demonstrated that prior public use had indeed occurred.

Lastly, the petitioner argued that it could legitimately expect that the board would not consider the alleged prior use to be novelty-destroying, because it had been mentioned for the first time in the third-party observations of 16 April 2008 and then later in the oral proceedings, but not in the board's communication. In addition, and contrary to the Enlarged Board's decisions in cases G 8/91 and G 9/91, the board had relied only on third-party observations for its reasoning.

VI. During the oral proceedings the petitioner expanded on the arguments already submitted in writing and asserted that the contested decision was not as clear as the boards' case law required. Referring to decisions T 763/04, T 246/08 and T 206/10, the petitioner argued that the board's written decision had failed to take due account of its argument that the drugs had been distributed under an implicit secrecy agreement. It had therefore been deprived of its right to be heard, in

contravention of Article 113(1) EPC 1973. That constituted a substantial procedural violation.

For the first time during the proceedings the petitioner submitted finally the argument that as the board had difficulties in understanding an argument as apparent from the second paragraph under point 3.5 of the decision its right to be heard was not respected. This argument was rejected by the chairman as too late, because it was not in the petition as filed.

- VII. Third-party observations were filed on 13 November 2012. The chairman of the Enlarged Board declared at the beginning of the oral proceedings that the Enlarged Board considered these observations to be inadmissible, because according to Article 115 EPC such submissions had to concern patentability, and patentability issues could not be the subject of review proceedings.

Reasons for the decision

Admissibility

1. The board's decision was sent to the petitioner by letter dated 10 November 2011. On 25 November 2011 the petitioner filed a petition for review under Article 112a EPC with the European Patent Office, at once providing a statement of grounds and at the same time paying the prescribed fee. It thus filed the petition in due time, i.e. within two months of notification of the board's decision (Article 112a(4), second sentence, EPC).

- 1.1 The present review will consider the grounds submitted by the petitioner within the two-month period under Article 112a(4) EPC and which, in the petitioner's opinion, constituted a fundamental violation under Article 112a(2) (c) EPC of its right to be heard under Article 113 EPC. In contrast, it will not consider the substance of the decision; review under Article 112a EPC is an exceptional means of legal redress, confined to ascertaining whether any fundamental procedural defect occurred in the appeal proceedings in question.
- 1.2 Under Rule 106 EPC, for a petition for review to be admissible the procedural defect alleged must also have been raised and dismissed during the appeal proceedings, unless raising it in those proceedings was not possible.
 - 1.2.1 The petitioner alleges that two separate procedural defects deprived it of its right to be heard. The first is that the letter dated 22 June 2011 from the registrar of board 3.3.02, forwarding third-party observations to the petitioner, was written in German rather than in the language of the proceedings, which was English. In the petitioner's view, the board should therefore have regarded both the letter and its annex as null and void and should have declined to admit them into the proceedings.
 - 1.2.2 The second is that in its decision the board ruled on public prior use - surprisingly for the petitioner, and contrary to the boards' established case law - on the basis of a mere assumption that the petitioner had "lost control" over the trial products because the participants had "free disposal" of them. These criteria had not been discussed during the proceedings,

so the petitioner had not been able to comment on them, either orally or in writing.

1.3 Regarding the first alleged procedural defect, the registry's letter was indeed not in the language of the proceedings (German rather than English), whereas the annexed third-party observations, which actually constituted the substantive content of the communication, were in English, the language of the proceedings.

1.3.1 At no point during the subsequent proceedings, and in particular at the oral proceedings before the board, did the petitioner object to the fact, as required by Rule 106 EPC, that the above-mentioned third-party observations were admitted in the proceedings and that its right to be heard had been infringed. Since however it was aware that the letter of 22 June 2011 was in the wrong language, that is what it could and should have done, as well as expressly arguing that its right to be heard under Article 113 EPC would be infringed if the observations on file were discussed in the oral proceedings. The minutes of the oral proceedings make no reference to such an objection; on the contrary, the minutes of the oral proceedings indicate "Novelty was then discussed in the light of the prior use introduced by a third party and of D4".

1.3.2 Therefore, the Enlarged Board cannot entertain the petition for review in so far as it argues that a document relevant for the decision should be deemed not received because it was not in the language of the proceedings, and that this infringed the petitioner's right to be heard.

1.4 Nor - again because it failed to raise the objection - can the petitioner maintain that if the Enlarged Board disagrees, and takes the view that it did indeed receive the letter, then it did not have enough time to comment on it.

1.5 Things are different however as regards the petitioner's argument that its right to be heard was infringed because the board's decision - surprisingly and contrary to consistent case law on assessing public prior use - was based not on the production of clear evidence but merely on an "assumption" of a "loss of control" on the part of the patentee which had led to the trial products' "free disposal". These criteria had not been mentioned and discussed in the oral proceedings, and the petitioner could therefore not have expected the board to regard them as relevant for the decision. As a result, it had not been possible to raise an objection under Rule 106 EPC. The Enlarged Board accepts this argument.

In the Enlarged Board's view, neither the minutes of the oral proceedings nor any other documents on file contain any suggestion to the contrary. The Enlarged Board therefore accepts that the petitioner only realised that the board's decision applied these criteria in assessing public prior use when receiving the written decision and therefore was unable to object to them beforehand. It therefore regards this part of the petition for review as not clearly inadmissible.

1.6 Further grounds in support of the petition for review which were raised during the oral proceedings and after

the two-month time limit under Article 112a(4) EPC are to be ignored as time-barred.

