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Datasheet for the decision of 8 May 2018

Case Number: T 0149/15 - 3.3.01

Application Number: 06836341.5

Publication Number: 1937276

IPC: A61K31/568, A61K9/06, A61K47/10, A61K47/14, A61K47/32, A61P15/00

Language of the proceedings: EN

Title of invention:
IMPROVED TESTOSTERONE GEL AND METHOD OF USE

Patent Proprietor:
Unimed Pharmaceuticals, LLC
Besins Healthcare Luxembourg SARL

Opponent:
Oser, Andreas

Headword:
Testosterone gel/UNIMED

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 87, 88, 111(1)
RPBA Art. 12(4)

Keyword:
Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no)
Priority - partial priority (yes) - embodiments in the divisional application do not belong to the prior art
Remittal to the department of first instance (yes)

Decisions cited:
G 0001/15, G 0002/98, T 2213/08, T 0808/09

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0149/15 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 8 May 2018

Appellant: (Patent Proprietor 1)	Unimed Pharmaceuticals, LLC c/o Abbott Laboratories 100 Abbott Park Road, Department 0377, Building AP6A-1 Abbott Park, IL 60064-6008 (US)
Appellant: (Patent Proprietor 2)	Besins Healthcare Luxembourg SARL 67, Boulevard Grande-Duchesse Charlotte 1331 Luxembourg (LU)
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Representative:	Prüfer & Partner mbB Patentanwälte · Rechtsanwälte Sohnckestraße 12 81479 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 January 2015 revoking European patent No. 1937276 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 937 276 was granted with the following independent claims 1, 7 and 8:

"*1. A hydroalcoholic gel pharmaceutical composition comprising:*

i. from 1.50 % to 1.70 % (w/w) testosterone;

ii. from 0.6 % to 1.2 % (w/w) isopropyl myristate;

iii. from 60 % to 80 % (w/w) of an alcohol selected from the group consisting of ethanol and isopropanol;

iv. a sufficient amount of a thickening agent to give the composition a viscosity in excess of 9000 cps; and

v. water.

...

7. The composition according to any of claims 1 to 6, for use in the treatment of hypogonadism in a male subject.

8. Use of testosterone for the manufacture of a composition according to any of claims 1 to 6 for treating hypogonadism in a male subject."

In addition, granted claim 9 reads as follows:

"*9. The composition for use according to claim 7 or the use of claim 8, wherein the subject has a pretreatment serum testosterone concentration less than 300 ng/dl.*"

II. The following documents are referred to in the present decision:

(1) Operating instructions of the programmable rheometer Brookfield DV-II+ Pro EXTRA. Manual No. M/09-166, Brookfield Engineering Laboratories, Inc., pages 1-79

(2) WO 2007/044976

(3) US 6,503,894

(4) WO 2006/027278

(5) WO 02/17926

(12) Declaration of Ramana Malladi dated 26 March 2014

(15a) C. Wang et al., J. Clin. Endocrinol. Metab., 2000, 85(8), 2839-2853

(15b) R.S. Swerdloff et al., J. Clin. Endocrinol. Metab., 2000, 85(12), 4500-4510

III. The patent was opposed on the grounds of Article 100(c), 100(b) and 100(a) EPC, for lack of novelty and inventive step.

IV. The appeal by the patent proprietors (appellants) lies from the decision of the opposition division revoking

the patent. The decision was based on the patent as granted (main request) and five auxiliary requests.

In the decision, the division concluded that the patent as granted did not add subject-matter and that the underlying invention was sufficiently disclosed. However, the composition in granted claim 1 was not novel over some of the formulations disclosed in tables 3, 11 and 22 of document (2), a divisional application of the patent. The formulations in document (2) belonged to the prior art because they enjoyed the priority date of 12 October 2005 while granted claim 1 had no priority right and its effective date was 12 October 2006. For the same reason, the subject-matter in claim 1 of auxiliary requests 3 and 5 was not novel either. In addition, auxiliary requests 1 and 2 added subject-matter and auxiliary request 4 was not admitted into the opposition proceedings.

V. With their statement of grounds of appeal dated 5 June 2015, the appellants filed seven claim sets as auxiliary requests 1 to 7.

VI. The opponent (respondent) replied to the statement of grounds of appeal by letter of 21 October 2015.

VII. In its preliminary opinion, annexed to a summons to oral proceedings, the board concurred with the opposition division that the patent as granted did not add subject-matter and that the underlying invention was sufficiently disclosed. However, on the issue of novelty vis-à-vis document (2), the board considered that, in accordance with G 1/15, granted claim 1 enjoyed the priority of 12 October 2005 for the formulations disclosed in tables 3, 11 and 22 of document (2). Therefore, those formulations did not

belong to the claim's prior art and could not anticipate its subject-matter.

VIII. The appellants' arguments, where relevant to the present decision, may be summarised as follows:

Amendments

The appellants maintained that the composition in granted claim 1 did not add subject-matter because it was supported by the combination of paragraphs [043] and [045] of the application as filed. Additional support could be found in the experimental part of the application, in paragraphs [010] and [023], and in claims 1 and 7 as filed.

Paragraph [043] disclosed a composition comprising 1.15% to 1.8% (w/w) testosterone and the components ii. to v. in granted claim 1. This generic composition was a hydroalcoholic gel, since it contained water and alcohol and had a viscosity of above 9000 cps. In addition, the composition could be combined with the testosterone ranges defined in paragraph [045], which were generally applicable to the invention. One of those ranges was the one in granted claim 1, 1.50% to 1.70% (w/w). An additional basis could be found in the composition used in the method of claims 1 and 7 as filed because, contrary to the respondent's opinion, the application made a direct link between the formulations and the methods according to the invention, for instance in paragraphs [010] and [023], which stated that the invention related to both testosterone gel formulations and methods of use.

With respect to the objection of added subject-matter in relation to granted claim 6 raised in appeal, the

appellants objected to its admission because it was different from the objection raised in opposition and created a fresh case. Thus, even though the two objections were based on an alleged lack of support for granted claim 6 in table 22 of the application as filed, while the objection in opposition had focused on the nature of the alcohol, in appeal it was directed to the expression "obtainable by".

Regarding the substance of the objection, table 22 provided full support for the composition in granted claim 6, which was limited by a list of specific components and their corresponding amounts, leaving no room for variability. Furthermore, table 22 defined not only a composition but also its method of preparation. Therefore, the definition of the composition as obtainable by combining the ingredients in table 22 had to be allowable. In this context, the expression "obtainable by" was equivalent to "obtained by", in accordance with the principles established in T 20/94.

Sufficiency of disclosure

In the appellants' view, the patent contained sufficient information for the skilled person to measure the viscosity of the hydroalcoholic gels according to granted claim 1 and to prepare them. In addition, he could select male subjects with the serum testosterone concentration required in granted claim 9 without undue burden.

On the aspect of viscosity, the appellants stressed that the patent taught in paragraph [035] that the viscosity of the claimed compositions was measured using a Brookfield RV DVII+ viscosimeter with an RV6 spindle, a rotation speed of 10 rpm and a temperature

of 20°C. This information was sufficient to obtain a reliable measure of viscosity, as had been explained in the expert declaration, document (12), and was apparent from the general measuring procedure disclosed on page 20 of document (1) for Brookfield DVII+ viscosimeters. According to that procedure, a 600 ml beaker was filled with the fluid up to the immersion groove on the spindle's shaft. Once the sample had been loaded, the motor was turned on and a time was allowed for stabilisation before reading the viscosity value. In addition, the use of a guard leg was optional and did not affect the correctness of the result obtained, as taught in document (1), page 63, paragraph 4. In conclusion, the essential parameters for measuring viscosity listed in document (1), page 55, that had not been mentioned in the patent in paragraph [035] were clear to the skilled person from the general procedure disclosed in document (1), page 63. So, the skilled person could carry out a reliable measurement with the information provided in the patent. In this context, the appellants noted that the fact that granted claim 1 did not define an upper viscosity limit was not an obstacle to carrying out the invention because the viscosity was limited in practice, as in the case underlying the decision T 2213/08. This lack of upper viscosity limit would not require a change of spindle type since the RV6 spindle was suitable for measuring viscosities within the range 1000 to 2000000 cps, which was appropriate for the gels of the invention, which in the examples in the patent had viscosities of around 25000 cps (see table 4).

Regarding the preparation of the claimed gels, the appellants argued that the amount and type of thickeners that could be used for achieving the viscosities in claim 1 belonged to the skilled person's

general knowledge: thickeners were generally used to increase viscosity and the fact that the range in granted claim 1 was broad made it even easier to prepare a composition fulfilling this condition. Furthermore, the respondent had not provided any proof of the contrary.

Turning to the issue of the selection of male subjects with a pretreatment serum testosterone concentration of less than 300 ng/dl (see granted claim 9), the appellants argued that the patent taught in paragraph [005] that maximum testosterone levels occurred at approximately 6:00 to 8:00 a.m. Thus, the skilled person simply needed to measure the testosterone level within that time period and check whether it was below 300 ng/dl. If that was the case, then the subject belonged to the patient group of granted claim 9. This assessment was normal practice in the identification of hypogonadal men, as shown in documents (15a) and (15b).

Partial priority - novelty over document (2)

Document (2) was a divisional of the application underlying the patent. Therefore, in accordance with the decision G 1/15, if document (2) benefited from priority for certain subject-matter, the patent did so too. Conversely, if the patent did not benefit from priority for certain subject-matter, document (2) could not do so either. Accordingly, the formulations disclosed in document (2) could not belong to the patent's prior art.

In addition, the respondent's argument that granted claim 1 could not benefit from partial priority because the priority application and the patent related to different inventions was wrong; the objective as stated

in paragraph [0009] of the priority application and in paragraph [0011] of the patent was literally the same.

IX. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

Amendments

The respondent argued that granted claim 1 added subject-matter because it did not find a proper basis in paragraphs [043] and [045] of the application as filed. Paragraph [043] disclosed a range of compositions which were not specified as being hydroalcoholic gels and which comprised a broader testosterone concentration range than the one in granted claim 1, namely 1.15% to 1.8% (w/w). The compositions in paragraph [043] had been disclosed as stand-alone embodiments and could not be combined with the testosterone ranges disclosed in paragraph [045], especially taking into account that the ranges in paragraph [045] had not been disclosed as preferred but merely as an anticipation of the ranges provided in the subsequent embodiments in paragraphs [047] to [049].

The method in claims 1 and 7 as filed was not a valid basis either because, in the application, methods and compositions were intended for different purposes. This was apparent from claims 1 to 35 (methods) and 36 to 44 (compositions) as filed. Thus, while the methods aimed to treat hypogonadism, the compositions were intended for transdermal delivery. Hence, a composition disclosed in a method claim could not constitute a basis for a composition claim, in spite of the references to methods and compositions in paragraphs [010] and [023] of the application as filed.

Regarding the objection of added subject-matter in relation to claim 6 raised in appeal, the respondent was of the view that it should be admitted because it was not a new objection but a further elaboration of the arguments already raised in opposition. The argument in both proceedings had been that table 22 in the application as filed was not a valid support for the composition in granted claim 6.

Turning to the substance of the objection, the respondent argued that granted claim 6 added subject-matter due to its dependency upon claim 1 in combination with its expression "obtainable by", which opened the composition in granted claim 6 to the addition of components not specified in table 22 of the application as filed, such as further thickeners or ingredients that assist in reaching the viscosity required in claim 1. In addition, while the alcohol in table 22 as filed was limited to ethanol, the dependency of granted claim 6 upon claim 1 extended the alcohol to ethanol and/or isopropanol. Lastly, the new claim dependency provided the information that the viscosity of the composition in table 22 as filed was higher than 9000 cps, information that had not been made available in the application as filed.

Sufficiency of disclosure

With regard to the viscosity range defined in granted claim 1, the respondent maintained that the patent lacked sufficiency of disclosure in two respects: it did not contain enough information to reliably measure the viscosity of the claimed compositions and it was missing information regarding the type and amount of

thickeners that could be used to reach those viscosities.

Thus, paragraph [035] indicated the viscosimeter, spindle, test speed and temperature that should be used for measuring viscosity. However, the paragraph failed to specify five parameters that, according to document (1), page 55, were essential for measuring viscosities. Those parameters were the sample container size, the sample volume, whether or not to attach the guard leg, the length of time or the number of spindle revolutions to record viscosity, and how the sample was prepared and/or loaded into the container. In the absence of indications regarding these parameters, the skilled person was not able to carry out a reliable measurement of viscosity, as confirmed by decision T 808/09. This was even more true considering that the viscosity range in granted claim 1 had no upper limit, since such a broad viscosity range could not be accurately measured without adjusting the spindle speed or the type of spindle (see document (1), passage bridging pages 72 and 73), operations on which the patent did not provide any information.

On the issue of the amount and type of thickening agents that could give the claimed composition with the required viscosity, the respondent argued that the patent illustrated only formulations containing a combination of 1.0% (w/w) Carbopol 980 with 7.00% (w/w) 0.1N sodium hydroxide (see tables 2, 3, 11 and 22). The skilled person was therefore missing the necessary information to prepare compositions with the required viscosity using thickeners and amounts other than those in the formulation examples.

As a result of this impossibility of reliably measuring viscosities and the lack of information on the amount and type of suitable thickening agents to achieve the required viscosity, the skilled person could not prepare the composition of granted claim 1 without undue burden.

With regard to the selection of male subjects having the pretreatment serum testosterone concentration defined in granted claim 9, the respondent questioned the skilled person's ability to unambiguously determine whether or not a subject belonged to the required group of patients since, as noted in paragraph [005] of the application, the serum testosterone concentration fluctuated during the day. In this respect, the teaching in documents (15a) and (15b) did not help because it did not represent common general knowledge and because it confirmed the problem of measuring serum testosterone levels due to their diurnal variations.

Partial priority - novelty over document (2)

According to the respondent, the case in hand was an exception to which the principle of partial priorities established in G 1/15 could not be applied. This arose from the fact that the assessment of priority and novelty were not governed by the same rules. Thus, while the assessment of priority required an analysis of the teaching in the application (same invention), that of novelty was an analysis of the facts disclosed, and required no consideration of priority.

In that context, the respondent noted that the appellants had not disputed the facts that document (2) disclosed formulations which fell under the scope of granted claim 1 (formulations 41, 48, 51, 53 and 55 in

table 3, formulation 59 in table 11, and the formulation in table 22) and that granted claim 1 as a whole did not benefit from priority. Moreover, the respondent added that granted claim 1 did not benefit from partial priority for the relevant formulations in document (2) either, for the following reasons:

Although the formulations in document (2) had also been disclosed in both the patent and its priority application, the patent and the priority application did not relate to the same invention, as required by Article 87(1) EPC for the acknowledgement of priority. Thus, while the problem in the priority application had been defined as the provision of an improved transdermal hydroalcoholic testosterone gel, especially in terms of viscosity compared with a marketed 1% testosterone gel (see paragraphs [0009], [0045], [0047] and [0048]), the patent did not relate to any improvement. This was apparent from a comparison of the viscosity values in table 4 of the patent for formulation 51 (according to granted claim 1, 20700 cps) with formulation 56 (control, 22033 cps). Hence, as the patent and its priority application did not relate to the same invention, the patent could not benefit from partial priority in the sense of G 1/15.

Thus, taking into consideration that, contrary to the assessment of priority, the examination of novelty did not require a consideration of the invention but merely an analysis of the facts disclosed, the respondent concluded that formulations 41, 48, 51, 53 and 55 in table 3, formulation 59 in table 11, and the formulation in table 22 of document (2) anticipated the subject-matter of granted claim 1.

X. The final requests of the parties were as follows:

- The appellants requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the patent as granted or, alternatively, on the basis of any of the auxiliary requests 1 to 7 filed with the statement of grounds of appeal. The appellants also requested that the objection of added subject-matter raised by the respondent with respect to granted claim 6 not be admitted into the appeal proceedings.

- The respondent requested that the appeal be dismissed or, alternatively, that the case be remitted to the opposition division for further prosecution.

XI. At the end of the oral proceedings, the board's decision was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Added subject-matter - main request (patent as granted)

2.1 Basis of claim 1

Granted claim 1 defines (see point I above) a hydroalcoholic gel pharmaceutical composition comprising the components i. to v., wherein component i. is from 1.50% to 1.70% (w/w) testosterone.

Paragraph [043] of the application as filed discloses a composition with the components i. to v. of granted claim 1 but with a broader testosterone concentration range, namely from about 1.15% to about 1.8% (w/w). The composition is a hydroalcoholic gel, since it contains ethanol and/or isopropanol and water, and has a viscosity in excess of 9000 cps. This becomes even clearer when reading paragraph [010] of the application as filed, which states that the invention relates to an improved transdermal hydroalcoholic testosterone gel, or when reading the experimental part of the application, which gives only hydroalcoholic gels as examples of compositions according to the invention. Thus, the composition in granted claim 1 represents a selection from the range disclosed in paragraph [043], which is characterised by a broader testosterone concentration.

The narrower testosterone concentration range in granted claim 1 may be found in paragraph [045] of the application as filed, which defines three testosterone concentration ranges according to the invention, all of which fall within the range in paragraph [043], namely 1.15% to 1.25%, 1.30% to 1.45% and 1.50% to 1.70%. Considering that paragraph [043] discloses a generic composition with a broader testosterone concentration range, and that paragraph [045] generally discloses testosterone concentration ranges according to the invention without making reference to any particular embodiment, the board considers that the disclosure in paragraph [045] is generally applicable to the compositions of the invention, including those in paragraph [043]. Hence, the composition in granted claim 1 was originally disclosed as the result of a limitation of the testosterone concentration range in

paragraph [043] to one of the alternative ranges proposed in paragraph [045].

This conclusion is reinforced by the fact that the method in claim 7 as filed makes use of a composition identical to that in granted claim 1, and by the statements in paragraphs [010] and [023] of the application as filed that the application relates to both testosterone gel formulations and methods of use.

The board is not persuaded by the respondent's argument that the compositions and methods disclosed in the application belong to different inventions (transdermal delivery vs treatment of hypogonadism) and that therefore the composition used in the method of claim 7 as filed would not be a composition according to the invention. It is manifest, not only from paragraphs [010] and [023] but also from the application as a whole, that the compositions of the invention are to be used in the methods of the invention, since a method of treating hypogonadism by transdermal administration obviously requires a composition with good transdermal delivery properties.

The board therefore agrees with the opposition division and the appellants that granted claim 1 does not add subject-matter (Articles 100(c) and 123(2) EPC).

2.2 Admission of the objection in relation to claim 6

The respondent raised an objection of added subject-matter in relation to granted claim 6 in both opposition and appeal proceedings. In the two cases, the objection disputed that table 22 in the application as filed was a valid support. However, the focus of the objection was different in each of the proceedings.

Thus, while in opposition it had been directed to the nature of the alcohol, in appeal it focused on the dependency of granted claim 6 and its expression "obtainable by".

Taking into consideration that in both proceedings the objection was based on the validity of table 22 as a support, that the opposition division concluded that table 22 indeed supported the composition of granted claim 6, and that the objection in appeal was raised at the earliest possible time in the proceedings (i.e. with the respondent's reply to the statement of grounds of appeal), the board decided not to hold the objection inadmissible (Rule 12(4) RPBA).

2.3 Basis of claim 6

Granted claim 6 is directed to a composition according to any of claims 1 to 5, obtainable by combining the ingredients disclosed in table 22 of the application as filed. This composition recites specific components in specific concentrations which add up to (rounding) 100% (w/w). In addition, the sentence preceding table 22 reads: "*The following table lists the ingredients combined to yield the study formulation used.*" Hence, the application as filed discloses both the composition in table 22 and its method of preparation by combining the listed ingredients. For this reason, the board agrees with the appellants that the application as filed provides a basis for the formulation of a claim defining the composition in table 22 as a product by process, i.e. as a composition "obtainable by" combining the ingredients in table 22.

The board cannot follow the respondent's argument that the claimed composition is open to the addition of

further components to achieve a viscosity in excess of 9000 cps because of its dependency upon claim 1 and its formulation as "obtainable by". As already mentioned, the composition in granted claim 6 is a specific embodiment which reflects the composition in table 22 and consists of concrete substances in amounts that add up to 100%. Moreover, read in the context of the application as filed, which discloses only viscosities in excess of 9000 cps (see paragraphs [035], [043] and [046] and tables 4 and 12, and independent claims 1, 36, 40 and 43), it was evident at the filing date that the composition in table 22 had to have a viscosity of above 9000 cps.

Accordingly, the composition in granted claim 6 does not add subject-matter (Articles 100(c) and 123(2) EPC).

3. Sufficiency of disclosure - main request

3.1 Claim 1

3.1.1 The respondent argued that the skilled person would not be able to prepare the composition in granted claim 1 without undue burden because the patent did not provide sufficient information on the method that should be used for reliably measuring viscosity and because there was only one example of a thickener, at a specific concentration, that would achieve the minimum viscosity defined in the claim. These two aspects are treated separately in points 3.1.2 and 3.1.3 below.

3.1.2 Regarding the issue of whether the patent contains sufficient information for measuring the viscosity of the composition in granted claim 1, the respondent noted that a repeatable viscosity test should specify

the nine parameters cited on page 55 of document (1), namely:

- Test temperature
- Sample container size
- Sample volume
- Viscosimeter model
- Spindle used
- Whether or not to attach the guard leg
- Test speed
- Length of time or number of spindle revolutions to record viscosity
- How sample was prepared and/or loaded into the container

In paragraph [0035], the patent specifies four of these parameters, namely the viscosimeter model (Brookfield RV DVII+), the spindle (RV6), the test speed (10 rpm) and the temperature (20°C). However, it does not give any explicit information on the other five (i.e. sample container size, sample volume, whether or not to attach the guard leg, length of time or number of spindle revolutions to record viscosity, and how the sample is prepared and/or loaded into the container). It therefore has to be investigated whether the skilled person could infer the necessary information on those five parameters from the patent disclosure or from his general knowledge.

It is evident that, once the viscosimeter model is specified in paragraph [0035], the skilled person would turn to its operating instructions for carrying out the measurements. The parties accepted document (1) as a representation of said operating instructions at the filing date, even though the document had no publication date.

Page 20 of document (1) depicts a general procedure for measuring viscosity. In particular, it starts by specifying that a 600 ml beaker is filled with the fluid up to the immersion groove on the spindle's shaft. Accordingly, the information on the viscosimeter and the spindle given in paragraph [0035] of the patent implicitly determines three further parameters: the sample container size (600 ml), the sample volume (up to the immersion groove on the spindle) and how the sample is loaded into container. Regarding the length of time or the number of spindle revolutions to record viscosity, point 10 of the expert opinion, document (12), notes that, when the sample has been loaded and the motor is turned on, there is an initial torque increase for a few seconds until a plateau within the range of 10 to 100 on the viscosimeter scale is reached. This plateau remains for typically several minutes, during which no viscosity change occurs, and it is then that the viscosity value is recorded by the apparatus and translated into cps. This process is reflected in document (1), at the bottom of page 20, which states that time has to be allowed for the reading to stabilise. So, the length of time or the number of spindle revolutions to record the viscosity is easily observed during the measuring process when the other parameters are given and does not need to be specified explicitly. Lastly, according to document (1), page 63, paragraph 4, the use of the guard leg with the RV6 spindle is optional and does not affect the correctness of the result.

In conclusion, the information given in paragraph [0035] of the patent in combination with the operating instructions of the viscosimeter specified therein is sufficient for the skilled person to carry out a

reliable measurement of the viscosity of the composition in granted claim 1.

In this respect, the case underlying the decision T 808/09 cited by the respondent cannot be compared to the one in hand. In T 808/09 (see Reasons, points 2.4.1, 2.4.3 and 2.4.4), the only information given in the application in relation to the measurement of viscosity was the temperature (ambient temperature), while in the case in hand, as discussed above, all the relevant information is provided directly or indirectly.

The board also notes that, contrary to the respondent's opinion, the reproducibility of the formulations in granted claim 1 is not precluded merely because the claim does not define an upper viscosity limit. On this point, the board concurs with the appellants that the viscosities in claim 1 would be limited in practice (see also T 2213/08, Reasons, point 6.2) since the claimed compositions are pharmaceutical gels and cannot have an unlimited viscosity. In this respect, the appellants drew attention to the fact that, according to the manufacturer (see appellants' letter of 26 April 2016, point II.1.35 and table on page 12), the RV6 spindle is suitable for measuring viscosities within the range of 1000 to 2000000 cps. This was not contested by the respondent. Thus, considering that the gels in claim 1 have viscosities above 9000 cps and that those illustrated in the examples in the patent are in the order of 25000 cps (see examples in table 4), it seems unlikely that a change of spindle or any other condition specified in paragraph [0035] of the patent would be needed in order to measure viscosities across the whole scope of claim 1. Moreover, the

respondent has not provided any evidence of the contrary.

The board therefore concludes that the skilled person can measure the viscosity of the composition in granted claim 1 without undue burden.

3.1.3 On the issue of the skilled person's ability to find the type and amount of thickeners that provide compositions as in granted claim 1 with a viscosity in excess of 9000 cps, the board concurs with the appellants that thickeners are well-known compounds and that they are used for increasing the viscosity of liquid compositions, some of which are cited in the patent in paragraph [0032]. In addition, a broad range of these compounds are commercially available and the concentration range at which they are effective is also generally known. Moreover, taking into consideration that claim 1 merely requires a viscosity value of more than 9000 cps, achieving that viscosity cannot represent any undue burden to the skilled person.

In this context, the fact that all the formulations illustrated in the patent were prepared with the same thickener and at the same concentration is not sufficient to raise serious doubts that the skilled person is able to prepare formulations according to claim 1 without undue burden.

3.2 Claim 9

The respondent disputed that the skilled person could identify without undue burden subjects having a pretreatment serum testosterone concentration of less than 300 ng/dl, as required in granted claim 9. The reason for this was the variations in testosterone

levels that occurred during the day. On this issue, the board observes that paragraph [0005] of the patent indeed states that the level of testosterone in young men varies during the day. However, it also teaches that the maximum level is reached at approximately 6:00 to 8:00 a.m. Thus, in order to identify subjects fulfilling the condition of granted claim 9, the skilled person would only need to assess their testosterone levels between 6:00 to 8:00 a.m. and check whether they are below 300 ng/dl. Furthermore, in view of documents (15a) and (15b) (see "Subjects" section in each of them), this appears to be a normal way of proceeding for identifying hypogonadal men.

Accordingly, the skilled person finds sufficient information in the patent to identify the subjects defined in granted claim 9.

3.3 In conclusion, the invention underlying the main request is sufficiently disclosed (Articles 100(b) and 83 EPC)

4. Priority of claim 1 of the main request - novelty over document (2)

Document (2) is a divisional application of the patent in suit which discloses several formulations falling under the scope of granted claim 1, namely formulations 41, 48, 51, 53 and 55 in table 3, formulation 59 in table 11, and the formulation in table 22. As document (2) is potential prior art in the sense of Article 54(3) EPC, it needs to be investigated whether its relevant content belongs to the prior art of granted claim 1, i.e. whether the effective date of the formulations in document (2) is earlier than that of granted claim 1.

The appellants have not disputed the fact that granted claim 1 as a whole has no priority right. However, following the principle of partial priorities established in G 1/15, the claim could still benefit from partial priority for the subject-matter potentially anticipated by document (2).

Decision G 1/15 gives clear instructions regarding the assessment of partial priority in generic "OR" claims. The relevant passage (point 6.4 of the Reasons for the Decision) reads as follows: "*In assessing whether a subject-matter within a generic "OR" claim may enjoy partial priority, the first step is to determine the subject-matter disclosed in the priority document that is relevant, i.e. relevant in respect of prior art disclosed in the priority interval. This is to be done in accordance with the disclosure test laid down in the conclusion of G 2/98 and on the basis of explanations put forward by the applicant or patent proprietor to support his claim to priority, in order to show what the skilled person would have been able to derive from the priority document. The next step is to examine whether this subject-matter is encompassed by the claim of the application or patent claiming said priority. If the answer is yes, the claim is de facto conceptually divided into two parts, the first corresponding to the invention disclosed directly and unambiguously in the priority document, the second being the remaining part of the subsequent generic "OR"-claim not enjoying this priority but itself giving rise to a right to priority, as laid down in Article 88(3) EPC.*"

Applying this principle to the case in hand leads to the result that formulations 41, 48, 51, 53 and 59 and the formulation in table 3 of document (2), which are

also disclosed in the priority document (see table 1 for formulations 41, 48, 51, 53 and 55, table 9 for formulation 59 and table 1.2.2:3 for the composition corresponding to the formulation according to table 22 of document (2)), form a first part of claim 1 of the main request for which the priority date of 12 October 2005 counts as the valid filing date. As a consequence, document (2) does not form prior art according to Article 54(3) EPC for these formulations.

In view of the fact that, according to the passage of G 1/15 cited above, the assessment of partial priority involves a comparison of the **subject-matter** disclosed in the priority document with the **subject-matter** of the generic "OR" claim, the respondent's reasoning that the assessment of priority and novelty are not governed by the same rules does not hold and is in contradiction of decision G 2/98 (OJ EPO 2001, 413), in which the concept of "the same invention" referred to in Article 87(1) EPC is equated with the concept of "the same subject-matter" referred to in Article 87(4) EPC (see point 2 of the Reasons for the Opinion). Moreover, G 1/15 (see point 5.1.2, second paragraph, of the Reasons for the Decision) concludes that the term "element" used in Article 88(3) EPC is to be understood as "subject-matter such as that ... disclosed **in the form of an embodiment or example specified in the description**" [emphasis by the board]. The formulations mentioned above undoubtedly constitute such elements according to Article 88(3) EPC for which partial priority may be claimed.

5. *Remittal*

It follows from the above that the objection leading to the revocation of the patent has been overcome and the

decision under appeal is to be set aside. However, the opposition division has examined neither the novelty of the subject-matter of the granted claims vis-à-vis documents (3) to (5) nor its inventive step. In order for these and other potential issues to be examined, and taking into account that both parties requested remittal, the board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the opposition division for further prosecution on the basis of the patent as granted (main request).

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 for further prosecution.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated