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Case Number: T 0361/18 - 3.3.04

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Composition for use in treating infertility

Patent Proprietor:
Ferring B.V.

Opponent:
James Poole Limited

Headword:
Infertility treatment/FERRING

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (yes)

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Case Number: T 0361/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 April 2021

Appellant: (Patent Proprietor)	Ferring B.V. Polaris Avenue 144 2132 JX Hoofddorp (NL)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
Representative:	Wise, Daniel Joseph Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 December 2017 revoking European patent No. 2 621 517 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chair	B. Claes
Members:	A. Schmitt
	M. Blasi

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 2 621 517, entitled "*Composition for use in treating infertility*".

II. An opposition had been filed against the patent in its entirety. The opposition proceedings were based on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) in Article 100(a) EPC and on the grounds in Article 100(b) and (c) EPC.

III. The opposition division decided, *inter alia*, that the subject-matter of claims 1 to 4, 7, 9 and 10 of the patent as granted and claim 1 of each of auxiliary requests 1 to 4 lacked novelty. The subject-matter of claims 1 to 12 of auxiliary request 5 was held not to involve an inventive step.

IV. With the statement of grounds of appeal, the appellant submitted sets of claims of a main request (being identical to auxiliary request 4 considered by the opposition division), four new auxiliary requests and four documents (A20 to A23). It presented arguments in support of the requests in the context of added subject-matter, sufficiency of disclosure, novelty and inventive step.

Claim 1 of auxiliary request 4 submitted with the statement of grounds of appeal reads:

"1. A product comprising follicle stimulating hormone (FSH) and human chorionic gonadotropin (hCG) for use in the treatment of infertility by controlled ovarian

stimulation to develop one or more top quality embryos, wherein the FSH is for administration at a dose of 75 to 250 IU FSH per day starting on day one of treatment and continuing for two to twenty days; and the hCG is for administration at a dose of 140 to 190 IU hCG per day starting on day one of treatment and continuing for two to twenty days."

Claim 2 of this request was dependent on claim 1.

V. With its reply to the statement of grounds of appeal, the opponent (respondent) submitted a document (A24) and presented arguments why the appeal should be dismissed.

VI. The board summoned to oral proceedings in view of corresponding requests of the parties and subsequently issued a communication pursuant to Article 15(1) RPBA setting out its preliminary opinion on the appeal. In the context of auxiliary request 4, the board expressed the view that it was not convinced that the claimed subject-matter lacked an inventive step.

VII. Oral proceedings were held by videoconference with both parties' consent. The appellant withdrew the previous main request and auxiliary requests 1 to 3 and confirmed that former auxiliary request 4 was the new main request. At the end of the oral proceedings, the chair announced the board's decision.

VIII. The following documents are referred to in this decision:

D3 Filicori *et al*. (2002) J. Clin. Endocrinol. Metab. 87(3), 1156-1161

D11 Filicori *et al*. (1999) Fertil. Steril. 72(6), 1118-1120

D12 Filicori *et al*. (1999) J. Clin. Endocrinol. Metab. 84(8), 2659-2663

D13 Filicori *et al*. (2002) Human Reprod. Update 8(6), 543-557

D18 Van Horne *et al.* (2007) Fertil. Steril. 88(4), 1010-1013

A21 Sullivan *et al.* (1999) J. Clin. Endocrinol. Metab. 84(1), 228-232

A22 Cedrin-Durnerin *et al.* (2004) Human Reprod. 19(9), 1979-1984

A24 Filicori *et al.* (2005) Fertil. Steril. 84(2), 275-284

IX. The appellant's arguments, as far as relevant to the present decision, are summarised as follows.

Consideration of document A24 in the appeal proceedings (Article 12(4) RPBA 2007)

Document A24 should not be considered in the appeal proceedings since it was not *prima facie* more relevant than other documents already on file. Moreover, it should have already been filed during opposition proceedings, considering that the dosage amounts of hCG as claimed in claim 1 of the main request were already present in independent claim 12 as granted.

Main request

Inventive step (Article 56 EPC) - claim 1

The claimed subject-matter differed from the protocol for treatment of infertility by controlled ovarian stimulation (COS) disclosed in the closest prior art document D18 in the higher dosage amount of hCG administered concomitantly with FSH from day one of the treatment.

The technical effect of this difference was an increase in the number of top quality embryos. This was evident from the results of the study disclosed in the patent showing that an increased number of top quality embryos was obtained when administering 150 IU of hCG per day compared to the other doses tested (Table IV; page 5, paragraph [0019]). The patent further showed that to obtain an increased number of top quality embryos, particular hCG serum levels were already required on day six of the treatment that were only achieved with a daily hCG dose of 150 IU (Table VI). This observation further linked the dose of 150 IU hCG per day to an increased number of top quality embryos.

The technical effect was thus disclosed in the patent and should be taken into account for the assessment of inventive step. Since document D18 neither analysed nor mentioned the number of top quality embryos, the objective technical problem was the provision of a product and dosage regimen for the treatment of infertility by COS which provided an increased number of top quality embryos.

The claimed solution to this problem, namely administration of hCG at a daily dose of 140 to 190 IU

starting on day one of treatment, would not have been obvious to the skilled person considering the disclosure in document D18 alone or in conjunction with the disclosure in documents D13 and A24.

Firstly, none of these documents was concerned with the development of "top quality embryos", a known technical term defined in the patent (page 4, paragraph [0008], and page 9, paragraph [0048]). The purpose of developing top quality embryos was different from achieving high pregnancy rates in infertility treatment. The latter was the main purpose of the cited disclosures. Secondly, none of these documents would have motivated the skilled person to increase the dose of hCG administered in the protocol of document D18 from day one of the treatment.

Document 18 (on page 1012, left-hand column, third paragraph) stated that the alleged correlation of enhanced oestrogen secretion and oocyte and embryo quality was mere speculation. It went on to report that this correlation was neither observed in the study of document D18 nor in the study of document A22 (reference (11) of document D18). Furthermore, the results of the study disclosed in document A21 (reference (6) of document D18) were incorrectly presented. In this study, the oestrogen production had only been analysed as an index of follicular development (page 231, left-hand column, first full paragraph), and embryo quality had not been examined at all. Therefore, the teaching of document A21 did not support the hypothesis that enhanced oestrogen secretion might lead to better quality oocytes and embryos.

Furthermore, document A24 (reference (5) in document D18) merely reported that the combination of FSH and hCG at a dose of 50 IU per day accelerated the development of ovarian follicles but did not correlate a higher ovarian oestrogen secretion with oocyte or embryo quality (page 278, left-hand column, fourth paragraph, reporting the results of document D11).

Document A24 mentioned a "low-dose hCG" of 50 to 200 IU per day only in the context of a different treatment protocol in which hCG was administered only from day eight of FSH treatment (page 278, left-hand column, fifth paragraph, to right-hand column, first paragraph). The skilled person would not have combined this fundamentally different treatment protocol with the treatment protocol of document D18. Furthermore, in the study of document D3, the results of which this passage of document A24 reported, treatment with FSH and hCG was found not to affect serum estradiol levels (document D3, page 1158, Table 3). The teaching of document A24 thus would not have motivated the skilled person to increase the hCG dose in the protocol of document D18 to 140 to 190 IU from day one onwards.

Also, document D13, a scientific review article, only reported a supplementation of FSH with 50 IU of hCG per day from day one of the treatment and thus likewise would not have motivated the skilled person to increase the hCG dose to 140 to 190 IU per day (page 548, left-hand column, middle of the second paragraph, and Figure 2, reporting the results disclosed in documents D11 and D12).

Furthermore, like document A24, document D13 only discussed a dose of 50 to 200 IU hCG per day in the context of the treatment protocol of document D3 in

which hCG administration was started only at day eight of FSH treatment (page 554, left-hand column, first full sentence). The skilled person would thus not have combined this treatment protocol with the one of document D18.

Moreover, no effect on embryo quality was reported in documents D13 and D3. This was in line with the results shown in the patent (Table V) that starting hCG administration only at day eight of the FSH treatment could not be sufficient to increase the quality of the embryo since high hCG serum levels were already required on day six of the treatment for this effect.

The teaching of document D13 thus would not have motivated the skilled person to increase the hCG dose in the protocol of document D18 from day one of treatment, either.

Therefore, the claimed subject-matter would not have been obvious to the skilled person from the teaching of document D18 alone or in combination with any of the cited documents and hence involved an inventive step.

X. The respondent's arguments, as far as relevant to the present decision, are summarised as follows.

Consideration of document A24 in the appeal proceedings (Article 12(4) RPBA 2007)

Document A24 was submitted in reply to the statement of grounds of appeal, in particular to newly submitted auxiliary request 4 and the appellant's allegation that the opposition division had misinterpreted the disclosure in document D18. Document A24 was reference (5) cited in document D18 and provided

evidence of what the skilled person would have understood by the term "low-dose hCG" used in a passage of document D18 relevant for the assessment of inventive step. It supported the teaching of document D18 that hCG stimulated oestrogen secretion and that increased oestrogen levels could increase embryo quality, and was thus relevant for the assessment of inventive step. Document A24 should therefore not be excluded from the appeal proceedings (Article 12(4) RPBA 2007).

Main request

Inventive step (Article 56 EPC) - claim 1

The claimed subject-matter differed from the disclosure in document D18, which represented the closest prior art in the amount of hCG administered to the patient, namely 140 to 190 IU of hCG per day instead of 100 IU per day. However, this difference was not associated with a technical effect.

Firstly, the results shown in the patent lacked statistical significance due to the small sample size, the overlap in the data from the different treatment groups and the resulting risk of false positives. Secondly, even if it were accepted that the patent disclosed an increase in the number of top quality embryos when particular doses of hCG were administered from day one of the treatment, this effect was already achieved with the hCG dose used in document D18 (100 IU per day) and thus could not be associated with the difference of the claimed subject-matter over the disclosure in document D18.

The latter was evident from Table IV of the patent, showing that an increase in the number of top quality embryos already occurred when 100 IU of hCG per day was administered, and acknowledged in paragraphs [0008] and [0019]. No statistically relevant difference in the number of top quality embryos was shown for 150 IU of hCG compared to 100 IU of hCG.

The objective technical problem should thus be formulated as the provision of an alternative rather than an improved product. The administration of an hCG dose falling within the claimed range would have been obvious to the skilled person in view of the teaching of document D18 combined with the teaching of either document D13 or document A24, irrespective of whether the claimed hCG dose was seen as an alternative or an improvement.

Document D18 highlighted the increase in ovarian oestrogen secretion and serum estradiol levels and the associated increase of better quality oocytes and embryos when hCG was administered from the first day of treatment (page 1012, left-hand column, third paragraph).

Furthermore, document D13 (reference (4) of document D18) was representative of what the skilled person's common general knowledge would have been in 2002 and reinforced the teaching of document D18 that low-dose hCG enhanced ovarian oestrogen production and stimulated the development of larger antral follicles (page 548, left-hand column, second paragraph) and that oestrogens improved follicle and oocyte quality and could result in the development of better embryos (page 548, left-hand column, third paragraph). On page 554, left-hand column, first full sentence, document D13

defined, with reference to document D3, "low-dose hCG" as a dose of 50 to 200 IU hCG per day and further suggested (on page 549, left-hand column, third paragraph) that "*higher LH activity ovulation-induction regimens should be explored to determine the optimal amount and timing*". The teaching of document D13 thus would have motivated the skilled person to increase the dose of hCG used in document D18 to improve embryo quality.

Document A24, a review from 2005 cited as reference (5) in document D18, also disclosed that hCG could be administered from day one of the treatment (page 278, left-hand column, penultimate paragraph, discussing the study of document D11) and that "low-dose hCG" would have been understood by the skilled person as 50 to 200 IU of hCG per day (page 278, left-hand column, last paragraph). The skilled person would have recognised from the context of these passages reviewing the relevant research in this field that the same "low-dose hCG" could also be applied in treatment protocols in which hCG was supplemented from day one of the treatment.

The appellant had argued, with reference to document A21, that the effects of hCG on oestrogen secretion and of oestrogen secretion on oocyte and embryo quality were controversial. However, since the review documents D13 and D18 published by leading authors in the field of COS supported this view, the skilled person would have had no reason to doubt that hCG increased oestrogen secretion and that higher oestrogen secretion was associated with a better quality of the resulting embryos.

Thus, the skilled person would have been motivated by the teaching of document D18, combined with either document D13 or document A24, to increase the dose of hCG in the protocol of document D18 to improve embryo quality. The subject-matter of claim 1 would therefore have been obvious to the skilled person and did not involve an inventive step.

XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request, filed as auxiliary request 4 with the statement of grounds of appeal.

XII. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Consideration of document A24 in the appeal proceedings (Article 12(4) RPBA 2007)

2. The appellant has requested that document A24 filed by the respondent in reply to the appeal be held inadmissible under Article 12(4) RPBA 2007. Pursuant to Article 12(4) RPBA 2007, the board has the power to hold inadmissible, *inter alia*, facts and evidence presented with the statement of grounds of appeal or the reply relating to the case under appeal and meeting the requirements of Article 12(2) RPBA 2007 that could have been presented in the proceedings before the opposition division.

3. With its statement of grounds of appeal, the appellant submitted four new documents including documents A21 and A22 cited in document D18 which, in the decision under appeal, had been considered to represent the closest prior art. These documents supported the appellant's argument that the opposition division had misinterpreted the teaching of document D18. The board had no reason to exclude A21 and A22 from the appeal proceedings nor was this requested by the appellant.

4. In reply to the appeal, the respondent submitted document A24, equally cited in document D18 in the same paragraph and context as documents A21 and A22. It provided evidence of what the skilled person would have understood by the term "low-dose hCG" used in document D18.

5. While it might have been possible for the respondent to file document A24 during opposition proceedings, the board considered the filing of document A24 to constitute a reasonable development in response to the statement of grounds of appeal and was aimed at providing further details relevant for the assessment of inventive step without changing the case under appeal. The aspect of *prima facie* relevance relied upon by the appellant is not a mandatory criterion under Article 12(4) RPBA 2007 and was not taken into account by the board.

6. Accordingly, the board saw no reason to hold document A24 inadmissible (Article 12(4) RPBA 2007) and consequently considered document A24 in the appeal proceedings.

Main request

7. In the context of the invention set out in the set of claims of the main request, the respondent has argued in the appeal proceedings solely that the subject-matter of claim 1 lacks an inventive step. Accordingly, this is the sole issue that needs to be decided.

Inventive step (Article 56 EPC) - claim 1

Closest prior art and difference

8. The parties agreed that the disclosure in document D18 represented the closest prior art. The board has no reason to diverge from this assessment.

9. Document D18 discloses two protocols for controlled ovarian stimulation (COS) for (subsequent) *in vitro* fertilisation comprising the daily administration of 150 or 225 IU of rFSH concomitantly with 50 or 100 IU of hCG for at least four days (page 1010, right-hand column, last paragraph). The patients receiving one of these two treatment protocols formed a single study group ("low-dose hCG-supplemented group") and were compared to a control group of patients that did not receive hCG supplementation ("rFSH-alone group"). No improvement compared to this control group as regards implantation and pregnancy rates were detected (Table 1, page 1012, left-hand column, second paragraph) despite higher levels of serum estradiol (Table 1, page 1012, left-hand column, third paragraph).

10. The subject-matter of claim 1 differs from these treatment protocols in that the hCG is for administration at a dose of 140 to 190 IU per day and

in that the infertility treatment by COS is "to develop one or more top quality embryos".

Technical effect and objective technical problem

11. The opposition division considered the technical effect associated with this difference to be an increased number of top quality embryos. In appeal, the respondent contested this effect, arguing, *inter alia,* that the data disclosed in document D18 and the patent could not be compared.

12. The board agrees with the respondent that since document D18 provides only the number of embryos resulting from the treatment but no information on their quality (Table 1), the data of document D18 and the patent cannot be directly compared. However, in the study disclosed in the patent, four patient groups were compared that received 0, 50, 100 or 150 IU of hCG per day concomitantly with 150 IU of FSH. The number of top quality embryos was analysed in relation to the hCG dose (Table V) and the serum hCG levels on day six of the treatment (Table V). Thus, the patent itself discloses a comparison of the number of top quality embryos developed after patients had received the same (50 or 100 IU) or higher (150 IU) amounts of hCG as administered in the study of document D18.

13. These data show that the mean number of top quality embryos increases with increased hCG doses, peaking at 150 IU of hCG (Table IV). A statistically significant higher number of top quality embryos was obtained when a daily dose of 150 IU of hCG had been administered compared to 50 IU of hCG (Table IV, paragraph [0055]). It is concluded that "*there was a significant influence of hCG on the number of day 3 top-quality embryos. The*

highest number was found in the group given 150 IU of hCG per day" (*ibid.*). The same conclusion is drawn in paragraph [0019]. Moreover, the data of Tables V and VI disclose that serum hCG levels on day six of the treatment of more than 8.0 IU/L were associated with a higher number of top quality embryos per patient (Table V) and that such hCG serum levels were only achieved when a hCG dose of 150 IU per day had been administered (Table VI).

14. In view of these data, the board sees no reason to doubt that the administration of higher daily doses of hCG from day one of the treatment is associated with the subsequent development of an increased number of top quality embryos.

15. The respondent further argued that the alleged technical effect could not be acknowledged as the data of Table IV were not statistically relevant due to the small sample size analysed for each patient group. Moreover, in view of the large standard deviations, no statistically significant difference in the number of top quality embryos was observed in the group treated with 150 IU of hCG compared to treatment with 100 IU of hCG. The technical effect was thus not associated with the difference of the claimed subject-matter to the disclosure of document D18.

16. Although the data of the patent show that an increase in the number of top quality embryos already took place when 100 IU of hCG was administered compared to doses of 0 or 50 IU of hCG, the same data imply a further increase in the number of top quality embryos with a daily dose of 150 IU of hCG (see above point 13.). Consequently, according to the patent, administering the claimed hCG doses (140 to 190 IU) rather than the

hCG dose used in document D18 (100 IU) further increases the number of subsequently developed top quality embryos.

17. In this context, the board notes that the mere allegation that a study conducted with more participants might not confirm a further increase in the number of top quality embryos when administering 150 IU of hCG is not, as such, sufficient reason to deny the occurrence of this effect since a study conducted with more participants might equally likely confirm the effect. Consequently, in the absence of any evidence to the contrary, the respondent's arguments in this matter are considered mere speculation.

18. In view of the above considerations, the board holds that the technical effect of an increase in the number of top quality embryos can be acknowledged for the claimed subject-matter.

19. The objective technical problem may therefore be formulated as the provision of a product comprising FSH and hCG for use in the treatment of infertility by COS which allows for an increased number of top quality embryos to be developed.

Obviousness

20. According to the decision under appeal and the respondent, the passage of document D18 discussing potential "*other benefits of low-dose hCG in addition to cost savings*" (page 1012, left-hand column, third paragraph) provided an incentive to the skilled person to increase the hCG dose used in the study of document D18 to improve oocyte and embryo quality.

21. However, as already set out above (point 12.), document D18 is not concerned with the development of top quality embryos. Moreover, administration of 50 or 100 IU of hCG is pooled into a single "low-dose hCG-supplemented group" (Table 1) and compared to treatment with FSH alone, implying that the authors of document D18 did not expect different outcomes with different hCG doses.

22. Furthermore, the board concurs with the appellant that this passage of document D18 reports conflicting results. On the one hand, with reference to document A24, "*[l]ow-dose hCG appears to be more effective in stimulating ovarian estrogen secretion than is rFSH alone*" and, with reference to document A21, "*[e]nhanced estrogen secretion may lead to better quality oocytes and embryos".* However, this hypothesis is subsequently contrasted with the observation that "*outcomes between the two groups in our study were the same*"; this "*supports the findings of a study* [document A22] *in which higher levels of E2 in supplemented cycles were not predictive of a better outcome*" (page 1012, left-hand column, third paragraph).

23. Thus, contrary to the respondent's assertion, document D18 does not teach that increased ovarian oestrogen secretion was associated with a better outcome in fertility treatment or embryo quality. Instead, document D18 discloses that in its study, no differences in treatment outcome were observed despite increased serum estradiol levels in the "low-dose hCG" group (page 1012, left-hand column, second paragraph, and point 9. above). Therefore, according to the teaching of document D18, hCG supplementation neither affects implantation and pregnancy rates nor is as

effective in stimulating follicles as FSH alone (page 1012, right-hand column, first paragraph).

24. The respondent has further submitted that the paragraph bridging the left and right columns on page 1012 of document D18 would have motivated the skilled person to increase the hCG dose because, according to this paragraph, "[*t*]*he ideal regimen for administration of low-dose hCG*" remained to be optimised. However, the board notes that in the subsequent part of this section of document D18, supplementation with hCG at time points other than concomitantly with FSH is discussed. Hence, in the board's opinion, the "*ideal regimen*" mentioned in this section only relates to the time point of hCG administration and not to its amount.

25. The board accordingly judges that the teaching of document D18 alone would not have provided the skilled person with an incentive to increase the dose of hCG administered in document D18.

26. In a further line of argument, the respondent argued that the common general knowledge as reviewed in documents D13 and A24 would have motivated the skilled person to increase the hCG dose, firstly, since the documents confirmed the effect of hCG on oestrogen secretion, follicle development and development of better embryos and, secondly, since they defined "low-dose hCG", a term also used in document D18, as encompassing 50 to 200 IU of hCG.

27. However, the board is not convinced by this argument, either. Both documents D13 and A24 summarise the results of two separate, independent and mutually exclusive treatment protocols in which hCG is either supplemented from the first day of FSH treatment or

after a week of treatment with FSH alone. As regards concomitant administration of FSH and hCG, both documents report the results of the same publications, documents D11 and D12, in which 50 IU of hCG were administered concomitantly with FSH, with this leading to enhanced oestrogen production and/or follicle growth (see document D13, page 548, left-hand column, second paragraph and Figure 2; and document A24, page 278, left-hand column, second and third paragraph). Thus, these sections of documents D13 and A24 disclose that supplementation with 50 IU of hCG per day is sufficient to achieve the reported effects and hence would not have provided an incentive to further increase the hCG dose.

28. In sections separate from the above, documents D13 and A24 summarise the results of the study of document D3, in which 0, 50, 100 or 200 IU daily hCG were administered from the eighth day of FSH treatment (document D13, page 554; document A24, page 278, left-hand column, last paragraph, and right-hand column, first paragraph; and document D3, Table 1). These hCG amounts are termed "low-dose hCG", and the same term is used in document D18 in the context of both its own treatment protocols and when discussing the protocol disclosed in document A24. However, as set out above (point 27.), documents D13 and A24 disclose that the observed effects of concomitant FSH and hCG administration were already achieved with a dose of 50 IU per day and do not provide any indication that these effects are dose-dependent. Thus, the teaching of documents D13 and A24 would not have prompted the skilled person to increase the hCG dose.

29. Furthermore, there is no evidence that documents D13, D18 and A24 use the term "low-dose" in a more general

sense and not just for the respective amounts administered in each separate treatment protocol. The board observes that the recited hCG doses are all "low" compared to the amounts of hCG administered in each treatment protocol after the gonadotropin treatment phase to trigger ovulation (5,000 to 10,000 IU of hCG; see page 1011, left-hand column, first full paragraph of document D18; page 548, left-hand column, first paragraph of document D13; and page 281, left-hand column, last paragraph of document A24).

30. In view of these considerations, the board holds that from the mere fact that the term "low-dose hCG" is used for 50 and 100 IU of hCG in the context of a first treatment protocol and for 50 to 200 IU of hCG in the context of a second unrelated treatment protocol, the skilled person would not have been motivated to increase the amount of hCG in the first treatment protocol. Thus, the respondent's arguments as regards this aspect do not convince the board.

31. Finally, the respondent argued that document D13 would have provided a further motivation to use doses of hCG within the claimed range since it disclosed on page 549, left-hand column, third paragraph, that "*higher LH activity ovulation induction regimens should be explored to determine the optimal amount and timing*". However, this passage of document D13 relates to the administration of LH in the treatment of a specific disease, hypogonadotrophic hypogonadism, which requires a different treatment protocol than COS. Moreover, there is no indication in this section of document D13 that the amount of LH in the treatment of this disease was correlated with subsequent embryo quality.

32. The board thus equally holds that this passage of document D13 would not have prompted the skilled person to increase the hCG amount in the treatment of COS according to document D18, either.

33. In view of the above considerations, the claimed subject-matter of the main request was not obvious in view of the teaching of document D18 alone or combined with any of the cited documents. It therefore meets the requirements of Article 56 EPC.

34. Claim 2, the sole further claim, is dependent on claim 1, and its subject-matter thus equally involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of claims 1 and 2 of the main request, filed as auxiliary request 4 with the statement of grounds of appeal, and a description to be adapted thereto.

The Registrar: The Chair:

B. ter Heijden B. Claes

Decision electronically authenticated