Allowability

2. In so far as the petition for review is admissible, it is clearly unfounded. The Enlarged Board cannot share the view that in the proceedings before the board the petitioner was deprived of its right to be heard. Even after hearing the petitioner in oral proceedings on 22 November 2012 it sees no reason to change its provisional assessment of the case as set out in the annex to the summons.

In taking its decision the Enlarged Board must bear in mind that review proceedings under Article 112a(2)(c) and (d) EPC are confined to procedural defects so fundamental as to be intolerable for the legal system and overriding the principle that proceedings which have led to a final decision should not be reopened in the interest of legal certainty and that substantive issues are excluded (consistent case law since R 1/08 of 15 July 2008, Reasons 2.1 and the *travaux préparatoires* there cited).

- 2.1 The Enlarged Board continues to take the view that the decision objected to could have been formulated more clearly. However, the flaws do not constitute the fundamental procedural defect of denying a party the right to be heard (Article 112a(2)(c) EPC), as is clear from an analysis of the passages in point 3.3 of the decision cited by the petitioner in support of its allegation that its right to be heard was infringed.

2.1.1 In said point 3.3 (first paragraph) the board begins by stating that the petitioner had not contested that clinical trials had been carried out before the priority date, and that the participants had not entered into confidentiality agreements and had been informed about all the active agents of the trial products, albeit not about the micronisation feature. The board continues by setting out (second paragraph) the criteria which, under established board of appeal case law, give rise to prior public use. According to the decision, these criteria are entirely consistent with what the petitioner indisputably conceded in the proceedings before the board. What this part of the decision may lack - an omission which however is made good at the end of point 3.3 - is a final conclusion that the facts not disputed by the petitioner already fulfil the criteria for public prior use under the boards' case law (see point 2.1.3 below).

2.1.2 In the next section of point 3.3 (fourth and fifth paragraphs) the board discusses the argument that decisions T 152/03 of 22 April 2004 and T 906/01 of 28 September 2004, cited by the petitioner in the appeal proceedings, had found that clinical trials were not public. But the board dismisses it because the trials underlying those decisions were conducted on clinic premises and involved devices implanted into a small number of patients. Under such circumstances, the trial devices could be assumed to have remained secret. Trials of that kind differed from the one in dispute in which a large number of participants without confidentiality agreements were given products to take home and did not return all the unused ones at the end.

- 2.1.3 The board then sums up as follows: "Therefore, it appears that after having handed out the drugs the respondent effectively lost control over them as the participants in the clinical trial were in no way barred from disposing of the drugs as they wanted". Point 3.3 ends by concluding that handing out the drugs to the participants made them publicly available.
- 2.2 The Enlarged Board does not agree with the petitioner that the English formulation "Therefore, it appears" expresses a mere "assumption". In its submission of 10 March 2009 (page 3, last paragraph), the petitioner itself uses the phrase to make a firm assertion: "As it appears from page 21 to 22 of D43, the proprietor entered into confidentiality agreements ...". Here, the petitioner is not making a mere assumption, but stating what it regards as an incontrovertible fact. Even though the Enlarged Board concedes that "it appears" could also be read as meaning "it is assumed", the interpretation "it is apparent" in the given context as analysed above is objectively the more likely one.
- 2.3 Nor is the Enlarged Board of Appeal convinced by the petitioner's objection that its right to be heard was infringed because the board's decision created new criteria for public availability - "loss of control" and "free disposal" - on which it had no opportunity to comment during the proceedings. The second paragraph of the decision's point 3.3 begins "It is established board of appeal case law...", leaving the reader in no doubt about the principles applicable under that case law on public prior use, namely "... that if a single member of the public ... has the theoretical possibility to access particular information, this

information is considered as being available to the public within the meaning of Article 54(2) EPC". It does not mention "loss of control" and "free disposal".

It does however make clear, to those familiar with board of appeal practice, that the criterion cited in the decision (point 3.3, second paragraph) as established case law, namely that even the theoretical possibility of access is novelty-destroying for an invention, sets higher confidentiality requirements than criteria such as "loss of control" and "free disposal". The Enlarged Board regards these two concepts as sub-categories of the "theoretical possibility to access" which suffices under the boards' consistent case law, and therefore does not consider them to be unexpected criteria on which the petitioner was unable to comment.

2.4 It is true that the decision's point 3.3 might have been more clearly structured. However, as shown above, these deficiencies did not constitute an infringement - let alone a "fundamental" one - of the petitioner's right to be heard.

2.4.1 After all, the petitioner was legally represented. In the appeal proceedings it should therefore have been familiar with the boards' established case law on the legal criteria for public prior use, including its implications for the pharmaceuticals field. Public prior use of the petitioner's invention was a crucial issue in the appeal proceedings, in the light of the trials conducted in the United States, the US court judgment and the exchange of submissions. It was therefore a pressing task for the petitioner to address

the issue in a comprehensive manner, and to raise any open questions itself. In view of the impartiality required of the boards in *inter partes* opposition appeal proceedings, it could not expect much in the way of helpful hints from the board.

2.4.2 Under the boards' established case law, there can be no doubt that an invention which reaches a third party without a confidentiality agreement has become public. As explained above, "loss of control" and "free disposal" are just ways of describing that. These formulations were therefore not decisive for the board's decision.

2.5 Consequently, there is no basis for assuming that the petitioner did not have sufficient opportunity to comment exhaustively on all aspects of public prior use which were relevant for the decision.

Order

For these reasons it is decided that:

The petition for review is unanimously rejected as clearly unallowable.

The Registrar:

The Chairman:

P. Martorana

W. van der Eijk