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Datasheet for the decision of 16 September 2025

Case Number: T 1402/24 - 3.3.07

Application Number: 16172415.8

Publication Number: 3103443

IPC: A61K9/20, A61K31/4045, A61P25/20

Language of the proceedings: EN

Title of invention:
METHOD FOR TREATING PRIMARY INSOMNIA

Patent Proprietor:
NEURIM PHARMACEUTICALS (1991) LIMITED

Opponents:
Generics (U.K.) Limited (former opponent)
Orifarm Generics A/S
Hamm&Wittkopp Patentanwälte PartmbB

Headword:
Method for treating primary insomnia / NEURIM

Relevant legal provisions:
EPC Art. 113(1), 54(2)
RPBA 2020 Art. 12(6)

Keyword:
Right to be heard - violation (no)
Novelty - (no)
Late-filed request - admitted in first-instance proceedings (no) - admitted (no)

Decisions cited:
T 1019/22, G 0001/24, T 2027/23

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Case Number: T 1402/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 September 2025

Appellant: (Patent Proprietor)	NEURIM PHARMACEUTICALS (1991) LIMITED 8 Hanechoshet Street Tel Aviv 69710 (IL)
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Respondent: (Opponent 3)	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 9 December 2024 revoking European patent No. 3103443 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent in suit (hereinafter "the patent").

The decision, announced at the end of the oral proceedings on 24 October 2024 and issued in writing on 9 December 2024, was based on the patent as granted as the main request, on auxiliary request 1 filed during the oral proceedings on 24 October 2024, and on auxiliary requests 2-7 filed (as auxiliary requests 1-6) on 23 August 2024.

II. Claim 1 of the main request read as follows:

"Use of at least one compound selected from melatonin in an effective amount within the range of 0.0025 to 50 mg, in the manufacture of a medicament for improving the restorative quality of sleep, in a patient suffering from primary insomnia characterized by non-restorative sleep, wherein the medicament is a prolonged release formulation and comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifier adjuvant or carrier."

Claim 1 of the auxiliary requests differed from claim 1 of the main request as follows:
- auxiliary request 1: the patient suffers from primary insomnia characterized by non-restorative sleep alone.
- auxiliary request 2: the patient suffers from primary insomnia characterized by non-restorative sleep as defined by DSM-IV or ICD-10.

- auxiliary request 3: the patient suffers from primary insomnia characterized by non-restorative sleep as defined by DSM-IV.
- auxiliary request 4: the patient is 55 years and older.
- auxiliary request 5: the patient is 55 years and older, and the amount of melatonin is 2 mg.
- auxiliary request 6: the patient is 55 years and older and suffers from primary insomnia characterized by non-restorative sleep as defined by DSM-IV.
- auxiliary request 7: the patient is 55 years and older and suffers from primary insomnia characterized by non-restorative sleep as defined by DSM-IV, and the amount of melatonin is 2 mg.

III. The following documents are relevant to the present decision:

D15: Haimov I et al "Melatonin replacement therapy of elderly insomniacs", Sleep, vol. 18, no. 7, 1995, pages 598-603
D20: "Annex I Summary of Product Characteristics", European Medicines Agency, 19 June 2012, pages 1-10, Retrieved from the Internet: URL: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-ProductInformation/human/000695/WC500026811.pdf
D27: "Guideline on medicinal products for the treatment of insomnia", 17 February 2011, pages 1 -21, XP055465468, Retrieved from the Internet: URL: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_ guideline/2011/02/WC500102351.pdf
D41: "Diagnostic and statistical manual of mental disorders" AMERICAN PSYCHIATRIC ASSOCIATION, 1994, pages 22, 23 and 553-557

D42: "The ICD-10 Classification of Mental and Behavioural Disorders", World Health Organization, 1992, pages 32 and 182-184
D50: Arendt J (co-ordinator) "In what circumstances is melatonin a useful sleep therapy? Consensus statement, WFSRS Focus Group, Dresden, November 1999", J. Sleep Res. (2000) 9, 397-398
D66: Sleep Management in Nursing Practice, Eds. Morgan & Closs, Churchill Livingstone, 1999, preface and pages 69-75
D81: P. J. Hauri, "Insomnia", Sleep disorders, vol. 19, no. 1, March 1998, pages 157-168
D89: Sadeh et al., (1995), “The role of actigraphy in the evaluation of sleep disorders”, Sleep, 18(4): 288-302

IV. The opposition division decided the following:

(a) The term "improving the restorative quality of sleep" was interpreted broadly as an improvement in any sleep parameter, including ease of falling asleep or staying asleep i.e. a holistic impression of all aspects of sleep, rather than an improvement in quality of sleep in the restricted sense of the diagnostic criteria i.e. treating non-restorative sleep (NRS). Accordingly, the subject-matter of the main request was not novel over D15.

(b) Auxiliary request 1 was not admitted into the proceedings.

(c) The subject-matter of auxiliary requests 2-7 also lacked novelty over D15.

(d) In an "Obiter Dictum, not part of the reasons for the present decision", the opposition division

expressed the view that the requirements of sufficiency of disclosure were not fulfilled for the main request as far as relating to the patient group younger than 55 years.

V. The appellant lodged their appeal against the above decision on 28 October 2024.

VI. Opponent 1 withdrew their opposition during the appeal proceedings on 16 January 2025. The sole remaining parties, apart from the appellant, are respondent-opponent 2 and respondent-opponent 3.

A request that the appeal proceedings be accelerated in view of pending national proceedings was presented by (former) respondent-opponent 1 on 25 November 2024. The Board informed the parties that the appeal proceedings were accelerated pursuant to Article 10(3) RPBA, and refused the appellant's request dated 20 December 2024 for a postponement of the oral proceedings. After the withdrawal of the opposition of (former) respondent-opponent 1, the appellant requested that the acceleration by cancelled, and respondent-opponent 2 requested that the acceleration be maintained. In a communication dated 12 March 2025 the Board informed the parties that it maintained the acceleration of the proceedings.

VII. With their statement setting out the grounds of appeal, the appellant defended their case on the basis of the same main request and auxiliary requests 1-7 as underlying the appealed decision.

VIII. The Board set out their preliminary opinion in a communication under Article 15(1) RPBA.

IX. Oral proceedings were held before the Board on 16 September 2025.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, alternatively, that auxiliary request 1 be admitted into the proceedings and that the patent be maintained on the basis of that request, or that the patent be maintained on the basis of one of auxiliary requests 2-7.

The appellant further requested that the Board disregard the *obiter dictum* comments on sufficiency of disclosure on pages 25-29 of the impugned decision, and submitted that these comments violated the appellant's right to be heard.

XI. Respondents-opponents 2 and 3 both requested that the appeal be dismissed, and that auxiliary request 1 not be admitted into the proceedings.

XII. The appellant's arguments relevant to the present decision may be summarised as follows:

(a) Obiter Dictum
The *obiter dictum* on sufficiency of disclosure in the appealed decision violated the appellant's right to be heard, because it deviated from the opposition division's preliminary opinion, had a direct influence on the legal dispute and contained part of the finding on which the decision was based (i.e. claim interpretation).

(b) Claim interpretation

The claims contained explicit requirements for "improving the restorative quality of sleep, in a patient suffering from primary insomnia characterized by non-restorative sleep". Non-restorative sleep was an independent symptom of primary insomnia, which patients may or may not suffer, as evidenced by the skilled person's common general knowledge. "Improving the restorative quality of sleep" had to be interpreted as relating to the same non-restorative sleep symptom and could only be assessed subjectively by asking the patient. The claims thus required the attainment of the treatment effect on the specific symptom of non-restorative sleep.

(c) Novelty

D15 did not disclose any way of measuring an impact on non-restorative sleep, since it used actigraphy which was an objective measurement performed while the patient was asleep, and so could not assess how a patient felt. Furthermore, D15 was a study carried out on patients that did not have primary insomnia, because these patients did not satisfy criterion (C) of DSM-IV.

(d) Admittance of auxiliary request 1

The opposition division should have admitted auxiliary request 1 into the opposition proceedings because this auxiliary request was directly responsive to the division's new claim interpretation that the patentee/ appellant became aware of for the first time at the oral proceedings.

XIII. The arguments of the respondents-opponents may be summarised as follows:

(a) Obiter dictum

The obiter dictum relating to sufficiency of disclosure in the appealed decision was well substantiated and based on submissions made earlier by the parties.

(b) Claim interpretation

The claims were to be interpreted according to the broader/holistic interpretation adopted by the opposition division, that is, they should be construed as directed to the treatment of primary insomnia.

(c) Novelty

D15 disclosed the treatment of patients with 2 mg controlled release melatonin as claimed. These patients satisfied all criteria (A)-(E) of D41 and thus suffered from primary insomnia as defined by DSM-IV (D41). D15 showed that melatonin resulted in a reduced activity level and hence that the patients' sleep was more restful and of higher quality.

Even if a narrow interpretation of claim 1 was adopted, D15 still anticipated the claimed subject-matter, because non-restorative sleep could be measured using an actigraph. D15 stated that the actigraphy measurements were used to determine subjective sleep quality.

(d) Admittance of auxiliary request 1

The appealed decision did not suffer from any error in the use of discretion to not admit auxiliary request 1, and was not to be set aside by the Board under Article 12(6) RPBA. Auxiliary request 1 was filed late, and the

subject of the proceedings had not changed. The introduction of the term "alone" from the background description was not allowable in view of Article 123(2) EPC.

Reasons for the Decision

1. Allegation of procedural violation

The appellant contends that the *obiter dictum* on sufficiency of disclosure in the appealed decision violates their right to be heard, because it deviates from the opposition division's preliminary opinion, has a direct influence on the legal dispute and contains part of the finding on which the decision is based (i.e. claim interpretation).

Article 113(1) EPC provides that the decisions of the EPO may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. In this case, the appealed decision is based essentially on a given claim interpretation (§1.1) and an ensuing lack of novelty (§1.3). The decision is not based on the reasoning of insufficiency of disclosure given in the *obiter dictum*. The appellant's right to be heard is hence not violated by the *obiter dictum*, irrespective of whether the appellant had the opportunity to comment thereon or of whether the reasoning in the *obiter dictum* would be sufficient. Contrary to the appellant's view, the *obiter dictum* does not contain part of the finding on which the decision is based, i.e. claim construction, since this finding on claim construction is part of the actual decision (§1.1) rather than the *obiter dictum*. The appellant's argument that the *obiter dictum* is

inappropriate due to its possible influence on separate legal disputes before national courts finds no support in T 1019/22 (see points 33.3-33.6 of the reasons).

The Board concludes that the opposition division did not commit a procedural violation.

2. Claim interpretation

2.1 The invention relates to melatonin for use in the treatment of primary insomnia when characterized by non-restorative sleep.

Claim 1 of the main request is drafted as a Swiss-type claim. It pertains to the use of melatonin in the manufacture of a medicament for a specific therapeutic indication, namely "for improving the restorative quality of sleep", and in a defined patient, namely "in a patient suffering from primary insomnia characterized by non-restorative sleep". Claim 3, drafted in the format of Article 54(5) EPC, essentially relates to the same subject-matter.

2.2 A main point of debate is how to interpret the claims. Following G 1/24, the claims are the starting point and the basis for assessing the patentability of an invention under Articles 52 to 57 EPC. The description and drawings shall always be consulted to interpret the claims when assessing the patentability of an invention under Articles 52 to 57 EPC. The Enlarged Board of Appeal otherwise referred to the existing body of case law from which the applicable principles of claim interpretation can be extracted (see point 10 of the reasons).

2.3 Primary insomnia is characterised on page 553 of the manual D41 (i.e. DSM-IV, cited and quoted in paragraphs [0001] and [0003]-[0005] of the patent) as follows:

"Diagnostic Features
The essential feature of Primary Insomnia is a complaint of difficulty initiating or maintaining sleep or of nonrestorative sleep that lasts for at least 1 month (Criterion A) and causes clinically significant distress or impairment in social, occupational, or other important areas of functioning (Criterion B). The disturbance in sleep does not occur exclusively during the course of another sleep disorder (Criterion C) or mental disorder (Criterion D) and is not due to the direct physiological effects of a substance or a general medical condition (Criterion E)."

While the guidelines D42 (i.e. ICD-10, also cited in the patent) use a different terminology, it was common grounds between the parties that they are synonymous:

"F51.0 Nonorganic insomnia
[...]
Diagnostic guidelines
The following are essential clinical features for a definite diagnosis:
(a) the complaint is either of difficulty falling asleep or maintaining sleep, or of poor quality of sleep;
(b) the sleep disturbance has occurred at least three times per week for at least 1 month;
(c) there is preoccupation with the sleeplessness and excessive concern over its consequences at night and during the day;

(d) the unsatisfactory quantity and/or quality of sleep either causes marked distress or interferes with ordinary activities in daily living."

2.4 Thus, the common general knowledge reflected in documents D41 and D42 indicates that primary insomnia (or nonorganic insomnia in D42) may or may not be characterised by non-restorative sleep (i.e. poor quality of sleep in D42), which is a symptom separate and different from difficulty initiating sleep (falling asleep) or maintaining sleep. It can be understood from D42 that difficulties falling asleep or maintaining sleep pertain to the quantity of sleep, as opposed to the (restorative) quality of sleep. The patient defined in claim 1 is accordingly a patient suffering from primary insomnia characterised by "non-restorative sleep" in the sense of D41 or D42.

Furthermore, the therapeutic indication is defined in claim 1 as the improvement of "the restorative quality of sleep" in patients suffering from non-restorative sleep. The therapeutic indication is thus not defined using the identical expression "non-restorative sleep". Instead, it uses the term "restorative quality of sleep", which does not as such appear in the prior art. Nonetheless, in the Board's view, within the same claim and in this logical context, the term "restorative" must consistently be given the same meaning. Accordingly, the expression "improving the restorative quality of sleep" should not be given a broader meaning covering improvement in any sleep parameter, including ease of falling asleep or staying asleep.

The features "restorative quality of sleep" and "non-restorative sleep" thus relate to the same specific parameter, and "improving the restorative quality of

sleep" means improving the symptom of non-restorative sleep. In other words, the Board does not agree with the holistic approach advocated by the respondents, and shares the appellant's opinion on this point.

2.5 However, the Board disagrees with the appellant regarding the actual interpretation of the expression "non-restorative sleep".

In the appellant's view, and based on D41 in particular, this symptom is a feeling and can only be measured subjectively by asking the patients for their feelings using certain questionnaires, as in examples 2 and 3 of the patent.

2.5.1 D41 contains the following statement on page 553 of D41, which the appellant regards as a definition of the expression "non-restorative sleep":

> "Individuals with Primary Insomnia most often report a combination of difficulty falling asleep and intermittent wakefulness during sleep. Less commonly, these individuals may complain only of nonrestorative sleep, that is, feeling that their sleep was restless, light, or of poor quality."

In the Board's view, the use of the word "feeling" in the above passage is compatible with the fact that the sentence relates to the complaint of the individuals. In other words, the passage equates a complaint of non-restorative sleep to a feeling that the sleep was restless, light, or of poor quality. This does not mean that a "non-restorative sleep" itself is a mere feeling. Rather, "non-restorative sleep" relates to a quality of the sleep period itself, namely whether the sleep was "restless, light, or of poor quality", and is

not limited to the patient's feeling about that quality.

The fact that D41 distinguishes non-restorative sleep in criterion A from daytime functioning in criterion B does not support the appellant's view that "non-restorative sleep" is a subjective feeling as opposed to the objective daytime functioning. These criteria differ in that "non-restorative sleep" characterises the sleep period, whereas criterion B concerns the daytime consequences of sleep quantity and/or quality.

2.5.2 The appellant further relied on the examples in support of their interpretation.

In examples 2 and 3 of the patent, the effect of a prolonged-release melatonin formulation was subjectively assessed by asking the patients:
- a question on quality of sleep ("How would you compare the quality of sleep using the medication with non-medicated (your usual) sleep?"), with results marked on a scale going from "more restless than usual" to "more restful than usual", and
- a question on waking state ("How do you feel now?"), with results between a "tired" and an "alert" endpoints.

It is however established case law that, for the purposes of judging novelty and inventive step, the description cannot be relied on to read into the claim an implicit restrictive feature not suggested by the explicit wording of the claim. This principle holds true in light of G 1/24, as explained in T 2027/23 (see points 3.5.2 to 3.5.6 of the reasons): a claim should not be interpreted, based on features set out in embodiments of an invention, as having a meaning

narrower than the wording of the claim as understood by the person skilled in the art.

In the present case, claim 1 does not contain any feature regarding the method for measuring the restorative quality of sleep. It follows from the above that the expressions "restorative quality of sleep" and "non-restorative sleep" refer to a quality of sleep and not to a feeling regarding this quality, and that these expressions do not imply any limitation as to the method for measuring this quality. Examples 2 and 3 of the description cannot be used to give a different, more restrictive meaning to these claim features.

2.5.3 Lastly, beside D41 and the examples of the patent, the appellant relied on D81, D89, D27 and D66.

However, these documents essentially discuss the methods for determining the restorative quality of sleep, but do not contain any definition of the expression "non-restorative sleep". As explained above, claim 1 does not contain any limitation as to the method for measuring the restorative quality of sleep. In addition, the Board does not consider that the documents cited by the appellant establish that only subjective, questionnaire-based methods can be used to measure this quality. On the contrary, the indication in e.g. D89 (see the discussion below) that objective measurement methods such as actigraphy are suitable for the assessment of sleep quality support the view that the restorative quality of sleep is not a mere feeling.

Thus, the European Medicines Agency Guidelines D27 indicates on page 9 (see §5.2.2.a)) that the tool chosen in these Guidelines for the assessment of subjective feelings is sleep questionnaires. This does

not mean that the assessment of restorative quality *per se* cannot be done using other tools. On the contrary, D27 states on the previous page (see §5.1.2) that sleep laboratory studies and actigraphic methods can be useful. The "poor relationship between objective and subjective measures of sleep disturbance" mentioned in D27 is not relevant since claim 1 is not limited to subjective measures.

D81 mentions objective measurement methods such as actigraphy among the tools for the evaluation of insomnia (see page 161). The mention that "wrist actigraph is not a very accurate tool to assess total sleep time" says nothing about the evaluation of sleep quality using actigraphy. In addition, the relative lack of accuracy of a measurement method does not altogether prevent this method from being used.

The article D89 concludes that actigraphy "can be used to distinguish between wakeful and sleep states, with wide margins of error for subjects lying awake motionless (e.g. insomnia patients)" (see page 300). However, this limitation of actigraphy is obviously not seen as a bar to its use for assessing the quality of sleep, considering the statement in the same article that "actigraphy provides useful measures of sleep-wake schedule and sleep quality" (see the summary on page 288; emphasis added by the Board).

Lastly, the textbook D66 states on page 74 that "As regards sleep quality, it should be emphasised that the experience of sleep is accessible only to the individual sleepers. Only they know whether their sleep has been restful and refreshing. In addition, criteria for a 'good night's sleep' are also, to some extent, personal. Whether individuals sleep for 2 hours per

night, or for 10 hours per night, if they awake, satisfied with their sleep quality, and can function efficiently during the day, then their sleep may be considered satisfactory (or normal for them)". This passage discusses sleep quality generally in the sense of experience of sleep and resulting daytime functioning. D66 does not convincingly show that the restorative quality of sleep in the sense of claim 1 should be understood as being limited to its subjective experience.

2.6 In conclusion, the therapeutic indication defined in claim 1, namely of "improving the restorative quality of sleep", is construed as relating to an improvement in respect of the specific symptom of non-restorative sleep, which is separate from sleep quantity and from the ensuing daytime functioning. A "non-restorative sleep" is understood as a sleep which is restless, light, or of poor quality. However, this term is not limited to the patient's subjective perception of that quality, and does not imply any limitation as to the method for measuring this quality. In particular, measurement tools such as actigraphy, which is considered in the prior art, are not excluded by claim 1.

3. Novelty over D15

3.1 Document D15 reports on a study investigating the effect of melatonin treatment on melatonin-deficient elderly insomniacs (see page 598, summary and column 2, third paragraph; page 599, column 1, "Subjects"). The authors found that melatonin, administered in the form of sustained-release tablets containing 2 mg melatonin (i.e. a formulation as defined in claims 1 and 3) improved sleep maintenance. Furthermore, long-term

treatment with sustained-release melatonin (1 mg) was effective in both initiating and maintaining sleep (see page 602).

3.2 According to the appellant, D15 neither discloses the treatment of the subjectively-determined "non-restorative sleep" nor the treatment of patients with primary insomnia.

3.2.1 Regarding the therapeutic indication, D15 does not contain any explicit mention of the "restorative" quality of sleep. D15 nonetheless reports that the activity level of the test subjects during sleep was determined by actigraphic measurements translating wrist movements into an electrical signal which was analysed to determine "mean activity level (the mean sum of actigraphic movements recorded during sleep divided by sleep duration). Activity level during sleep can be viewed as an index of the restfulness of the sleep period" (see the paragraph bridging pages 599 and 600). In addition, a comparison between patients with or without sleep disorders before treatment with melatonin was carried out to "validate the subjective sleep quality" (see the beginning of the section "Results" on page 600). The study further revealed that significantly higher sleep efficiency and lower activity level were achieved in the insomniac groups with both sustained-release melatonin treatments in comparison with placebo (see the 2nd paragraph of the right-hand column on page 600, Figure 1 and Table 2).

In the Board's view, these lower activity levels and hence improved restfulness of the sleep period amounts to "improving the restorative quality of sleep" in the sense of claim 1. The restful quality of sleep is explicitly mentioned as part of the definition of a

non-restorative sleep in D41. It follows that D15 discloses the efficacy of a melatonin composition as claimed for improving the restfulness of the sleep period and thus for improving the restorative quality of sleep.

Considering the Board's interpretation of "restorative quality of sleep" as not limited to a feeling, it is not necessary to assess whether D15 discloses any improvement as to subjective sleep quality.

3.2.2 Regarding the patient group, the Board agrees with the respondents that the elderly insomniacs of D15 qualify as primary insomnia patients.

According to the appellant, D15 suggests that the efficacy of melatonin is mediated via circadian effects, and that the subjects of D15 thus fail to comply with criterion C of D41 (see the grounds of appeal, page 46-51). Criterion (C) of D41 mandates that "The disturbance in sleep does not occur exclusively during the course of another sleep disorder".
This argument is not convincing, because D15 does not identify the patients studied therein as suffering from circadian rhythm disorders (which include types such as jet lag, shift work and delayed sleep types, see D41, page 555). The only mention of circadian rhythm disorders in D15 is in relation to other studies on the effect of melatonin in the prior art (see the background introduction on page 598, left column). On the contrary, D15 explicitly indicates that any "significant sleep apnea syndromes which could be related to physiologically based insomnia, or any medical illness that might interfere with sleep" were ruled out in the subjects (see the sentence bridging the left and right columns on page 599). This sentence

thus explicitly discloses that the patients met criterion (C) of D41. The fact that the elderly patients in D15 suffered from melatonin-deficient insomnia or that the treatment was viewed as a melatonin replacement therapy (see page 602, left, second paragraph) does not contradict this conclusion, as there is no suggestion that age related decrease in endogenous melatonin production as such amounts to "another sleep disorder" in the sense of criterion (C). On the contrary, this working hypothesis is the same as in the summary of product characteristics (SmPC) of Circadin®, the appellant's medicinal product falling within the scope of the present claims (see document D20, page 2, "Therapeutic indications", and page 7, "Rationale for use").

The appellant does not contest the finding that all other criteria of D41 are met by the patients of D15 (see the appealed decision, §1.3.1.3 on page 17; see also the letter of respondent-opponent 2 dated 5 June 2025, pages 17-18 and 63-65, the letter of respondent-opponent 3 dated 12 June 2025, pages 12 and 15-16; see the appellant's grounds for appeal, page 38, paragraph [115]).

The appellant sought to cast doubt on the credibility of D15 by referring to D50. This later review D50 expresses the view that "Evidence that melatonin can be useful in the treatment of insomnia in older people is inconsistent", citing not only D15 but also another article (see the paragraph bridging pages 397 and 398). However, this does not call into question the data and results disclosed specifically in D15 nor contradict the fact that the disclosure of D15 anticipates the claimed subject-matter.

3.3 Accordingly, the claimed subject-matter lacks novelty over D15.

4. Auxiliary requests

4.1 Admittance of auxiliary request 1

4.1.1 The appellant filed auxiliary request 1 during the oral proceedings before the opposition division. Claims 1 and 3 of auxiliary request 1 differ from claims 1 and 3 as granted (i.e. of the main request) in that the patient is defined to suffer from primary insomnia characterized by non-restorative sleep alone.

The opposition division did not admit auxiliary request 1 into the proceedings because it was filed late, and the subject of the proceedings did not change, and because it was not clearly allowable (see the appealed decision, §1.4.3).

4.1.2 Under Article 12(6) RPBA, the Board shall not admit requests which were not admitted in the proceedings leading to the decision under appeal, unless the decision not to admit them suffered from an error in the use of discretion or unless the circumstances of the appeal case justify their admittance.

4.1.3 The appellant maintains that they could not have reasonably expected that the opposition division would have arrived at an interpretation that all primary insomnia patients have non-restorative sleep. The Board does not share this view, because this interpretation had already been put forward by respondent-opponent 3 as early as with their notice of opposition dated 9 February 2022 (see page 9 under the heading "3.1 Claim interpretation"): "Any treatment of primary

insomnia aims at improving the restorative quality of sleep, because insomnia is commonly characterized by non-restorative sleep (HW1 [D67 (=D41)] and HW2 [D77]). The granted claims are *not* restricted to those patients who complain *only* of non-restorative sleep". Hence auxiliary request 1 could and should have been filed already in response to the oppositions. The filing of this request only at the oral proceedings was accordingly late.

4.1.4 With regard to *prima facie* allowability under Articles 76(1) and 123(2) EPC, the appellant rightly underlined that a case-by-case analysis of the structure and content of the description was necessary in order to come to a conclusion for a particular case (see the Case Law of the Boards of Appeal, 11th edition, 2025, II.E.1.11.3). Here, the appellant relies on page 1, third paragraph of the (earlier) application as filed. This passage states that, according to the definition of primary insomnia in the DSM-IV (i.e. D41), "The predominant complaint is difficulty initiating or maintaining sleep, or non-restorative sleep, for at least one month [...]. Furthermore, according to the definition, non-restorative sleep alone is sufficient to establish the diagnosis of primary insomnia, providing it results in impaired daytime functioning".

The Board shares the opposition division's reservations regarding added subject-matter. This paragraph appears under the heading "Background to the invention" and relates to the establishment of the diagnosis of primary insomnia according to DSM-IV (D41), but is not meant to characterise the claimed therapeutic indication or patient group. Paragraph [0001], describing generally the invention as pertaining to the treatment of "primary insomnia (as defined by DSM-IV

[...])" does not establish a link with the diagnosis based solely on non-restorative sleep of paragraph [0003].

4.1.5 In addition, the amendment also gives rise to the question whether the requirements of support of Article 84 EPC are fulfilled. This is because the patent does not contain any instance of a patient suffering from non-restorative sleep alone. In fact, it is common ground between the parties that the primary insomnia patients studied in the patent were not selected for any predominant complaint and thus were not selected as suffering only from non-restorative sleep.

In view of the above the Board does not consider that the opposition division exercised its discretion according to the wrong principles or in an unreasonable way. The circumstances of the appeal case do not justify that the decision of the opposition division to not admit auxiliary request 1 be overruled.

Accordingly, auxiliary request 1 was not admitted into the appeal proceedings.

4.2 Auxiliary requests 2-7

Claims 1 and 3 of auxiliary requests 2-7 differ from claims 1 and 3 of the main request in that:
- the patient is defined to suffer from primary insomnia characterized by non-restorative sleep "as defined by DSM-IV or ICD-10" or "as defined by DSM-IV", and/or
- the patient is defined to be "55 years and older", and/or
- the amount of melatonin is defined to be 2 mg.

None of these limitations establish any differentiating feature over D15 (see 3.1). The teaching of D41 (DSM-IV) was already taken into account in the context of the main request. The patients in D15 are elderly insomniacs aged 73.1 ± 3.9 years (see page 599, left column) and the slow-release composition of D15 contains 2 mg melatonin.

Accordingly, none of the auxiliary requests 2-7 meet the requirement of novelty.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated