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**Datasheet for the decision
of 18 September 2015**

Case Number: T 1828/10 - 3.3.01

Application Number: 00939710.0

Publication Number: 1189619

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A61K31/565, A61K31/566,
A61K31/57, A61P15/00

Language of the proceedings: EN

Title of invention:

ADMINISTRATION OF NON-ORAL ANDROGENIC STEROIDS TO WOMEN

Applicant:

Watson Pharmaceuticals, Inc.

Headword:

Kit for a mixed oral and transdermal administration of an
estrogen/androgen combination/WATSON

Relevant legal provisions:

RPBA Art. 15(3)
EPC Art. 56

Keyword:

Oral proceedings - held in absence of appellant
Inventive step - obvious modification

Decisions cited:

T 1704/06, T 0991/07, T 1867/07

Catchword:



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Case Number: T 1828/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 18 September 2015

Appellant: Watson Pharmaceuticals, Inc.
(Applicant) 311 Bonnie Circle
Corona, CA 91718 (US)

Representative: Walker, Ross Thomson
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 17 February
2010 refusing European patent application No.
00939710.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman A. Lindner
Members: G. Seufert
L. Bühler

Summary of Facts and Submissions

- I. The applicant (appellant) lodged an appeal against the decision of the examining division refusing the European patent application No. 00 939 710.0.
- II. The present decision refers to the following documents:
- (1) WO 95/03764
 - (2) US 5,872,114
 - (6) Ph. Sarrel *et al.*, The Journal of Reproductive Medicine, Vol. 43, No. 10, 1998, pages 847 to 856
 - (7) K. Miller *et al.*, Journal of Clinical Endocrinology and Metabolism, Vol. 83, No. 8, 1998, pages 2717 to 2725
 - (8) Ch. Meier *et al.*, Arch. Intern. Med., Vol. 168, No. (1), 2008, pages 47 to 54
- III. The decision of the examining division was based on the set of claims filed with letter of 3 July 2008. The division, starting from document (6) as the closest state of the art, held that the claimed subject-matter did not involve an inventive step. According to the division, the disease to be treated and the target group of patients in the present application were the same as in document (6). Both were concerned with the improvement or prevention of incidences and/or symptoms associated with androgenic steroid deficiency in women having an elevated level of sex hormone binding globulin (SHBG). The effect of the combined administration of estrogen and androgen was also considered to be the same in the present application and in document (6), namely an increase in level of free testosterone. The only difference was seen in the mixed route of administering the estrogen/androgen combination (oral administration

for the estrogen and transdermal administration for the androgen), as opposed to the purely oral administration disclosed in document (6). In the absence of any comparison with the prior art, the examining division considered that the problem to be solved was to provide an alternative way of administering the estrogen/androgen combination. The selection of alternative routes of administration and the adjustment of the required amounts was considered to be a task that the expert in the field routinely accomplished without requiring inventive skills, especially since no unexpected or surprising effect was associated with selecting the transdermal administration of the androgen. Furthermore, the division observed that transdermal administration of androgens was well known in the art, as illustrated in documents (1) and (2), and therefore suitable to achieve therapeutic plasma levels.

- IV. In the statement of grounds of appeal, the appellant maintained the request underlying the decision under appeal as the main request and filed an auxiliary request.
- V. In a communication accompanying the summons to oral proceedings, the board expressed its preliminary opinion. In particular, the board indicated that it agreed with the examining division's choice of the closest state of the art and its formulation of the technical problem. One of the main issues to be discussed in this context at the oral proceedings would be whether transdermal administration of testosterone required any inventive ingenuity in view of the prior art (i.e. documents (1) and (2)). In this context, the board also introduced *ex officio* document (7), which was cited on page 8 of the application and disclosed the treatment of women having an elevated SHBG level via

transdermal administration of testosterone. In addition, the board expressed its concerns as to whether the claimed subject-matter complied with Articles 123(2), 54 and 84 EPC.

VI. In reply to the summons, the appellant filed a new main request and first to fifth auxiliary requests.

Claim 1 of the main request reads as follow:

"1. A kit for the use in reducing, improving or preventing the incidence and/or intensity of symptoms associated with androgenic steroid deficiency in a woman, wherein the woman is receiving oral estrogen supplementation and wherein the woman has an elevated level of sex hormone binding globulin (SHBG) level above 84 nmole/L, the kit comprising a transdermal dosage form of testosterone that administers 50 mcg/day to 3000 mcg/day of testosterone and an estrogen in an oral dosage form."

Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the sex hormone binding globulin level is above "**185 nmole/L**".

Claim 1 of the third auxiliary request is identical to claim 1 of the second auxiliary request.

Claim 1 of the fourth and fifth auxiliary requests is identical and differs from claim 1 of the second auxiliary request in that the estrogen in an oral dosage form is "**conjugated equine estrogen and is administered in an amount of 0.2 to 3.0 mg/day**".

- VII. By fax of 17 September 2015, the appellant informed the board that it would not attend the oral proceedings, which had been scheduled for the following day.
- VIII. The arguments of the appellant, as far as they concern the decisive issues, can be summarised as follows:

Document (6) was not directed to the same target group of patients and therefore was not a suitable starting point for the assessment of inventive step. The purpose of the present invention was to treat women who received estrogen supplementation and had an elevated or substantially elevated SHBG level (84 or 185 nmol/L). As was apparent from the statement on page 849, left column, penultimate paragraph, of document (6), the women to be treated received a two-week supply of placebo tablets between the current estrogen treatment and the subsequent estrogen/androgen treatment. Such a washout period resulted in complete metabolic clearance of steroid hormones. Accordingly, the women in document (6) did not have an elevated or substantially elevated level of SHBG. Furthermore, it was apparent from Table II of document (6) that the maximum SHBG level in the women before the washout period was 11.55 nmole/L, based on the calculation described in document (8), whilst the present invention was directed to the treatment of women with a minimum SHBG level of 84 nmole/L. Moreover, document (6) did not indicate that the administration of testosterone would reduce the SHBG levels in women receiving oral estrogen.

Documents (1), (2) and (7) would not be considered by the person skilled in the art. In particular, he would not readily accept that a different mode of administration would actually work. The dosage form was

a relevant factor and could not simply be ignored. This was apparent from the disclosure on page 2, line 13, to page 3, line 8, of document (1). Moreover, in the context of combination therapy, document (1) taught that the estrogen and androgen were both administered transdermally. Document (2) did not disclose the transdermal delivery of testosterone, but involved the delivery of a steroid precursor, and the issue of ensuring that sufficient quantities were provided had again been overlooked by the examining division. Furthermore, document (2) specifically taught away from orally administering steroids and, therefore, from a therapy that combines oral and transdermal administration, as was apparent from column 6, line 67, to column 7, line 3, and column 18, lines 45 to 49. Neither document (1) nor document (2) provided any teaching or guidance regarding the effect of transdermal testosterone administration on elevated SHBG levels caused by oral administration of an estrogen. They therefore could not provide any reason why the skilled person would substitute the oral administration of methyltestosterone of document (6) with a transdermal administration of testosterone.

Document (7) taught the transdermal administration of testosterone to women with AIDS wasting syndrome. More importantly, it also disclosed that SHBG levels remained the same or were higher after the treatment (Table 2 of document (7)). Hence, the skilled person would have been discouraged from replacing the oral administration of methyltestosterone, which lowered SHBG levels, with the transdermal administration of testosterone. In addition, the passages on page 2718, left-hand column, lines 7 to 10, on page 2723, lines 16 to 25, and on page 2724, left-hand column, lines 13 to 18, would have further led

the skilled person away from transdermally administering testosterone.

- IX. The appellant requested in writing that the decision under appeal be set aside and a patent be granted on the basis of the main request or, alternatively, on the basis of one of the first to fifth auxiliary requests, all filed with letter of 18 August 2015.
- X. At the end of the oral proceedings, which took place as scheduled in the absence of the appellant, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. Non-appearance at oral proceedings before the board
 - 2.1 In response to the board's objections in the communication accompanying the summons to oral proceedings, a new main request and new first to fifth auxiliary requests were submitted. As announced (see point VII above), the appellant did not attend the oral proceedings before the board to which it had been duly summoned. The board therefore had to consider whether it was in a position to decide on these new requests without violating the appellant's right to be heard (Article 113(1) EPC).
 - 2.2 According to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be

treated as relying only on its written case. The explanatory note to this article states that "This provision does not contradict the principle of the right to be heard pursuant to Article 113(1) EPC, since that Article only affords the opportunity to be heard and, by absenting itself from the oral proceedings, a party gives up that opportunity" (CA/133/02 dated 12 November 2002, p. 20).

- 2.3 According to established jurisprudence of the boards of appeal (see T 1704/06, point 7 of the Reasons; T 991/07 point 2 of the Reasons; T 1867/07, point 3 of the Reasons), an appellant who submits amended claims after oral proceedings have been arranged and subsequently does not attend these proceedings must expect that the board may decide that the new claims are not allowable owing to deficiencies, such as lack of novelty or inventive step, "even if the claims had not been discussed before and were filed in good time before the oral proceedings" (see T 1704/06, point 7.6 of the Reasons). This will particularly be the case if an examination of these deficiencies is to be expected. In the present case, the appellant had been informed with the board's communication that inventive step would be one of the main issues at the oral proceedings. In these circumstances, the appellant had to expect that the board would examine and decide on this issue during the oral proceedings.

- 2.4 The board was therefore in a position to take a final decision at the oral proceedings despite the absence of the duly summoned appellant, without violating the appellant's right to be heard.

Main request and first auxiliary request

3. Inventive step (Article 56 EPC)

3.1 Claim 1 of the main request is directed to a kit for the treatment/prevention of incidences and/or intensity of symptoms associated with androgenic deficiency, comprising a transdermal dosage form of testosterone and an estrogen in an oral dosage form. The amount of testosterone that is administered is 50 to 3000 mcg/day. The woman to be treated is receiving oral estrogen and has an elevated level above 84 nmol/L of sex hormone binding globulin (see point VI above).

Incidences or symptoms associated with androgenic deficiencies include sexual dysfunction, which can manifest in loss of sexual desire, decreased sensitivity to sexual stimulation, decreased arousability and capacity for orgasm, diminished vital energy, etc. (see page 13, lines 5 to 13, of the application).

3.2 Contrary to the appellant, the board sees no reason to deviate from the examining division's choice of the closest state of the art (see point III above). Document (6) teaches oral administration of an estrogen/androgen combination in order to ameliorate the symptoms associated with androgenic deficiency, such as sexual dysfunction, in postmenopausal women who, due to estrogen therapy, have an elevated level of SHBG (see page 847, right-hand column, to page 848, left-hand column, "Results" and "Conclusion", in particular the disclosure on page 848, middle of the left-hand column, referring to an increase in free androgen during estrogen/androgen therapy and its beneficial effect on sexual sensations, page 854, right-hand column, lines 9 to 13, and page 854, right-hand column, line 33. to page 855, left-hand column, line 2). The board therefore also concurs with the examining division's findings that

the medical condition to be treated, namely the amelioration of incidences or symptoms associated with androgenic deficiencies, and the target group of patients in the present application, namely women with an elevated SHBG level, are the same as in document (6).

3.3 The board does not accept the appellant's argument that the washout period in the study described in document (6) was a clear sign that this document was not directed to the same target group of patients and therefore was not a suitable starting point for the assessment of inventive step (see point VIII above). The washout period is a sign of good scientific practice and does not change the fact that the targeted patients are women on estrogen therapy who experience inadequate symptomatic relief, including decreased libido and decreased energy levels. Women on estrogen therapy have an elevated SHBG level, as clearly stated in document (6) (see page 854, right-hand column, lines 9 to 13, page 854, right-hand column, line 33, to page 855, line 6). Hence, the target group of patients in document (6) is the same as the target group envisaged by the present application, namely women who receive estrogen supplementation and have an elevated SHBG level, irrespective of whether the actual study has been conducted on patients having been subjected to a washout period.

3.4 In support of its argument that the target group of patients is different, the appellant also referred to Table II of document (6) as evidence that women on estrogen therapy did not, by the mere fact of being on estrogen, qualify as a group of patients that have an elevated or substantially elevated SHBG level. According to the appellant, the maximum SHBG level for these women was 11.55 nmol/L.

3.5 The board notes that the normal level of SHBG according to the application lies at 36 to 185 nmol/L (see page 17, lines 5 to 6). A value of 11.55 nmol/L for the maximum level of SHBG before the washout period - calculated by multiplying $89.6 + 40.2$ (129.8) $\mu\text{gDHT/dl}$ (see Table II, second column, row 3) with a factor 8.896 (see document (8), page 51, figure 1) - would be well below even the normal lower limit. In the board's opinion, this is not credible for women who received estrogen supplementation for an average duration of more than 12 months, in view of the clear disclosure in document (6) that estrogen therapy significantly stimulates synthesis of SHBG and increases SHBG levels (page 854, right-hand column, lines 9 to 13, page 854, right-hand column, line 33, to page 855, left-hand column, line 2). Hence, there are serious doubts as to whether the calculation provided by the appellant is correct. In this context, the board also notes that the value of 11.55 nmol/L (129.8 $\mu\text{gDHT/dl}$) contradicts previous calculations by the appellant indicating that a SHBG level of 48.7 $\mu\text{gDHT/dl}$ (see table II, column 7, row 3) after the washout period corresponded to an SHBG level of 56.64 nmol/L (see point 1.8 of the decision under appeal). The latter is in keeping with the expectation that after an appropriate washout period the SHBG level would return to a more or less normal levels. In addition to the contradictory information provided by the appellant, the board also notes that table II refers to an SHBG $\mu\text{gDHT/dl}$ level. In document (6), the abbreviation DHT stands for dihydrotestosterone (see page 854, right-hand column, lines 13 to 15). Hence, it cannot be excluded that Table II reflects a particular fraction of the SHBG level, which cannot be directly compared with the presently claimed SHBG levels. It is known in the art and has been acknowledged in the

application on page 6, line 29, to page 7, line 11, that SHBG binds a variety of sex hormones.

Hence, the board concludes that Table II of document (6) cannot support the appellant's position that the target group of patients in document (6) and in the present application are different.

- 3.6 The effect to be achieved by the present invention is to increase the amount of free (bioavailable) androgen in order to ameliorate the symptoms associated with androgen steroid deficiency. This is the same effect as envisaged in document (6), as correctly observed by the examining division. Accordingly, the problem to be solved in the light of document (6) is the provision of an alternative route of administration of the estrogen/androgen combination in order to improve and/or prevent symptoms associated with androgen deficiency in women receiving estrogen supplement and having an elevated SHBG level.

The proposed solution is a kit which comprises a transdermal dosage form of testosterone that administers 50 to 3000 mcg/day of testosterone and an estrogen in an oral dosage form.

- 3.7 The board has no reason to doubt that the claimed kit can be used to solve the aforementioned technical problem.
- 3.8 It then remains to be decided whether the proposed solution is obvious in view of the prior art.

The board concurs with the examining division that the selection of an alternative route of administration and the adjustment of the appropriate amount is a routine

task for the person skilled in the art. Furthermore, the teaching of document (6), which is illustrated by administering esterified estrogen and methyltestosterone, is not limited to the use of specific androgens or estrogens. On the contrary, throughout document (6) reference is made to estrogen/androgen therapy in general. No advantages or surprising effects associated with the use of testosterone as the androgen component and its transdermal administration are apparent in the application or have otherwise been demonstrated by the appellant. The selection of testosterone as the androgen component and the transdermal route of administration are neither critical nor purposive and merely represent arbitrary selections of no technical significance. Such selections do not require any inventive ingenuity, in particular taking into account that the transdermal administration of androgens is well known in hormone replacement therapy of postmenopausal women for the purpose of restoring their sexual function (see document (1), claim 1, page 2, lines 1 to 10; document (2), column 7, lines 11 to 16, column 19, third complete paragraph). The adjustment of the amount of testosterone to be administered also lies well within the ordinary skills of the person skilled in the art.

3.9 According to the appellant, the skilled person, when searching for a solution to the technical problem, would have been deterred from replacing the oral administration of methyltestosterone with a transdermal administration of testosterone, because the different modes of administration produced different plasma levels of the drug and metabolites.

3.10 However, the appellant has not provided any evidence to that effect. In particular, there is no evidence at all

that adequate levels of free androgens, particularly of free testosterone, which are responsible for the beneficial effects on sexual sensation and desire, could not have been achieved if the androgen, in the present case testosterone, were administered transdermally instead of orally.

3.11 Furthermore, the appellant argued that the skilled person would not seriously consider replacing the oral administration of the androgen disclosed in document (6) with transdermal administration as taught in documents (1) and (2) and that these documents in fact taught away from the mixed administration as presently claimed (see point VIII above).

3.12 The board does not agree.

The passage on pages 2 and 3 of document (1) on which the appellant relied in this respect discusses the disadvantages of certain dosage forms available for androgen therapy, such as implantable pellets of testosterone or injectable testosterone ester, which do not provide a stable physiological hormonal level. As a solution to overcome these disadvantages document (1) proposes the transdermal administration of testosterone. At best, the aforementioned passage would discourage the skilled person from administering the androgen in the form of pellets or injections. Furthermore, as explained in point 3.8 above, selecting an alternative way of administering the androgen does not require inventive skills. Document (1) merely serves as evidence that transdermal administration of androgens in order to achieve therapeutic plasma levels is technically feasible. Whether this document additionally discloses a transdermal co-administration of estrogen (see claim 5) is irrelevant in this context.

With respect to document (2), the board notes that the passages in column 6, line 67, to column 7, line 3, and column 18, lines 45 to 49, allegedly teaching away from orally administering steroids, refer to the disadvantageous or less preferred administration of the **androgenic steroid**. This is clearly apparent from the respective context, which mentions dehydroepiandrosterone (DHEA) and DHEA derivatives (see column 6, line 65, to column 7, line 3) and sex steroid precursors (column 18). The latter, according to the invention of document (2), is DHEA or a DHEA derivative. Hence, at best, the cited passages teach away from oral administration of the androgenic steroid. The board also notes that oral administration of steroids is not excluded in document (2) (see column 19, third paragraph, column 18, lines 45 to 47), it is merely less preferred for the androgenic steroid. For the sake of completeness, it is also noted that in the context of an estrogen/androgen administration document (2) refers to the possibility of administering the estrogen orally (see column 18, lines 10 to 21). The appellant's argument that document (2) taught away from the oral administration of steroids and consequently from the presently claimed mixed way of administration is therefore not convincing, irrespective of the fact that the androgenic steroid differs from the one presently claimed.

The board further notes that document (7), like documents (1) and (2), is evidence that androgens, in particular testosterone, can be administered transdermally to subjects/patients in need of such substances. In addition, it shows that such an administration increases the level of free testosterone in women with elevated SHBG levels (see table 1 on

page 2719, which reflects the baseline clinical characteristics of women with AIDS). This is the same effect as document (6) and the present application want to achieve. Moreover, document (7) indicates on page 2723, left-hand column, lines 16 to 28, that the increase in free testosterone after transdermal delivery of testosterone was also observed in menopausal women, albeit to a lesser extent. The appellant's argument that document (7) would lead the skilled person away from substituting the oral administration of methyltestosterone in document (6) with the transdermal administration testosterone is therefore not convincing, irrespective of whether or not the mechanism (increasing testosterone levels or decreasing SHBG levels) by which the increase of free testosterone is achieved is the same or not.

Equally unconvincing is the appellant's argument that the passage on page 2724, left-hand column, lines 13 to 20, of document (7) would lead the skilled person away from replacing the oral administration of the androgen in document (6) with a transdermal administration. This passage refers to the difficulty of comparing anabolic effects (i.e. effect on muscle and lean body mass) in women with AIDS with those in postmenopausal women on oral androgen therapy. A prejudice against the transdermal administration of the androgen, as implied by the appellant, is not apparent to the board. It should also be noted that, in the absence of any comparison between the oral administration of the androgen according to document (6) and the presently claimed transdermal administration, alleged but unsupported differences in anabolic effects are not relevant in the assessment of inventive step. Finally, in the board's opinion, the statement on page 2718, left-hand column, lines 7 to 10, indicating that

the delivery of a physiological testosterone dosage is difficult in women, is already disproved by the disclosure of document (7).

3.13 For the sake of completeness, the board also notes the following:

In claim 1 of the main request the elevated SHBG level is specified as being above 84 nmol/L. The board has understood the introduction of this value as a response to the board's clarity objection with respect to the meaning of the term "elevated" or "substantially elevated" (see point 2.4.1 of the board's communication attached to the summons). It has no bearing on the assessment of inventive step as set out in point 3.8 above. In particular, it does not change the fact that the target group of patients is still the same as in document (6). Indeed, it is not even apparent that the presently claimed elevated SHBG level is a distinguishing feature (see point 3.5 above).

3.14 For the aforementioned reasons, the board concludes that the subject-matter of claim 1 of the main request, and, due to its identical wording, also the subject-matter of claim 1 of the first auxiliary request do not involve an inventive step (Article 56 EPC). Consequently, the main request and the first auxiliary request are not allowable.

Second and third auxiliary requests

4. Inventive step

4.1 Claim 1 of the second and third auxiliary requests differs from claim 1 of the main request in that the

woman to be treated has an elevated SHBG level of 185 nmol/L.

- 4.2 As explained in point 3.13 above, the specification of 185 nmol/L replaces the unclear expression "substantially elevated" and has no bearing on the assessment of inventive step. It changes neither the target group of patients nor the formulation of the technical problem to be solved as defined in point 3.6 above. The specification of a higher threshold for the SHBG level, assuming that document (6) does not disclose such levels, cannot support an inventive step, as no particular effect has been shown to be linked therewith. Nor has the appellant provided any arguments - and none are apparent to the board - as to why the skilled person would not consider transdermal administration of the androgen in these circumstances. Accordingly, the same observations and conclusion as in point 3 above apply, with the consequence that the second and third auxiliary requests must also be refused for lack of inventive step (Article 56 EPC).

Fourth and fifth auxiliary requests

5. Inventive step

- 5.1 Claim 1 of the fourth and fifth auxiliary requests differs from claim 1 of main request in that the woman to be treated has an elevated SHBG level of 185 nmol/L and the estrogen dosage is defined as conjugated equine estrogen in an amount of 0.2 to 3.0 mg/day.
- 5.2 As already explained in points 3.13 and 4.2 above the definition of a specific threshold for the SHBG level cannot support an inventive step. Furthermore, no technical benefit as compared with the closest prior art

is linked to use of the presently claimed estrogen or to its combination with testosterone as androgen component. The problem to be solved therefore remains the same as defined in point 3.6 above.

- 5.3 Conjugated equine estrogen is a known estrogen supplement, commercially available under the trade name "Premarin" (see application page 6, line 15) and typically administered in amounts of 0.3 to 2.5 mg/per day per 50 kg of body weight when administered orally (see document (2), column 18, lines 12 to 13 and 18 to 21), which corresponds to the presently claimed dose. Its selection as the oral estrogen to be administered in an amount which is typical for oral administration is neither critical nor purposive. It merely represents an arbitrary selection made from well-known estrogenic hormones such as estradiol, estrone, 17- β -estradiol, esterified estrogen, conjugated equine estrogen, etc., which does not require inventive skills. In this context, the board emphasises again that the teaching of document (6) is illustrated with, but not limited to the use of esterified estrogen. Hence, the introduction of the particular estrogen supplement in the claimed amount has no bearing on the assessment of inventive step given in point 3 above and the same conclusion as drawn in point 3.14 still applies. Consequently, the fourth and fifth auxiliary requests must also be refused for lack of inventive step of the subject-matter of claim 1 (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated