

UPC_CFI_1587/2025

Decision of the Court of First Instance of the Unified Patent Court

Central Division - Milan section

issued on 09 October 2026

concerning EP 4223296

Headnotes:

1. The party alleging added matter must identify, by means of a specific comparison, the subject-matter of the original disclosure that is said to have been extended in the later application or divisional patent. The mere fact that the original application contains numerous embodiments and theoretically allows a very large number of combinations does not establish added matter. Although this may raise issues of clarity or drafting technique, an extension of subject-matter arises only where the granted claim conveys technical information that the skilled person could not derive directly and unambiguously from the application as filed, contrary to Articles 123(2) and 138(1)(c) EPC. Procedural fairness under recital 5 of the Preamble to the RoP requires each party to plead its grounds of challenge clearly and with sufficient specificity. The Court can neither cure deficiencies in those grounds nor supplement them of its own motion, since doing so would substitute the Court for the challenging party and compromise its impartiality.

2. Where the alleged contribution to the art lies in the identification of a physiologically or pathologically distinct patient subgroup, the patent must provide sufficient technical information to identify that subgroup and to make it credible that the medicinal product is suitable for the claimed therapeutic use in that subgroup. In that context, the precise therapeutic dosage need not be stated in the independent claim, provided that the skilled person, on the basis of the patent, the prior art and common general knowledge, can select a safe and effective dose without undue burden in the exercise of their routine competence.

3. An inventive-step objection cannot be sustained by reconstructing the claimed solution with knowledge of the patent. Where an obviousness attack can be constructed only by selecting and combining numerous (more than 10) disclosures addressing different technical questions, none of which supplies the missing pointer or gives the skilled person a reason to consult the others, the resulting mosaic is indicative of an ex post facto analysis rather than the course the skilled person would have followed at the effective date.

CLAIMANT:

BIOGARAN a company registered with SIREN number 405 113 598, headquartered at 15 Boulevard Charles de Gaulle, 92700 Colombes, France

Representatives: Marianne GABRIEL, Lawyer at the Paris Bar and representative before the UPC, together with Jean-Baptiste LECŒUR, of the law firm CASALONGA SAS - 31 rue de Fleurus, 75006 Paris, France.

Hereinafter 'the Claimant'

DEFENDANT:

H. LUNDBECK A/S Ottiliavej 9, 2500 Valby-Copenhagen, Denmark

Representatives: Benoît Strowel, Amandine Métier, Alix Fourmaux and Nathalie Rodriguez Arigon, of the law Firm HOYNG ROKH MONEGIER - 33 rue Vivienne, 75002 Paris, France.

Hereinafter 'the Defendant'

PATENT AT ISSUE: European Patent no. 4223296 owned by LUNDBECK

Hereinafter: “the Patent” or “EP’296”

Deciding Judge:

This decision is issued by the panel composed of the following judges:

Andrea Postiglione	Presiding Judge and Judge-Rapporteur
Anna-Lena Klein	Legally qualified Judge
Eric Enderlin	Technically qualified Judge

Language of the proceedings:

English

Subject-matter of the proceedings:

Revocation action. Here: final decision

SUMMARY OF THE FACTS

On 14 November 2025, BIOGARAN (hereinafter “the Claimant”) filed the present revocation action with the UPC Central Division (Milan section) against LUNDBECK (hereinafter “the Defendant”), seeking revocation of the European Patent ‘296 with respect to all national designations in the contracting member states of the Agreement on a Unified Patent Court.

On 9 February 2026, the Defendant lodged a defence to the statement for revocation and filed an application to amend the Patent, containing three conditional auxiliary requests (hereinafter AR1, AR2 and AR3).

In its Reply of 9 April 2026, BIOGARAN contested LUNDBECK’s arguments and maintained its request to revoke EP’296 in its entirety.

On 12 March 2026, LUNDBECK filed an application for provisional measures against BIOGARAN before the Paris Local Division (UPC_CFI_903/2026), relying both on EP 3345604 and EP ‘296 pursuant to Article 62 UPCA and Rule 206 RoP. Given the related proceedings on provisional measures, pending in Paris, it was proposed that the two cases (UPC_CFI 1587/25 and UPC_CFI 903/26) be heard in parallel. Following that proposal, the parties agreed that the application for provisional measures before the Paris Local Division would be withdrawn.

By order of 17 April 2026, a new Judge-Rapporteur was subsequently designated, namely the judge currently acting in that capacity, and the date of the oral hearing was set for 15 September 2026.

On 19 June 2026, LUNDBECK filed an Application asking the Court to disregard certain sections of BIOGARAN's Rejoinder, and in the alternative, to be granted leave under Rule 36 RoP to file a further written response. In response, on 27 June 2026, BIOGARAN filed a letter to the Judge-Rapporteur. On 1 July 2026, the Judge-Rapporteur issued a communication to the parties concerning LUNDBECK's Application of 19 June 2026 and BIOGARAN's response of 27 June 2026. The communication indicated that the issues raised would require the involvement of the panel. LUNDBECK was given until 8 July 2026 to file brief written submissions, and BIOGARAN until 15 July 2026 to respond.

The written phase was closed thereafter.

An online interim conference (IC) was held on 28 August 2026. The outcome of the interim conference is set out in the procedural order issued on 2 September 2026.

The oral hearing was held in person in Milan on 15 September 2026.

At the outset of the oral hearing, the parties waived their right to a public announcement of the Court's decision (Art. 35(5) UPCS). It was agreed that the final decision would be filed in the CMS without a reading in open court.

THE PARTIES

BIOGARAN is a simplified joint-stock company, registered in the Nanterre Trade and Companies Register under SIREN number 405 113 598. BIOGARAN was founded in 1996 to specifically address the emergence of what was, at that time, a nascent and little-known market: generic medicines. Today, BIOGARAN has become a major player in the pharmaceutical industry in just a few years. BIOGARAN is a French company active in the generic medicines sector. According to the company, nearly 90 % of its medicines are manufactured in Europe, with effects on regional employment and local economic activity and with the stated aim of reducing the environmental impact associated with its operations.

LUNDBECK is a Danish pharmaceutical company founded in 1996; it is engaged in the manufacture of generic drugs and specializes in the research and development of innovative treatments for brain disorders. The defendant works in the field of neuroscience: it has allegedly pioneered some of the most widely used and effective antipsychotic and antidepressant treatments and devotes a significant portion of its annual revenue to the development of innovative medicines. In 2025, LUNDBECK invested DKK 5 billion in research and development, which amounts to approximately 20 % of its total revenue.

BIOGARAN requests:

a) That patent EP'296 and all its claims be declared invalid for added matter, lack of sufficiency of disclosure, lack of novelty and lack of inventive step; that LUNDBECK's auxiliary requests 1, 2 and 3 be dismissed and declared invalid for added matter, lack of sufficiency of disclosure, lack of novelty and lack of inventive step;

b) and as a consequence:

- that all the claims of patent EP'296 be revoked;

- that the Court order that the judgment to be rendered be recorded in the European Patent Register (including the Unitary Patent Register) and the National Patent Registers (including the French Patent Register), at the request of the Registry or of the most diligent party, at the sole expense of LUNDBECK.

c) that LUNDBECK be ordered to pay BIOGARAN (i) the sum of EUR 300 000 (three hundred thousand euros) in reimbursement (i) of the costs incurred in connection with this Revocation Action and (ii) of the fees and costs paid for bringing this Revocation Action.

LUNDBECK requests:

A. As a main request, that the Statement for Revocation of EP '296 be dismissed in its entirety;

B. As a subsidiary request, insofar as the Court considers the claims of EP '296 to be insufficiently disclosed as contended in the Statement for Revocation, that the Court hold that the Application to Amend EP '296 submitted as Auxiliary Request 1 is admissible, and that EP '296 be amended accordingly;

C. Or, as a subsidiary request, that the Court hold that the Application to Amend EP '296 submitted as Auxiliary Request 2 is admissible, and that EP '296 be amended accordingly;

D. As a further subsidiary request, that the Court hold that the Application to Amend EP '296 submitted as Auxiliary Request 3 is admissible, and that EP '296 be amended accordingly;

E. That the value in dispute be set at a value that appears reasonable to the Court and that is below EUR 250 000.00 (in the Defence to revocation); In the alternative, that the value in dispute be set at a value that appears reasonable to the Court and that is below EUR 2 000 000 (the issue of the value of proceedings has been agreed by the parties in the IC);

F. That BIOGARAN be ordered to pay LUNDBECK an interim award on costs of the legal costs as provided under Article 69 of the Agreement on a Unified Patent Court in conjunction with Rules 118(5), 119 and 150(2) of the Rules of Procedure, to be set at EUR 100 000, which corresponds to 50 % of the ceiling for the recoverable costs in a case with a value of EUR 2 000 000;

G. That all above orders be declared directly effective and enforceable.

THE PATENT

1. European Patent EP '296, entitled "Nalmefene for reduction of alcohol consumption in specific target populations", concerns the use of nalmefene to reduce alcohol consumption in selected patients with alcohol dependence.
2. EP'296 is a divisional patent deriving from the international application WO 2014/001427 (WO'427), filed on 27 June 2013 and claiming priority from four United States applications filed between 27 June 2012 and 15 March 2013. The Patent was granted on 29 January 2025, and its unitary effect was registered on 5 February 2025.
3. The Patent forms part of an uninterrupted sequence of European divisional applications originating from the European regional phase of WO 2014/001427. That sequence comprises EP 2866808, followed by EP 3138564, EP 3345604 and, ultimately, EP 4223296. The related patents and applications concern the same general subject-matter.
4. EP 2866808 was revoked at LUNDBECK's request, while EP 3138564 was revoked by the EPO Board of Appeal.
5. Following the preliminary opinion issued by the EPO Opposition Division (OD) early this year, LUNDBECK announced at the outset of the oral hearing before this Court its intention to align the patent text with the version amended before the Opposition Division. Accordingly, in the present proceedings, LUNDBECK requested that it be allowed to unconditionally amend the Patent by deleting dependent claims 7 and 9, corresponding to the text of the amended claim set filed with the OD and with this UPC Court of First Instance by communication lodged on 14 September 2026. This text corresponds to the conditional AR4.
6. The amendment is admissible under Rule 30.2 RoP, read together with Rules 49.2 and 50.2 RoP.
7. Rule 30.3 RoP is also relevant here in so far as it requires the patent proprietor to inform the Court of pending parallel proceedings concerning the patent, thereby enabling the Court to take account of the EPO opposition proceedings and of the preliminary opinion that prompted the amendment.
8. The Court takes note that AR4, proposed originally as conditional on (partial) invalidity of the Patent, has now been requested unconditionally. The Court allows this auxiliary request (AR4), which corresponds to a unilateral patent limitation.
9. According to the Court of Appeal in Meril Italy v. Edwards Lifesciences, decision of 25 November 2025, UPC_CoA_464/2024, UPC_CoA_457/2024, UPC_CoA_458/2024, UPC_CoA_530/2024, UPC_CoA_532/2024, UPC_CoA_533/2024, UPC_CoA_21/2025 and UPC_CoA_27/2025, a subsequent request to amend may be admitted where, having regard to all the circumstances, the proprietor shows that the amendment could not reasonably have been made earlier and that it will not unreasonably hinder the other party in the conduct of the action. The same approach follows from the Düsseldorf Local Division's order of 2 August 2024 in Fujifilm v. Kodak, UPC_CFI_355/2023, and the Mannheim Local Division's order of 27 June 2024 in Panasonic v. OPPO, UPC_CFI_210/2023. In the present case, the deletion of dependent claims 7 and 9 was prompted by a preliminary

assessment of the OD in the parallel EPO proceedings; this amendment merely removes two dependent claims, introduces no new technical subject-matter, simplifies the dispute and does not require BIOGARAN to address any new validity issue.

10. Its admission is therefore consistent with procedural fairness, equality of arms and also with the front-loaded character of UPC proceedings. The text of the Patent as amended will be attached at the end of this document.

INADMISSIBILITY OF LATE-FILED DOCUMENTS AND ARGUMENTS

11. In its Rejoinder, BIOGARAN advanced a substantially expanded line of argument based on the following five documents introduced into the proceedings for the first time:

- Anton 2004 (Anton et al., “A Multi-site Dose Ranging Study of Nalmefene in the Treatment of Alcohol Dependence”, Journal of Clinical Psychopharmacology, Vol. 24, No. 4, August 2004, pp. 421–428);
- Klingemann 2001 (Klingemann et al., Promoting Self-Change from Problem Substance Use: Practical Implications for Policy, Prevention and Treatment, Kluwer Academic Publishers, 2001);
- NLAES 1998 (NIAAA, Drinking in the United States: Main Findings from the 1992 National Longitudinal Alcohol Epidemiologic Survey (NLAES), U.S. Alcohol Epidemiologic Data Reference Manual, Vol. 6, 1st ed., November 1998.);
- Johnson 2007 (Johnson et al., “Topiramate for Treating Alcohol Dependence: A Randomized Controlled Trial”, JAMA, Vol. 298, No. 14, 2007, pp. 1641–1651); and
- Van den Brink 2013 (Van den Brink et al., “Efficacy of As-Needed Nalmefene in Alcohol-Dependent Patients with at Least a High Drinking Risk Level: Results from a Subgroup Analysis of Two Randomized Controlled 6-Month Studies”, Alcohol and Alcoholism, Vol. 48, No. 5, 2013, pp. 570–578).

12. BIOGARAN'S new priority attacks against granted claims 7 and 9 and the corresponding dependent claims of Auxiliary Requests 1 to 3 are also based on the EPO Opposition Division's preliminary opinion of 6 May 2026.

13. LUNDBECK challenged these attacks with an application dated 19 June 2026, highlighting that BIOGARAN was not entitled to use a late procedural opinion of the EPO to add a line of attack that had been available to it from the beginning of the UPC proceedings. Should the Court find that granted claims 7 and/or 9, or the corresponding dependent claims of Auxiliary Requests 1 to 3, are not entitled to the claimed priority, LUNDBECK requests leave, pursuant to Rule 30.2 RoP, to file Auxiliary Requests 4 to 8. The requests were twofold. Procedurally, LUNDBECK asks the Court to disregard BIOGARAN'S late-filed arguments and exhibits, or alternatively to admit Auxiliary Requests 4 to 8. On the merits, LUNDBECK primarily asks the UPC Milan Central Division to dismiss the

revocation action and maintain EP'296 as granted; alternatively, to maintain it in part or on the basis of one of the auxiliary requests.

14. BIOGARAN replied that a Rejoinder may include arguments and supporting evidence that clarify, support or further substantiate a position already taken in due time, provided that they respond to matters raised in the Reply or are closely related to them. BIOGARAN argued that the contested material should be admitted under the principles of proportionality, flexibility, fairness and the right to be heard, as it further substantiates existing positions or responds to LUNDBECK's later arguments.

15. The Court does not allow those documents and the new arguments.

16. Firstly, BIOGARAN did not expressly seek leave under Rule 263 RoP to amend its case.

17. Secondly, the Court strongly relies on the front-loaded nature of UPC proceedings.

18. As already affirmed by this Central Division in UPC_CFI 597/24 (order of 11 April 2024 in EOflow Co. Ltd v. Insulet Co.) *'According to Art. 54 UPCA, the burden of proof is on the party who puts forward the facts, a rule which is specified by Rules 171 and 172 RoP, according to which the party who puts forward a fact which is disputed or likely to be disputed by the other party must indicate the means of proving it. This means that whenever a party proposes to bring an action before the UPC, it must take care to collect in advance the documents supporting the claim. The procedure before the UPC is in fact a front-loaded procedure, where the written procedure allows the parties to confront with replies and rejoinders based on a wealth of knowledge and documents that are supposed to be stable and consolidated from the very moment the claim is filed. In general, the parties are obliged to present their complete case as early as possible (RoP Preamble, para. 7, last sentence). Rule 222.2 RoP provides for the admissibility of new evidence in the appeal only if such evidence "could not reasonably have been expected during the proceedings before the court of first instance". The same may apply to the stages of the first instance proceedings; this means that when a party files an action before this Court, it must take care to show and possess the evidence in support of the claim in advance. Therefore, in a revocation action, prior art (potentially detrimental to the patent or not) cannot be filed at a later stage. The filing of prior art at late stage, or at the stage of the replies prevents the opponent from filing full observations (reply and rejoinder) on a crucial point of the legal assessment. This is contrary to the adversarial principle laid down in Art. 76 UPCA. Submission of a document at a later stage appears to be justified only if the party submitting it proves that the document was not previously available or could not have been submitted earlier'*.

19. Given the above, the five documents relied upon in the Rejoinder were already available and could have been filed earlier. They do not merely substantiate existing submissions, but support new priority, novelty and inventive-step attacks.

20. Those attacks are therefore late-filed and inadmissible.

21. Nor may BIOGARAN rely on the EPO Opposition Division's preliminary opinion to introduce those attacks indirectly: that provisional assessment, issued in separate proceedings, cannot replace the

timely, specific and substantiated pleading required before the UPC. As noted above, it would also be contrary to the duties of good faith and diligence and to the requirements of fairness referred to in recital 5 of the Preamble to the RoP to extract arguments raised by the EPO in opposition proceedings and import them into the UPC proceedings in a manner that deprives them of the necessary adversarial exchange.

22. The admission of these arguments at the Rejoinder stage would undermine procedural economy, equality of arms and the orderly conduct of the written procedure. Accordingly, documents Anton 2004, Klingemann 2001, NLAES 1998, Johnson 2007 and van den Brink 2013 are inadmissible insofar as they are relied upon in support of those additional attacks.

23. Consequently, the Auxiliary Requests that LUNDBECK wished to submit in the event that BIOGARAN's additional attacks were admitted are likewise inadmissible, except for Auxiliary Request 4. AR4 was *unconditionally* renewed at the oral hearing on the basis of the intervening limitation of the Patent in the parallel EPO opposition proceedings.

24. Patent limitation is regarded by this Court as a *fait accompli*. The need to ensure consistency between the patent texts examined in the parallel proceedings requires that the same amended text submitted before the EPO be admitted in the present action.

TECHNICAL BACKGROUND OF THE INVENTION – ALCOHOL DEPENDENCE

25. The term "alcohol dependence" is a commonly known term for the skilled person (see below). Para. [0027] of the Patent provides the following explanation:

"...the term "alcohol dependence" is defined as the presence of three or more of the seven areas of life impairment related to alcohol in the same 12-month period. These impairments include 1) tolerance, 2) withdrawal, 3) the alcohol is often taken in larger amounts or over a longer period than was intended, 4) persistent desire or unsuccessful efforts to cut down or control alcohol intake, 5) a great deal of time is spent in activities necessary to obtain alcohol, intake alcohol, or recover from its effects, 6) important social, occupational, or recreational activities are given up or reduced because of alcohol consumption, 7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol consumption."

26. Against that background, the parties agree that alcohol dependence is a heterogeneous clinical condition and that neither the diagnosis itself nor the frequency of drinking necessarily describes a uniform patient population.

27. The Patent and the parties' submissions refer to several parameters capable of characterising patients, including the severity of dependence, alcohol consumption patterns, medical and psychiatric history, and the social and behavioural consequences associated with drinking.

28. Alcohol consumption may also be assessed independently of the severity of dependence, for example by recording daily drinking through the 'Timeline Follow Back' method and calculating total alcohol consumption and the number of heavy drinking days over a defined period.

29. On that basis, patients may be assigned a Drinking Risk Level (DRL) according to the World Health Organization categories. For the purposes of the Patent, a high DRL corresponds to consumption exceeding 60 g of pure alcohol per day for men and 40 g per day for women, while higher thresholds define the very-high-risk category.

30. These consumption-based measures are clinically distinct from dependence-severity scores: a patient's level of consumption does not, by itself, establish the degree of physiological dependence or necessarily predict the response to treatment.

31. The technical context is completed by the known use of nalmefene to reduce alcohol consumption.

32. Nalmefene is, according to [0003], a known opioid system modulator, with a distinct μ , δ , and κ receptor profile, acting as an antagonist at the μ and δ receptors and as a partial agonist at the κ receptor, and thereby modulating effects mediated by both exogenous and endogenous opioid agonists.

33. The clinical usefulness of nalmefene comes, at least in part, from its ability to promptly and selectively reverse the effects of these opioid agonists.

34. Nalmefene has primarily been developed for use in the management of alcohol dependence, [0004]. The invention relates to a nalmefene for use in the reduction of alcohol consumption in a patient with alcohol dependence [0009].

35. Earlier studies had investigated daily or targeted administration, including administration when drinking was considered imminent.

36. The dispute does not therefore concern the chemical identity of nalmefene or its general suitability for reducing alcohol consumption, both of which were known. Rather, it concerns the technical significance of selecting alcohol-dependent patients who display a high Drinking Risk Level at the initial assessment and maintain that level during a subsequent observation period.

PERSON SKILLED IN THE ART

37. The definition of the person skilled in the art was extensively discussed during the interim conference in order to allow the parties to possibly plead based on a homogeneous definition of the skilled person.

38. BIOGARAN had not provided a definition of the person skilled in the art in its written submissions. LUNDBECK, by contrast, identified that person, at paragraph §39 of its initial pleading, as a clinician with experience in treating patients who have been identified as possibly having alcohol-related difficulties, including patients who may have alcohol dependence.

39. During the IC and the oral hearing, BIOGARAN argued that, in their view, the skilled person should be understood as a person having broad knowledge of alcohol dependence and experience in reducing alcohol consumption with a view to limiting the risk of alcohol-related harm.

40. The Court does not consider that the skilled person must necessarily be characterised by a particular concern for the health of people affected by alcohol dependence or by the broader social consequences of alcohol misuse. Rather, the skilled person is a clinician who treats and studies alcohol dependence, is generally aware of the health and social risks associated with alcohol dependence and alcohol abuse and is primarily engaged in investigating the condition and seeking new therapeutic solutions.

41. The Court recalls that, in UPC_CFI_552/25, decision of 4 May 2026, CD Milan already observed that the person skilled in the art is a notional figure who must be defined without reference to subjective or subjectivising characteristics. In that decision, the Court stated that *“the person skilled in the art, outlined in Art. 56 EPC, is a notional figure who represents an average level of knowledge in a specific technical field and whose knowledge reflects the common general knowledge (CGK) at the priority date. This fictitious individual cannot be identified with any real person working in the technical domain of the invention. The skilled person is not required to possess (or disregard) a distinct affiliation, nor is it necessary; therefore, differentiating characteristics such as connections to a specific company are not admissible”*.

42. It follows that the skilled person must be defined by reference to what that person knows and to the relevant common general knowledge, rather than by reference to the purpose for which that knowledge is applied or to what the skilled person cares.

43. Against that background, BIOGARAN’s proposed definition appears to place excessive emphasis on the therapeutic objective of addressing the consequences of alcohol consumption. That approach does not fully correspond to the focus of the Patent, which is not directed to the general treatment of alcohol dependence as such, but to *“nalmeфene for use in the reduction of alcohol consumption in a patient with alcohol dependence”* [0001].

44. BIOGARAN’s approach overweighs the social consequences of alcohol dependence. Those consequences are mentioned in the Patent, but they play only an eventual and contingent role in the stated purpose of the invention. Paragraph [0007] of the Patent states that *“There is a need for a new treatment for use in reduction of alcohol consumption. Reduction of alcohol consumption is likely to provide benefits associated with decreased risk of health-related harm and decreased number of adverse social consequences”* (emphasis added by the Court). The therapeutic focus of the Patent is therefore the reduction of alcohol consumption in a selected population of patients, rather than the comprehensive treatment of alcohol dependence as such. In particular, the Patent is not directed to curing alcoholism or alcohol dependence, but to reducing alcohol consumption in the defined patient subgroup.

45. On that basis, the Court identifies the skilled person as a clinician with experience in treating patients who have been identified as possibly having alcohol-related difficulties, for example, patients who may have alcohol dependence.

THE OBJECTIVE PROBLEM

46. The Court of Appeal has more than once clarified that the technical problem must be objectively identified from the perspective of the skilled person, taking account of the common general knowledge at the effective date and of the contribution made by the claimed invention as a whole. In *Meril Italy and others v Edwards Lifesciences*, decision of 25 November 2025 in UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024 and UPC_CoA_533/2024, the Court of Appeal stated: *‘It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the person skilled in the art, with their common general knowledge, as at the application or priority date (also referred to as the effective date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the person skilled in the art, on the basis of the application, understands is (are) achieved with the claimed invention. 9. In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution....The relevant field of technology is the specific field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art in the art of the specific field must be expected to be aware’.*

47. Accordingly, the identification of the objective problem is the starting point for the assessment of the patent in terms of validity. It requires the Court to determine, from the patent itself and without hindsight, the technical contribution which the skilled person understands to arise from the claimed invention. The problem must therefore reflect the teaching and technical effect disclosed in the patent but must not already contain the features by which the claim provides its solution.

48. According to BIOGARAN, the technical problem is the reduction of alcohol consumption or, alternatively, the identification, within the broader population of alcohol-dependent patients [0001][0027] treated with Nalmefene, of a subgroup in which Nalmefene is more effective in reducing alcohol consumption. BIOGARAN thus presents the problem as one of patient stratification: starting from a known treatment and a known therapeutic purpose, the skilled person would seek to identify those patients who are more likely to reduce their alcohol consumption.

49. That formulation must be considered in light of the patent’s own presentation of the technical contribution. EP 296 highlights the [0007] need for a new treatment for use in reduction of alcohol consumption. Reduction of alcohol consumption is likely to provide benefits associated with decreased risk of health-related harm and decreased number of adverse social consequences. The efficacy of Nalmefene in the reduction of alcohol consumption in patients with alcohol dependence

(DSM-IV) has been evaluated in two efficacy studies (Study 12014A and Study 12023A) and one safety study (Study 12013A) as described in the examples [0031]. All three studies were randomized, double blind, parallel-group and placebo-controlled. The studies included outpatients, aged ≥ 18 years, with a primary diagnosis of alcohol dependence [0032]. A patient was eligible for participation in the study if, in the 4 weeks preceding the Screening Visit (Baseline period), he/she had > 6 HDDs, at least a medium DRL (calculated as mean daily alcohol consumption in g/day i.e. > 40 g/day for men and > 20 g/day for women calculated as mean daily alcohol consumption over the 4 week period preceding the screening visit), and ≤ 14 consecutive abstinent days. The timeline followback (TLFB) method was used to obtain estimates of the patient's daily drinking.

50. The Court finds this definition of the technical problem persuasive.

51. The objective technical problem cannot be formulated as the provision of treatment of patients suffering from alcohol dependence, since that treatment already formed part of the state of the art. Actually, LUNDBECK formulates the technical problem in substantially similar terms, namely as the “identification of a sub-group of patients with alcohol dependence who benefit particularly from treatment with Nalmefene” (§§ 290–292 of the Defence to Revocation).

52. Lundbeck nevertheless attributes a more specific meaning to that formulation. In its view, the invention does not consist merely in selecting patients who drink heavily or display more severe alcohol dependence, but in identifying a subgroup defined by the cumulative criteria of alcohol dependence, a high DRL at baseline, maintenance of that high DRL after an observation period of 1–2 weeks, and as-needed administration of Nalmefene, which corresponds in broad terms to the proposed solution. In fact, [0033] at the initial visit (screening visit), the patients' clinical status, social situation, and alcohol consumption pattern have been evaluated. After a 1- to 2-week observation period the drinking risk level was re-assessed by calculating mean daily alcohol consumption in g/day over the 1- to 2-week observation period, and treatment with Nalmefene was initiated together with counselling with focus on motivating the patients to adhere to the treatment and to change their drinking behaviour.

53. The Court observes that the parties' formulations substantially overlap, except for LUNDBECK's more specific formulation, which appears to reflect the solution already proposed by the patent. As the Court of Appeal has clarified, the objective technical problem must not be identified on the basis of knowledge of the claimed solution, since that would introduce hindsight into the inventive-step assessment.

54. In the Court's view, the objective technical problem could be formulated as the identification of the subgroup of alcohol-dependent patients who derive an improved therapeutic benefit from treatment with nalmefene. This formulation reflects the technical contribution disclosed in the patent while avoiding any pointer to the claimed solution. In particular, it does not refer to a high DRL at baseline, the maintenance of that high DRL after an observation period, or the as-needed administration of Nalmefene. Those features belong to the claimed solution and must be examined only at the subsequent stage, when assessing whether the skilled person, starting from a realistic

prior-art disclosure and seeking to solve the identified problem, would have been prompted to arrive at the claimed subgroup with a reasonable expectation of success.

CLAIM CONSTRUCTION

55. The Patent seeks to solve the technical problem through this independent claim:

1. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

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a) identifying a patient with alcohol dependence

i) who has a Drinking Risk Level (DRL) corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women, and

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ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment,

wherein said observation period following initial assessment is 1-2 weeks, and

b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

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And through these dependent claims:

2. Nalmefene for use according to claim 1, wherein said patient does not require immediate detoxification.
3. Nalmefene for use according to any of claims 1 or 2, wherein said patient is subject to ongoing motivational support.
4. Nalmefene for use according to any of claims 1-3, wherein said patient is subject to counseling focused on enhanced treatment adherence and reduced alcohol consumption.
5. Nalmefene for use according to claim 4, wherein said counseling is performed according to the BRENDA model.
6. Nalmefene for use according to any of claims 1-5, wherein said patient is a patient for whom immediate abstinence is not a treatment goal.
7. Nalmefene for use according to any of claims 1-6, wherein said nalmefene is to be used for a treatment period of 6-12 months, such as 6 months.
8. Nalmefene for use according to any of claims 1-7, wherein patient is an adult or an adolescent.
9. Nalmefene for use according to any of claims 1-8, wherein said patient is 12 years or older, such as 14 years or older, such as 16 years or older, such as 18 years or older.
10. Nalmefene for use according to any of claims 1-9, wherein said nalmefene is used in a dose of 10-20 mg such as 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg or 20 mg.
11. Nalmefene for use according to any of claims 1-10, wherein said nalmefene is used in a dose of 18 mg.
12. Nalmefene for use according to any of claims 1-11, wherein said nalmefene is used in the form of a pharmaceutically acceptable acid addition salt.
13. Nalmefene for use according to any of claims 1-12, wherein said nalmefene is used in the form of the hydrochloride salt.
14. Nalmefene for use according to any of claims 1-13, wherein said nalmefene is used in the form of the hydrochloride dihydrate.
15. Nalmefene for use according to any of claims 1-14, wherein said nalmefene is used in a crystalline form.
16. Nalmefene for use according to any of claims 1-15, wherein said nalmefene is used in an oral dose form such as tablets or capsules.
17. Nalmefene for use according to any of claims 1-16, wherein said nalmefene is used in combination with a further active ingredient.

18. Nalmefene for use according to any of claims 1-17, wherein said patient does not fall into one or more of the following categories: patients taking opioid analgesics, opioid-addicted patients without successful withdrawal, patients with acute symptoms of opioid withdrawal, patients for whom recent use of opioids is suspected, patients with moderate or severe hepatic impairment, patients with moderate or severe renal impairment.

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56. As the Court of Appeal has made clear (UPC_CoA_335/2023, order of 11 March 2024 – NanoString v. 10x Genomics), the patent claim is not only the starting point, but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection. The patent claim is to be interpreted from the point of view of a person skilled in the art. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European patent.

57. The claim interpretation must be carried out from the point of view of a person skilled in the art. The skilled person will try to arrive at an interpretation of the claim that is technically sensible and will take into account the whole disclosure of the patent.

58. Furthermore, the patent must be construed in a technically sensible manner, by a ‘mind willing to understand, not a mind desirous of misunderstanding’ (see, e.g., UPC_CFI_497/2024 and UPC_CFI_571/2024 (CD - Milan section), decision issued on 23 October 2025, para. 2.2 – bioMérieux v. Labrador).

59. Finally, claim construction is a matter of law (UPC_CoA 768/2024, decision issued on 20 April 2025, para. 37 - Insulet v. EOfFlow).

60. Against this legal background, the Court observes that the parties disagreed on the interpretation of a feature of the main claim:

1. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

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a) identifying a patient with alcohol dependence

i) who has a Drinking Risk Level (DRL) corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women, and

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ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment,

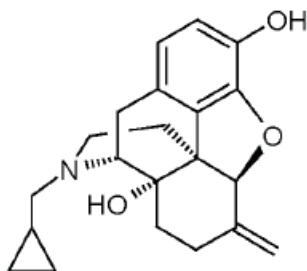
wherein said observation period following initial assessment is 1-2 weeks, and

b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

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61. EP'296 describes a second medical use of the chemical compound (substance or composition) called Nalmefene, [0002] [17-(cyclopropylmethyl)-4,5- α -epoxy-6-methylenemorphinan-3,14-diol], in a disease treatment (alcohol consumption reduction).

62. Nalmefene has the following general formula:



63. Independent claim 1 of the Patent can be reproduced in the form of a breakdown of features as follows:

1. a compound 'for use' in reduction of alcohol consumption aimed at
2. a patient with alcohol dependence, further fulfilling the following characteristics
 - 2.1. specific Drinking Risk level (corresponding to consumption > 60 g/day of pure alcohol for men and > 40 g/day for women)
 - 2.2. maintenance of the DRL of alcohol consumption after an observation period following initial assessment
 - 2.2.1 the observation period being one to two weeks
3. a treatment dose

Feature 1. Nalmefene 'for use' in reduction of alcohol consumption

64. As to the 'compound', reference is made to 'Nalmefene [0002] with chemical name of [17-(cyclopropylmethyl)-4,5- α -epoxy-6-methylenemorphinan-3,14-diol], a compound already known at the priority date, having been actively used in the management of alcohol dependence, [0004]. Nalmefene encompasses all forms of the compound, including the free base and pharmaceutically acceptable salts, in anhydrous or solvated (e.g. hydrate) form, and in amorphous or crystalline forms, [0011].

65. A patent claim directed to the use of a drug in a specific group of patient hinges on the suitability of a known substance for a particular therapeutic purpose, i.e., on a new technical effect of a known substance in the treatment of that specific group of patients. In other words, the claim is fundamentally concerned with the identification of a new and specific group of patients for an innovative medical application. This applies regardless of whether the wording of the patent claim is directed to the use of the drug, to its preparation for a specific purpose (Swiss-type), or explicitly to the substance itself for a specific therapeutic purpose.

66. This feature interpretation is undisputed (R. 171.2 RoP). The Court shares this interpretation.

Feature 2. Patient with alcohol dependence

67. The claim identifies a specific condition that serves as a criterion for the identification of the group suitable for the medical treatment with nalmefene: alcohol dependence.

68. As referenced by the Patent's specification, according to the WHO ICD-10 classification, and (DSM-IV-TR) 4th edition, 'alcohol dependence' is a syndrome characterised by physiological, behavioural and cognitive features in which alcohol use takes increasing priority over other behaviours. A definitive diagnosis generally requires three or more typical features within the previous year, such as 1) tolerance, 2) withdrawal, 3) the alcohol is often taken in larger amounts or over a longer period than was intended, 4) persistent desire or unsuccessful efforts to cut down or control alcohol intake, 5) a great deal of time is spent in activities necessary to obtain alcohol, intake alcohol, or recover from its effects, 6) important social, occupational, or recreational activities are given up or reduced because of alcohol consumption, 7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol consumption [0027].

69. In the Court's view, 'alcohol dependence' is a meaningful claim-limiting feature because it defines a clinically identifiable patient population, rather than merely describing the purpose of the treatment. Within the broader category of patients with alcohol-related problems, the Patent selects those who, according to the WHO classification, fall within the category of alcohol-dependent patients because they exhibit at least three of the characteristic features of dependence, understood as a multifactorial disorder classified under both the psychiatric and medical sections of the International Classification of Diseases. Alcohol dependence may be regarded as a disease which involves factors of various kinds, including genetic, organic, psychological and environmental factors.

70. Accordingly, a patient with alcohol dependence is one who meets the diagnostic criteria for that specific disease.

Feature 2.1. specific Drinking Risk level (corresponding to consumption > 60 g/day of pure alcohol for men and > 40 g/day for women)

71. The Patent then selects a further narrower target group for treatment by means of three additional criteria: a specific (high or very high) Drinking Risk Level, the maintenance of that level after an observation period following the initial assessment, and the determination of an observation period of one to two weeks.

72. EP'296 must therefore be understood as relating to a subgroup-selection invention, rather than a second medical use in general.

73. Claim 1 and features 2.1, 2.2. and 2.2.1. are not directed to the reduction of alcohol consumption in a patient with alcohol dependence in general, as maintained by BIOGARAN, but to a narrowly defined subgroup of patients, identified by cumulative criteria, and to a dosing regimen (feature 3).

74. Since the claim is directed to the identification of a subgroup of patients for whom the therapy is specifically intended, these features cannot be assessed in isolation. They must be read together (2, 2.1. 2.2, 2.2.1), as cumulative and functionally connected criteria aimed at the direct and precise identification of the patient group for whom the claimed treatment is intended.

75. The term "drinking risk level" abbreviated DRL is interpreted in the light of the WHO's criteria according to Table 1 below, provided in the Patent specification ([0015]):

Table 1: WHO Drinking Risk Levels (DRLs) of Alcohol Consumption

DRL	Total Alcohol Consumption (g/day)	
	Men	Women
Very high risk	>100	>60
High risk	>60 to 100	>40 to 60
Medium risk	>40 to 60	>20 to 40
Low risk	1 to 40	1 to 20

76. Drinking Risk Levels according to Table 1 can be assessed [0016] e.g. by calculating the mean daily alcohol consumption, expressed in g/day, over a specified period.

77. The skilled person therefore understands from paragraph [0016] of the Patent that "daily" consumption is not determined by averaging consumption within each individual day (as a "snapshot"), but by dividing the total alcohol consumed during the relevant period by the number of days in that period. Assessment of DRL is carried out by the skilled person, a specialist, physician or other healthcare providers based on patients' estimates of their alcohol consumption. The skilled person, as defined above, is a clinician familiar with both the multifactorial nature and the characteristic features of alcohol dependence. Such a clinician would understand that alcohol dependence may persist even where, on certain days within the assessment period, alcohol consumption is within normal limits or entirely absent.

78. This is also apparent from [0059] of the Patent that explains that the patients' alcohol intake (g/day) was estimated based on national definitions of standard units and to define the standard units, a standard drink conversion card was distributed to each patient at the Screening Visit. Each patient was also provided with a calendar that he/she could use to support his/her input to the TLFB. For all the variables derived from the TLFB data, baseline was defined as the month (that is, 4 weeks /28 consecutive days) preceding the Screening Visit. The skilled person understands from the paragraph above that mean daily alcohol consumption need not be assessed on a daily basis, since the explanation of the use of the calendar states that 'dates when nalmefene was taken/not taken were recorded using the TLFB method'.

79. The skilled person also understands that the expression "high risk" or "at least high risk" is intended to cover both the high and very high risk groups, i.e. patients with a DRL corresponding to a total alcohol consumption of > 60 g/day in men and > 40 g/day in women, and that "high drinking risk level" or "high DRL" are used in this inclusive sense (see [0017]).

Feature 2.2. maintenance of the DRL of alcohol consumption after an observation period following initial assessment

80. According to feature 2.1., the patient included in the targeted group must have a high DRL and (according to feature 2.2.) maintain that DRL after an observation period which, as set out in feature 2.2.1. is "1-2 weeks".

81. The term "Early Reducer", abbreviated as "ER", is relevant to the interpretation of the claim and has an exclusionary effect, even though it does not itself constitute a feature of the claim. Paragraph [0018] defines an ER as a patient "included in the three Lundbeck phase III studies (12014A, 12023A and 12013A) who had considerably reduced the alcohol consumption in the period between screening and randomisation. More specifically, patients defined as ERs have reduced their alcohol consumption from high or medium DRL to a level below medium drinking risk level i.e. said patients had an alcohol consumption of 0-40 g/day for men and 0-20 g/day for women estimated as the mean daily alcohol consumption in a 1-2 week period between screening and randomization".

82. EP '296 thus distinguishes between ERs and patients who do not show a comparable spontaneous reduction in alcohol consumption during the observation period, i.e. patients who maintain their DRL of alcohol consumption after the 1–2 weeks observation period following initial assessment. The Patent reports that, in the total population excluding ERs, the effect of nalmefene on HDDs and TAC is more pronounced than in the total study population (see [0036]). For patients who have a high DRL at initial assessment and maintain that DRL after the observation period, the effect of nalmefene on HDDs and TAC compared with placebo is described as "even further pronounced" (see [0037]).

83. ERs are therefore not suitable for inclusion in the relevant subgroup and are intentionally excluded from the scope of the claim. Accordingly, the Court interprets feature 2.2 as a claim-limiting feature that operates to exclude ERs.

Feature 2.2.1 the observation period being one to two weeks

84. It is defined as an observation period, in accordance with clinical practice, following initial assessment of the DRL, during which the patient's drinking is monitored without initiation of nalmefene administration. This period is said to be "preferably 1–2 weeks most preferably about 2 weeks." (para. [0019]). The person skilled in the art understands that the period claimed is preferably but not necessarily 14 days (two weeks).-Then, according to Feature 2.2.1, once the patient has been identified as meeting the criteria in step (2.1) (alcohol dependence, high DRL according to the > 60 / > 40 g/day thresholds for men and women, respectively, and maintenance of that DRL after the (about) 2-week observation period), the second step of claim 1 consists in administering nalmefene to that specific patient.

Feature 3. Administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

85. The person skilled in the art understands the sub-feature "to be administered as-needed" in Feature 3 as a specifically defined dosing instruction. For the avoidance of doubt, the expression "as-needed" does not refer to the quantity of nalmefene administered, such as 'as much as needed'. This is undisputed also between the parties. It refers instead to the patient-triggered circumstance of administration: the patient takes the prescribed single dose on those days or hours on which he or she perceives a risk or need of drinking alcohol, preferably 1-2 hours before the anticipated drinking episode. The amount of nalmefene remains a separate dosage issue and is not determined by the mere use of the wording "as-needed".

86. The skilled person will, thus, understand this from the definitions section of the Patent that explains [0014] that "as-needed dosing" means that "on each day a patient perceives a risk of drinking alcohol, one dose of nalmefene should be taken" [0014] and further specifies both the preferred timing of administration and the course to be followed where the patient has already started drinking without having taken nalmefene.

87. In particular, [0014] states that "as-needed dosing" indicates that on each day a patient perceives a risk of drinking alcohol, one dose of nalmefene should be taken, "preferably 1–2 hours prior to the anticipated time of drinking". If the patient has already started drinking alcohol without taking nalmefene, the dose should be taken as soon as possible thereafter. The clinical-study protocol adopted by LUNDBECK likewise required nalmefene or placebo to be "taken as-needed", in the manner described above (see also [0059]).

88. BIOGARAN argued that, because patients with alcohol dependence face a persistent risk of drinking, they may take nalmefene at any time. On that basis, it sought to minimise the limiting effect of this claim feature. This runs counter to the interpretation of the claim as being aimed at suggesting the administration of nalmefene only when the patient perceives the risk of being exposed to alcohol consumption. Against this background there might also be days where nalmefene is not taken.

89. The Court recalls the above-mentioned WHO ICD-10 classification, and (DSM-IV-TR) 4th edition, under which 'alcohol dependence' is a syndrome characterised by physiological, behavioural and cognitive features in which alcohol use takes increasing priority over other behaviours. Typical features of alcohol dependence include (2) withdrawal, and/or (4) a persistent desire or unsuccessful efforts to cut down or control alcohol intake and (7) alcohol use continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol consumption [0027].

90. Against this background, this feature should be construed as defining the practical dosing instruction that gives operative content to the "as-needed" regimen: an anticipatory, single-dose, patient-triggered administration on days when the patient perceives a risk of drinking, is unable to

prevent alcohol intake and consumption despite knowledge of their addiction, where the administration preferably occurs 1–2 hours before the expected drinking episode.

91. The claim construction for the dependent claims is undisputed.

PRIORITIES

92. Before assessing the grounds of lack of novelty and inventive step, the Court must determine which priority claims may validly be invoked and which documents are admissible for this purpose.

93. European patent EP'296 originates from a chain of divisional applications ultimately deriving from international application WO'427: WO 2014/001427 → EP 2 866 808 (European regional phase entry) → EP 3 138 564 (divisional) → EP 3 345 604 (divisional) → EP 4 223 296 (divisional), respectively WO'427, EP'808, EP'564, EP'604, EP'296.

From WO'427, EP'296 claims four priorities:

- P1: 27.06.2012 US 201261664804
- P2: 02.11.2012 US 201261721539
- P3: 13.12.2012 US 201261736740
- P4: 15.03.2013 US 201361788810

94. The Claimant submits that claim 1 of EP'296 is not entitled to the priority of P1. This is not disputed by the Defendant, as already observed by this Court in the Order under R. 105.5 RoP.

95. The Claimant also submits that claim 1 is not entitled to any of priorities P2-P4 considering that the skilled person needs to combine several embodiments and therefore cannot directly and unambiguously deduce the claimed subject-matter from the priority application; additionally, the DRL (drinking Risk Level) is not defined in the same way in patent EP'296 as in priority documents P1, P2 and P3. The group of patients concerned by the treatment is therefore not the same. In EP'296 the DRL is assessed by calculating the average 'mean' alcohol consumption, whereas in priority documents P2 and P3 DRL is based on the Total daily amount of alcohol (TAC). The group of patients in EP'296 and in the claimed priorities would not be the same.

96. As to the first objection, it is clear that claim 1 finds a basis in both P2 and P3, as set out by the Defendant in its Statement of Defence with the following table:

Claim 1 of EP296	Embodiments in Biogaran Exhibit 3.8 (P2) and Exhibit No. 3.9 (P3) ¹⁰
Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps; a) identifying a patient with alcohol dependence i) who has a Drinking Risk Level (DRL) corresponding to consumption > 60 g/day of pure alcohol for men and > 40 g/day for women, and ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment, wherein said observation period following initial assessment is 1-2 weeks, and b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.	E12. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps; a) identifying a patient with alcohol dependence i) who has a high drinking risk level, and/or ii) who maintains the level of alcohol consumption after an observation period in accordance with clinical practice, and b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking. E13. Nalmefene according to any of embodiments 5 and 7-12, wherein said observation period is 1-2 weeks. E14. Nalmefene according to any of embodiments 12-13, wherein said patient identified in step a) has a drinking risk level corresponding to consumption ≥ 60 g/day of pure alcohol for men and ≥ 40 g/day for women such as > 60 g/day of pure alcohol for men and > 40 g/day for women.

97. Further, support for claim 1 is found in claims 12–14 of both P2 and P3. Embodiments E12-E14 are clearly linked together, as E13 and E14 are referring to E12, and E14 is referring to E12 and 13.

98. With regard to the calculation of the DRL, as submitted by the Defendant, P2 states that the relevant patient population has a DRL corresponding to consumption of ≥ 60 g/day of pure alcohol for men and ≥ 40 g/day for women (see Table 1 page 2, setting out ranges for different levels of risks defined by the WHO, and claims 1-2 of P2). As already observed above, the skilled person, faced with the expression "60 g/day" or "40 g/day" in the clinical context of alcohol dependence, would naturally understand this as an average daily consumption over a period of time, not as an isolated single-day reading (as submitted by the Claimant).

99. The person skilled in the art would deduce from the Patent relevant prior art ('EMA Guidelines on the development of medicinal products for the treatment of alcohol dependence' page 6) that 'alcohol dependence' may also involve days of abstinence:

treatment has ceased. The course of alcohol dependence is often characterised by periods of abstinence with recurring periods of relapses. Therefore, a relapse after a longer period of abstinence

100. Therefore, the subject-matter of claim 1 of the Patent appears to be directly and unambiguously derivable from at least P2 and P3, including the combination of the features E13 and E14.

101. The same applies to the dependent claims. However, any issue concerning claims 7 and 9 no longer requires determination, since the Court has already allowed their deletion by admitting the corresponding amendment.

102. EP'296 can therefore validly claim priority from P2. Therefore,

- Exhibit SmPC for Selincro, published on 13 March 2013 (Selincro (Nalmefene) 18 mg, Summary of Product Characteristics (SmPC), EMA, 2013);
- Exhibit Mann, 2013 (Mann et al., Biol. Psychiatry 2013; 73:706–713); and

- Exhibit EMEA Assessment report, 13/12/2012 (EMA/CHMP, Selincro (Nalmefene))
- Assessment Report, 13 December 2012, EMEA/H/C/002583/0000)
- are not prior art pursuant to Art.54(2) EPC.

ADDED MATTER

103. Under Article 65(2) UPCA and Article 138(1)(c) EPC, a European patent must be revoked with effect for a Contracting Member State where its subject-matter extends beyond the content of the application as filed or, in the case of a patent granted on a divisional application, beyond the content of the earlier application as filed.

104. According to BIOGARAN, the parent application WO'427 presents, among numerous alternatives, the following features:

- nalmefene for use in the reduction of alcohol consumption in a patient with alcohol dependence,
- wherein:
 - a) the patient
 - (i) has a DRL of > 60 g/day of pure alcohol for men and > 40 g/day of pure alcohol for women, and
 - (ii) maintains this DRL after an observation period of 1-2 weeks following initial assessment,
 - b) nalmefene is administered as needed

105. BIOGARAN argues that embodiments E1-E135 disclosed in WO'427 give rise to millions of possible combinations and that the subject-matter of EP'296 therefore does not comply with Article 138(1)(c) EPC. It adds that, even if embodiments E24, E25 and E26 (reproduced below) were combined, that combination would still be inadmissible since the "and/or" alternatives would not enable the skilled person to derive directly and unambiguously, without further information, whether the observation period constitutes an essential feature of the invention.

- E24. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;
- a) identifying a patient with alcohol dependence i) who has a high DRL, and/or ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment, and
 - b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.
- E25. Nalmefene according to embodiment 24, wherein said observation period following initial assessment is 1-2 weeks, such as about 2 weeks.
- E26. Nalmefene according to any of embodiments 21-25, wherein said patient identified in step a) has a DRL corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women.

106. LUNDBECK disputes that EP'296 contains subject-matter extending beyond the content of the earlier applications as filed. Relying on both UPC and EPO standards, it submits that the decisive test is whether the claimed subject-matter is directly and unambiguously derivable from the earlier disclosure, as stated in the above-mentioned case law of the Court of Appeal. According to LUNDBECK, claim 1 of EP'296 corresponds directly to the combination of original claims 1–3 of WO 2014/001427, which already disclosed all essential elements of the invention: treatment with nalmefene, identification of patients with a high DRL, maintenance of that DRL after an observation period, and as-needed administration. It further submits that the description of WO'427 independently discloses the same combination through structured and cross-referenced embodiments E24–E26 and E1–E2–E6–E23.

107. LUNDBECK also refers to the statement in WO'427 that the embodiments may be claimed separately or in any combination, which, in its view, confirms the permissibility of the combination adopted in the claim. It submits that equivalent bases exist for all dependent claims. It therefore concludes that every granted claim of EP'296 is directly and unambiguously derivable from the parent applications and complies with Article 138(1)(c) EPC and Article 65(2) UPCA.

108. The Court considers that BIOGARAN's first added-matter objection concerning WO'427, lacks the necessary substantiation in the general form in which it was advanced. The objection refers to the difficulty of tracing the patent at issue through the plurality of wordings contained in the parent application but does not identify with sufficient specificity which elements of EP'296 allegedly extend beyond the original disclosure or could not have been directly and unambiguously derived from it by the skilled person.

109. The applicable test is that set out by the Court of Appeal in *Abbott v. Sibio*, UPC_CoA_382/2024, decision of 14 February 2025: *“There is added matter if the claim as granted contains subject-matter that extends beyond the content of the application as filed. In order to ascertain whether there is added matter, the Court must thus first ascertain what the skilled person would derive directly and unambiguously using his common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content.”* (para. 52 of the grounds). *“The Court must ascertain what the skilled person would derive directly and unambiguously using their common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter shall also be considered as part of its content. The assessment of added matter cannot be restricted to only those parts of the application as filed which the proprietor indicated as a basis for an amended claim during the examination proceedings at the EPO. A proper understanding of these parts requires an assessment of their content in the context of the disclosure of the application as a whole”* (para. 53).

110. In fact, as clarified by the Court of Appeal in *Sibio v. Abbott*, UPC-CoA-884/2025, decision of 13 August 2026 (headnotes 1 and 2) *“One situation where added matter may arise is when claimed subject-matter is obtained by importing one or more features from a certain embodiment in the*

application into a claim, while omitting one or more other features of this embodiment which were presented in combination with the imported feature(s) in the disclosure of this embodiment. This is referred to as an 'intermediate generalisation'. This is generally considered to be unallowable if there is a clearly recognisable functional or structural relationship among the omitted feature(s) and the claim features, also referred to 'an extricable link' between the omitted feature(s) and the claim features. 2) The technical effect that the invention aims to achieve, and whether an omitted feature contributes thereto, is relevant for the assessment of added matter. It is relevant when considering whether the skilled person would understand from the disclosure of the application as a whole that there is a structural or functional relationship between the omitted feature and the other features of the claimed embodiment or, in other words, when considering whether there is an inextricable link with such other features or, yet differently worded, whether such omitted feature is essential to the invention".

111. Accordingly, the party alleging added matter must identify, by means of a specific comparison, the subject-matter of the original disclosure that is said to have been extended in the later application or divisional patent.

112. BIOGARAN was therefore required to specify which features of EP'296 were absent from WO'427 (and only WO'427 since no arguments have been put forward as to the other parent applications) or resulted from an impermissible generalisation or extension of its disclosure.

113. The mere fact that the original application contains numerous embodiments and theoretically allows a very large number of combinations does not, in itself, establish added matter. Although this may raise issues of clarity or drafting technique, an extension of subject-matter arises only where the granted claim conveys technical information that the skilled person could not derive directly and unambiguously from the application as filed, contrary to Articles 123(2) and 138(1)(c) EPC.

114. As an impartial body, the Court cannot further develop or investigate an objection stated only in general terms. Doing so would amount to an inadmissible *ex officio* examination of a ground for invalidity raised by a party.

115. Procedural fairness under recital 5 of the Preamble to the RoP requires each party to plead its grounds of challenge clearly and with sufficient specificity. The Court can neither cure deficiencies in those grounds nor supplement them of its own motion, since doing so would substitute the Court for the challenging party and compromise its impartiality.

116. The Court therefore regards the first part of the added-matter attack as insufficiently substantiated. However, given the present uncertainty as to the degree of specificity required for such an attack, and pending further guidance from the Court of Appeal, the Court has nevertheless carried out a comparative examination of WO'427 and EP'296.

117. The Court acknowledges that this approach has, to a limited extent, involved an *ex officio* assessment.

118. In any event, for the reasons set out below, the added-matter objection is unfounded.

119. Claim 1 finds a direct basis in WO'427. The original application discloses nalmefene for reducing alcohol consumption, the identification of a patient with a high DRL, maintenance of that DRL after an observation period, and as-needed administration, although those features are expressed through linked embodiments. Claim 1 of the Patent reads as follows:

1. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

- a) identifying a patient with alcohol dependence

- i) who has a Drinking Risk Level (DRL) corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women, and
 - ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment,

wherein said observation period following initial assessment is 1-2 weeks, and

- b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

120. The Court has examined the initial parent application WO'427, EP'296 as filed, and each earlier application as filed, namely EP'604 and EP'564, in order to verify both the original basis and the continuity of disclosure throughout the divisional chain. At page 17, WO'427 expressly discloses embodiments E24, E25 and E26. Those embodiments are intended to be read in combination, since they expressly refer to one another.

- E24. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

- a) identifying a patient with alcohol dependence i) who has a high DRL, and/or ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment, and
- b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

- E25. Nalmefene according to embodiment 24, wherein said observation period following initial assessment is 1-2 weeks, such as about 2 weeks.

- E26. Nalmefene according to any of embodiments 21-25, wherein said patient identified in step a) has a DRL corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women.

Therefore:

- Nalmefene for use in reducing alcohol consumption in a patient with alcohol dependence,
- the two-step approach of identifying the patient based on both a high DRL and/or maintenance of that DRL after an observation period,
- the specific duration of the observation period (1–2 weeks),

- the specific DRL thresholds (> 60 g/day in men and > 40 g/day in women), and
- the "as-needed" administration.

121. The same passages E24, E25 and E26 are reproduced without modification throughout the successive divisional applications up to and including EP'296. The disclosure has therefore remained continuous from the initial parent application WO'427 to EP'296. Likewise, each dependent claim finds a basis in embodiments E29–E45 of WO'427, with the same continuity of disclosure preserved throughout the divisional chain from WO'427 to EP'296.

122. The skilled person would therefore derive directly and unambiguously the combination defined in claim 1 of EP'296 from the initial parent application WO'427 as filed.

123. BIOGARAN maintains that the 135 embodiments E1–E135 disclosed in WO'427 generate millions of possible combinations. It further submits that reliance on embodiments E1, E2, E6 and E23 would still require a selection as to the duration of the observation period, and that reliance on embodiments E24, E25 and E26 would entail replacing "and/or" in the disclosure with "and" in claim n. 1.

124. Those arguments are not persuasive. Embodiments E24, E25 and E26, relied on by both parties, provide a direct and unambiguous basis for the challenged subject-matter. Neither Article 138(1)(c) EPC nor Article 65(2) UPCA requires multiple independent disclosures in support of claim 1. The decisive question is whether claim 1 has a clear and unambiguous basis in the application as originally filed. Once that basis is established, no additional or cumulative support is required. It is therefore unnecessary to determine whether embodiments E1, E2, E6 and E23 could provide an alternative basis.

125. As regards "and/or" in embodiment E24, this wording expressly includes, as one of the disclosed alternatives, the simultaneous presence of the two features corresponding to features (i) and (ii) of Claim 1 of the Patent. Claim 1 merely limits the claimed subject-matter to that expressly disclosed alternative and therefore does not add subject-matter. Accordingly, E24 provides a basis for the combination of these features in Claim 1.

E24. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

- a) identifying a patient with alcohol dependence i) who has a high DRL, and/or ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment, and
- b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

E25. Nalmefene according to embodiment 24, wherein said observation period following initial assessment is 1-2 weeks, such as about 2 weeks.

E26. Nalmefene according to any of embodiments 21-25, wherein said patient identified in step a) has a DRL corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women.

126. The requirements of Article 138(1)(c) EPC, as referred to in Article 65(2) UPCA, are therefore satisfied for claim 1 of the main request.

127. The same conclusion applies to claims 2–18. Their subject-matter is supported by embodiments E29–E45 of WO’427 and the references contained therein, with continuity of disclosure preserved throughout the divisional chain from the initial parent application WO’427 to EP’296.

128. There is no need to adjudicate about dependent claims 7 and 9, since these have been deleted at the specific request of the patentee.

INSUFFICIENT DISCLOSURE

129. The Court recalls that, pursuant to Article 83 EPC, a European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

130. Pursuant to Article 65(2)(c) UPCA, a patent may be revoked if the grounds referred to in Article 138(1) EPC apply, including insufficiency of disclosure under Article 138(1)(b) EPC, which reflects the requirement laid down in Article 83 EPC.

131. In interpreting and applying that requirement, the Court follows the principles set out by the UPC Court of Appeal in Amgen Inc. v. Sanofi-Aventis Deutschland GmbH et al., UPC_CoA_528/2024, decision of 25 November 2025, according to which: *“Sufficiency has to be examined on the basis of the patent as a whole, thus on the basis of the claims, description and drawings, from the perspective of the skilled person with his common general knowledge at the filing or priority date.”* The Court further notes that: *“The test to be applied is whether the skilled person is able to reproduce the claimed subject-matter on the basis of the patent without any inventive effort and without undue burden.”* As explained by the Court of Appeal: *“An invention is sufficiently disclosed if the patent specification shows the skilled person at least one way – and in case of functional features: one technical concept – of performing the claimed invention.”* Moreover: *“Where a claim contains one or more functional features, it is not required that the disclosure includes specific instructions as to how each and every conceivable embodiment within the functional definition(s) should be obtained.”*

132. Against this legal framework, the issue is whether the patent, read as a whole and through the eyes of the skilled person equipped with the common general knowledge available at the relevant date, enables the claimed invention to be realised across the scope of the claims without requiring inventive activity or imposing an undue burden on the skilled person.

133. BIOGARAN files three attacks based on the Patent’s insufficiency (A – B – C):

A) A certain group of patients is excluded from the trials: this results in insufficiency

134. According to the Claimant's documents, Rounsaville et al. (Rounsaville et al., Drug Alcohol Depend. 2003; 70(2): 117–125) and Humphreys et al. (Humphreys & Weisner, Am J Psychiatry 2000; 157:588–594), show that excluding patients compromises the generalizability of the results (Rounsaville p.4, section 3.2) and that the results are not reliable (Rounsaville et al., p.5, section 3.4)

or cannot be assumed to apply to excluded patients (Humphreys et al. p.588, right column). According to BIOGARAN, it is therefore not credible that the therapeutic effect is achieved across the entire range of the claim, and the results are not reliable.

135. As a preliminary point, BIOGARAN's insufficiency attacks, including the following ones, must be assessed from two distinct but connected perspectives: feasibility and credibility. Feasibility (Art. 83 EPC) concerns whether the skilled person can practically carry out the claimed treatment without undue burden. Conversely, credibility concerns whether, on the basis of the patent disclosure and the common general knowledge of a person skilled in the art at the filing date, it is credible that the claimed therapeutic effect is achieved across the scope of the claim.

136. In the present case, the practical feasibility of the claimed treatment is not in dispute. BIOGARAN does not allege that the skilled person would be unable to identify alcohol-dependent patients with a high DRL maintained after the observation period, or to administer nalmefene on an as-needed basis.

137. The objection is instead directed to the credibility of the therapeutic effect in patients who were not included in the clinical trials.

138. The Court maintains that this attack is not successful.

139. The fact that certain categories of patients were excluded from the trials does not, as such, make the effect non-credible for those patients. A lack of statistically significant results in a smaller subgroup does not establish lack of efficacy where the study was powered for the overall population. The Court notes that the Court's assessment is in line with the EPO's assessment (see, e.g., EPO T 136/24). Serious doubt arises only where the opponent identifies a particular subgroup and substantiates, by verifiable facts, a reason why the treatment would not work in that subgroup.

140. In the present case, BIOGARAN has merely alleged, but not demonstrated by verifiable facts, that the effect would not be achieved in the excluded populations (see UPC_CoA_528/2024 headnote 9: *"The burden of presentation and proof lies with the party invoking invalidity of the patent"*). In the absence of such evidence, and in light of the clinical data disclosed for the claimed subgroup, the Court considers the therapeutic effect sufficiently credible.

141. The fact that the clinical trials excluded patients with substance-abuse disorders other than alcohol dependence, or with significant depressive or psychotic co-morbidities, does not in itself establish insufficiency of disclosure. Such exclusion criteria are common in clinical studies and are normally used to ensure internal validity, patient safety and methodological reliability. They do not amount, without further evidence, to a technical teaching that nalmefene would not achieve the claimed therapeutic effect in every patient not enrolled in the trials.

142. The articles relied upon by BIOGARAN, Rounsaville et al. and Humphreys et al., support the general proposition that restrictive inclusion and exclusion criteria may limit the external validity of clinical trial results. They do not, however, demonstrate that the therapeutic effect disclosed in

EP'296 cannot be obtained in the subgroup defined by claim 1, nor do they provide verifiable facts capable of giving rise to serious doubts as to sufficiency.

143. Contraindications are clinical considerations relating to the administration of a medicinal product to particular patient populations and their management falls within the ordinary knowledge and competence of the person skilled in the art. As such, they do not, in themselves, appear to have any bearing on whether the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art.

144. The Court considers, in line with the established practice before the EPO, that it is not required to exclude from the claims every possible patient population or therapeutic application for which the invention does not work. Such a requirement would, in practice, be impossible to fulfil. The Court further considers that there is no requirement in the context of sufficiency of disclosure (Article 83 EPC) of second medical uses, for the claims expressly to exclude all non-working patient groups.

145. Lack of credibility arises when serious grounds are present to suggest that the technical effect disclosed by the patent cannot be achieved. Mere uncertainty or doubts are not sufficient to substantiate insufficiency. The patent is read by a person skilled in the art. The skilled person knows that a teaching cannot elaborate on all possible combinations of the technical effect. In that regard, the person skilled in the art knows that if nalmefene is effective in a heterogeneous group of patients it is likely to be effective also in patients with psychotic co-morbidity and depression. The exclusion of those patients does not, in itself, imply that the treatment lacks efficacy in the excluded patient population. In conclusion, the burden of proof to the contrary lies with the Claimant, who has not established that this is the case.

B) The patentee has not demonstrated that the treatment can be achieved without motivational support. This results in insufficiency.

146. The second insufficiency objection concerns the so-called BRENDA model. The Claimant submits (item 4.3.2 of the Statement of claim) that the invention is insufficiently disclosed on the ground that the motivational support disclosed in the Patent, para. 22 (reference is made to document 'Starosta, Exhibit 9.3 describing: the BRENDA model, integrating psychological treatment and Pharmacotherapy for the treatment of alcohol use disorders') is described in the Patent as necessary and, therefore, as an essential feature of the invention, while it is not reflected in the claims.

147. To better explain the so-called BRENDA model, reference is made to documents Karhuvaara et al. (Karhuvaara et al., Alcohol Clin Exp Res. 2007; 31(7):1179–1187) and Starosta et al. (Starosta et al., J Psychiatr Pract. 2006; 12(2):80–89) submitted by the Claimant.

148. Karhuvaara et al. describes the BRENDA model as a mild emotional support, which does not include abstinence promotion but rather focuses on the importance of regular administration of medication:

The study procedures did not include any formal, manual-guided psychosocial treatment; however, some elements of the psychosocial intervention called BRENDA (Voipicelli et al., 2001) were adopted. These elements were biopsychosocial assessment, feedback to the subject on these assessments, simple advice to reduce alcohol drinking, and monitoring of the treatment progress. The main emphasis was on the correct use of the study medication. Abstinence was not promoted and no treatment goals were set. It should be noted that the subjects were not made aware of the concepts and definitions regarding efficacy variables, such as a HDD.

149. Starosta et al. clarifies that the BRENDA model is based on biopsychological evaluation, interviews, empathic understanding of the patient's situation, needs identified jointly by patient and clinician, advice tailored to those needs, further assessment and discussion aimed to enhance motivation. After a preliminary assessment, the BRENDA approach can be administered in as little as 15 minutes, although it can also take longer when patients first begin, and may stretch over several weeks.

150. If this is true, Starosta et al. appears to describe such motivational support as an adjunct to the medicinal treatment that may enhance its efficacy, rather than as an indispensable feature of the treatment.

151. Furthermore, also here, the Claimant does not appear to have established that the invention would not work in the absence of such motivational support.

152. Moreover, paragraph [0058] of the Patent contradicts BIOGARAN's allegation. It states that a motivational and adherence-enhancing intervention according to the BRENDA model was administered in the studies, thereby showing that counselling formed part of the clinical-study setting. As the Court of Appeal also held in the decision cited above, sufficiency must be assessed on the basis of the patent as a whole, including the claims, the description and the drawings. Read in that manner, the patent renders the claimed therapeutic effect credible in light of the clinical studies disclosed in the description.

153. It follows that the BRENDA model is not an essential technical feature of the claimed invention or that the therapeutic effect depends on that specific model rather than on the administration of nalmefene to the selected patient group.

154. Additionally, also Karhuvaara et al. (page 1186) testifies that nalmefene administration appears to be effective when simply combined with medical treatment

In conclusion, targeted nalmefene appeared to be effective and useful in reducing heavy drinking when combined with simple medical management, which suggests that this approach may be suitable for use in nonspecialist outpatient settings. This reduction in heavy drinking was

155. Here, too, BIOGARAN has not identified any evidence showing that, without that specific counselling model, the skilled person would be unable to perform the claimed treatment or that the claimed effect would cease to be credible. Since sufficiency does not require every ancillary condition of the clinical protocol to be reproduced in the claim (following headnote 7 in the above-cited Court of Appeal decision in UPC_CoA_528/2024: *‘A fair protection requires that variants of specifically disclosed embodiments that are equally suitable to achieve the same effect, which could not have been envisaged without the invention, should also be protected by the claim. Consequently, any non-availability of some embodiments of a functionally defined claim is immaterial to sufficiency, as long as the skilled person through the disclosure is able to obtain suitable embodiments within the scope of the claim’*), the absence of a BRENDA limitation from claim 1 does not render the invention insufficiently disclosed.

156. The second objection must therefore also be rejected.

C) The dosage of nalmefene. The patent discloses only the dosage of 18mg.

157. The Claimant further submits that the invention is insufficiently disclosed on the ground that claim 1 simply indicates that nalmefene is to be taken on an ‘as-needed’ basis, with no mention of any dose of nalmefene, and further questions the expressions ‘in a therapeutically effective amount’ (page 3, lines 8-11) and ‘in an amount sufficient to produce the intended effective response’ (page 7, lines 22-32 of the Patent) in the specification of the Patent, concluding that the original teaching made clear that the dosage was not optional.

158. According to the Claimant, the claim encompasses very high doses and a high dose regimen, which may cause severe side effects, as well as very low doses which are not likely to have any therapeutic effects and therefore do not credibly enable the person skilled in the art to obtain the claimed therapeutic effect, namely the reduction in alcohol consumption.

159. The Court does not share this conclusion.

160. The dosage of nalmefene is provided for in dependent claims 10 and 11. Dependent claim 10 reads: Nalmefene for use according to any of claims 1-9, wherein said nalmefene is used in a dose of 10-20 mg such as 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg or 20 mg. Dependent claim 11 reads: Nalmefene for use according to any of claims 1-10, wherein said nalmefene is used in a dose of 18 mg.

161. BIOGARAN maintains that, based on [0044], the dosage of 18 mg represents the preferred embodiment.

162. The Court observes that [0044] refers to ‘a’ preferred embodiment, whereas [0025] describes that only ‘in one embodiment’ is the therapeutically effective amount 18 mg.

163. The Panel is of the opinion that the dosage of 18 mg does not correspond to a preferred embodiment.

164. Paragraph [0044] clearly suggests that the range of dosage of the pharmaceutical composition typically lies between 10 and 20 mg.

165. That said, the specific issue raised by the Court at the interim conference was whether the information available in the Patent was sufficient to render the claimed therapeutic effect credible also for doses below 18 mg, given that the clinical studies disclosed in the patent were conducted exclusively using the 18 mg dose. This Court basically agrees with the EPO's findings in T 0728/21 (Vertex), 16 November 2023, where the EPO Board held, for example, that, for a second-medical-use claim, the patent must make it credible at the filing date that the claimed composition is suitable for the therapeutic use. A deficient disclosure cannot be cured by post-published evidence.

166. This said, the Court maintains that the therapeutic effect is disclosed for the whole range of dosage. The credibility of a therapeutic effect may derive not only from the patent itself but also from the prior art.

167. In fact, as will be explained in more detail below, in the present case, the therapeutic use of the product for the same disease was already known in the prior art, as was an appropriate dosage of the product, as disclosed in the documents submitted by the Claimant and accepted in the present proceedings. Moreover, the alleged contribution of the invention does not appear to reside in the dosage regimen, which is not a feature of claim 1, but rather in the identification of a specific patient group showing an improved response to the treatment.

168. Further, the patent need not necessarily contain clinical data. It is sufficient if it provides specific and verifiable technical information establishing a rational basis for the claimed therapeutic effect, rather than a mere unsupported assertion.

169. Additionally, the Court agrees with EPO's findings in T 609/02, where the Board further held that therapeutic suitability may derive credibility from the prior art where the relevant effect was already known. Such prior art need not form part of the common general knowledge.

170. Moreover, once the patent provides a credible disclosure, an insufficiency objection requires serious doubts that are supported by verifiable facts. Mere uncertainty, or the absence of a statistically significant clinical benefit in a later study, is not enough. Post-published evidence cannot establish credibility for the first time but may be considered when assessing whether an effect made credible at the filing date has been convincingly disproved.

171. Conclusively, there is no such general proposition that every second medical use claim must, as a matter of sufficiency, recite the precise dosage in the independent claim. In other words, it is not necessary to provide clinical proof for every conceivable embodiment.

172. These principles have been set out by the UPC Court of Appeal's order of 26 February 2024 in NanoString Technologies Inc. v. 10x Genomics Inc. (UPC_CoA_335/2023): the description and drawings must always be used as explanatory aids for interpretation, not just to resolve any ambiguities in the claim language, such that only after examination of the description and drawings does the scope of the claims become apparent (headnote 2, paragraph 2). However, Art. 138(b) EPC establishes a more specific principle which is decisive here: where the claimed therapeutic effect is a functional technical feature of the claim, the patent must make it credible, at the filing date, that substantially all embodiments falling within the claim can achieve that effect without undue burden.

173. On further examination of the points mentioned above, it can be noted that this Court is full aware of EPO's findings in G 2/21 (points 74-77) according to which, in the context of second medical use claims, the claimed therapeutic effect is not a merely external advantage relied upon for inventive step; it is part of the claimed subject-matter itself. Consequently, the question of whether that therapeutic effect is achieved must be assessed under Article 83 EPC, as an issue of sufficiency of disclosure. This means that, where a known therapeutic agent is claimed for a new therapeutic application, the patent must make it plausible, at the filing date, that all the claimed dosages are suitable for that specific therapeutic use.

174. Although the UPC is not bound by decisions of the EPO, the reasoning set out above is persuasive.

175. Nevertheless, in the present case, the therapeutic contribution relied upon by the proprietor find supports in the patent itself and in the prior art. It is not the general use of nalmefene in alcohol dependence, which was already known, but the achievement of a more pronounced reduction of alcohol consumption in a narrowly defined subgroup of patients, namely alcohol-dependent patients with a high DRL who maintain that level after the observation period.

176. Karhuvaara et al. (Targeted Nalmefene with simple medical arrangements in the treatment of heavy drinkers), which is acknowledged by both parties to be among the closest prior-art documents and which is expressly referenced in the Patent, referring to previous studies (Anton et al. and Mason et al.) where the starting dosage was 5 mg, discloses (page 1186) that nalmefene shows effectiveness already at the lowest patent-disclosed dosage of 10 mg:

Although the mechanism of these effects remains undetermined, it seems justified to conclude that it is possible to minimize, or even eliminate, the occurrence of these effects with a low starting dose. For many subjects, drinking seemed to be well controlled with a 10 mg dose, suggesting that the dose should probably be adjusted individually. One of the aims of the study was to evaluate the suit-

177. Consequently, the skilled person – based on the description as filed [0025], [0036] and [0044], the prior art dosages, the ranges and guidance provided in the description, the exemplified effective dose of 18 mg in the presented clinical trials and the common general knowledge – would be able to select suitable dosing regimens without undue burden and would also positively consider the full range of disclosed dosages, although claim 1 does not specify any particular dosage or dosage range.

178. The precise therapeutic dosage need not, in fact, necessarily be stated in the independent claim where, upon construing the patent as a whole, including the description and the drawings, the skilled person can identify that dosage precisely and unambiguously. It forms part of common general knowledge that excessively low doses may be ineffective and excessively high doses toxic. Determining a safe and effective dose is ordinarily a routine task for the skilled person. The application additionally disclosed an effective regimen.

179. The determination of the dose appears to form part of the common general knowledge of the skilled person and does not constitute, in the case at hand, an undue burden. Indeed, as no convincing evidence to the contrary is provided by the Claimant, it appears that the skilled person would, in the ordinary course of implementing the invention, select dosage regimens that would reasonably be expected to achieve the claimed therapeutic effect, whilst avoiding doses which, in the light of the prior art and the known safety profile of nalmefene, would be expected to produce unacceptable adverse effects or to be therapeutically ineffective.

180. Conclusively, the Claimant has not established that the invention would not work with dosage regimens other than those specifically disclosed in the Patent, such as the 18 mg dosage tested in the clinical trials reported in the examples. The burden of proving otherwise lies with the Claimant and they provided no sufficient factual basis for seriously doubting that, on the basis of the experimental results reported in the Patent and the prior art, the skilled person could carry out the claimed therapeutic application using other dosage regimens without undue burden. The Court therefore considers, contrary to the Claimant's submissions, that the requirement of sufficiency of disclosure is met.

NOVELTY

181. Under Article 54(1) and (2) EPC, a claimed invention lacks novelty where a single item of prior art makes available to the skilled person, directly and unambiguously, all the features of the claim, whether explicitly or implicitly, taking account of the skilled person's common general knowledge at the relevant date.

182. Where the claimed substance or composition is already known, novelty can only reside in the specific therapeutic use claimed. As the UPC held, (LD Düsseldorf, 13 May 2025, UPC_CFI_505/2023, headnote 1) "*such a therapeutic use can be a new indication or an indication for a new group of patients.*" Accordingly, where novelty is said to arise from the definition of a patient subgroup, the decisive issue is whether that subgroup defines a genuinely new therapeutic use within the meaning of Article 54(5) EPC.

183. This approach is consistent with the established case law of the Boards of Appeal of the EPO (see, inter alia, T 19/86, OJ EPO 1989, 24; T 893/90; T 233/96; T 1399/04; and T 734/12), which recognizes that a patient subgroup may confer novelty only where it constitutes a physiologically or pathologically distinct subgroup over that disclosed in the prior art and thereby defines a genuinely different therapeutic use. The mere identification of a subset of patients is therefore insufficient. Rather, the defining characteristics of the claimed subgroup must bear a functional relationship to the therapeutic effect relied upon, so that the claimed treatment conveys a distinct therapeutic teaching not directly and unambiguously disclosed in the prior art.

184. Against this legal framework, the assessment must focus on whether the prior art directly and unambiguously discloses the treatment of the patient group defined in claim 1 of the Patent. If the claimed patient group merely constitutes a subset of patients already encompassed by the prior art,

the requirement of novelty is, *prima facie*, not met. Conversely, where the claimed patient population is defined by physiological or pathological characteristics that are functionally linked to the therapeutic effect relied upon, the claimed subject-matter may satisfy the novelty requirement under Article 54(5) EPC.

185. As already clarified in the section on claim construction, the existence of a patient subgroup should not, however, be regarded as constituting the therapeutic use independently of the treatment itself. The therapeutic intervention remains the administration of the known medicinal product for the treatment of the disease concerned. The patient subgroup instead defines the technical context in which that therapeutic intervention gives rise to a distinct therapeutic use. What characterizes the claimed invention is therefore not the identification of a class of patients as such, but the recognition that the claimed therapeutic effect is specifically associated with patients possessing the defining characteristics of the claimed subgroup. Accordingly, the invention lies not in the selection of patients *per se*, but in the identification of a technically meaningful relationship between the defining characteristics of the claimed patient population and the therapeutic effect achieved by the treatment. The patient subgroup is thus not the object of the invention in itself; rather, it constitutes the technical feature that renders the claimed therapeutic use novel.

186. This interpretation also ensures consistency with other categories of second medical use claims recognized under Article 54(5) EPC, including claims directed to a new therapeutic indication, a new route of administration or a new dosage regimen. In each case, novelty derives from a technical feature that gives rise to a distinct therapeutic teaching. In the case of a patient subgroup, that technical feature is the demonstrated relationship between the defining characteristics of the subgroup and the therapeutic effect achieved by the claimed treatment.

187. The assessment should therefore proceed in two successive steps.

188. In the First step, it must be determined whether the claimed subject-matter discloses a genuine invention. Since nalmefene is known, the invention cannot reside in the product itself or in the mere definition of a patient subgroup.

189. It must therefore be determined whether the patient subgroup defined in claim 1, namely a patient who:

- (i) has a DRL corresponding to consumption > 60 g/day of pure alcohol for men and > 40 g/day for women (feature 2.1.); and
- (ii) maintains the DRL of alcohol consumption after an observation period of 1-2 weeks following the initial assessment (features 2.2. and 2.2.1).

bears a functional relationship to the claimed therapeutic effect.

190. In particular, it must be assessed whether the Patent teaches that treatment with nalmefene has a pronounced effect on the reduction of alcohol consumption specifically in a patient having the defined characteristics of claim 1, thereby providing a distinct therapeutic teaching within the meaning of Article 54(5) EPC.

191. The answer is affirmative. EP'296 does not merely select patients who drink heavily. It selects, by feature 2, alcohol-dependent patients who, by feature 2.1, first have a high DRL and who, by feature 2.2, then maintain that high DRL after a defined observation period following initial assessment, the duration of which is specified by feature 2.2.1. That second assessment has a clinical meaning. Among patients diagnosed with alcohol dependence it excludes early reducers, 'patients included in the three Lundbeck phase III studies (12014A, 12023A and 12013A) who had considerably reduced the alcohol consumption in the period between screening and randomisation' [0018], and identifies patients whose drinking behaviour persists despite the initial clinical contact and observation period.

192. According to the Patent, this subgroup of alcohol-dependent patients, though more stable in their general drinking propensity, shows a more pronounced reduction in heavy drinking days and total alcohol consumption when treated with nalmefene. The clinical effect is apparent.

193. Indeed, the example part of the Patent discloses three clinical trials (see paras. [0053]-[0064], and Table 6, studies 12014A, 12023A and 12013A) showing the efficacy of nalmefene administered in an amount of 18 mg in an as-needed dosing regimen for the treatment of patients with alcohol dependence. The experimental results are presented in Table 6 for different groups of alcohol dependent patients, including the "Total population," "High DRL at baseline," "Total excl. ERs," and "High DRL at baseline & randomisation":

- The group "Total excl. ERs" excludes patients from the total group who significantly reduced alcohol consumption in the 1-2 weeks between screening and randomisation.
- The group "High DRL at baseline & randomisation" pertains to patients who had a high DRL at baseline and maintained that high DRL until randomisation. A pronounced effect of nalmefene is shown for this group.

194. The effects of nalmefene were evaluated based on two parameters (para. [0034] of the Patent):

- HDD: corresponding to days on which patients maintained a high level of alcohol consumption, according to the WHO scale, i.e. more than 60 g/day for men and more than 40 g/day for women (see para. [0013] of the Patent);
- Total alcohol consumption ("TAC") in g/day over a period of one month (28 days) (para. [0012] of the Patent).

195. The results presented in Table 6 of the Patent (reproduced below) for the three clinical studies demonstrate that nalmefene has a higher efficacy specifically in the patients who had a high DRL at baseline and who maintained a high DRL after the observation period, i.e. the patient as defined in claim 1 of the Patent.

Table 6. Results (Mixed model repeated measures (MMRM) analysis) at Month 6.

Study	Endpoint	Population	Mean difference to placebo in the change from baseline to month 6	p-value
12014A	HDD	Total population	-2.3 days/month	0.002
		High DRL at baseline	-2.6 days/month	0.006
		Total excl. ERs	-3.1 days/month	<0.001
		High DRL at baseline & randomisation	-3.7 days/month	0.001
	TAC	Total population	-11.0 g/day	<0.001
		High DRL at baseline	-12.2 g/day	<0.001
		Total excl. ERs	-14.5 g/day	<0.001
		High DRL at baseline & randomisation	-18.3 g/day	<0.001
12023A	HDD	Total population	-1.7 days/month	0.012
		High DRL at baseline	-2.1 days/month	0.010
		Total excl. ERs	-2.0 days/month	0.012
		High DRL at baseline & randomisation	-2.7 days/month	0.025
	TAC	Total population	-5.0 g/day	0.088
		High DRL at baseline	-6.6 g/day	0.062
		Total excl. ERs	-7.0 g/day	0.037
		High DRL at baseline & randomisation	-10.3 g/day	0.040
12013A	HDD	Total population	-0.9 days/month	0.160
		High DRL at baseline	-1.1 days/month	0.253
		Total excl. ERs	-1.4 days/month	0.082
		High DRL at baseline & randomisation	-2.6 days/month	0.071
	TAC	Total population	-3.5 g/day	0.232
		High DRL at baseline	-5.6 g/day	0.219
		Total excl. ERs	-7.9 g/day	0.036
		High DRL at baseline & randomisation	-15.3 g/day	0.031

196. This efficacy appears to be higher in these patients than:

- in the total study population, which also included patients with a medium DRL at baseline;
- in the patient population who had a high DRL at baseline, thus also including patients who did not maintain their high DRL after the observation period (Patent, para. [0035]);
- in the total study population, excluding "ERs" ("Early Reducers"). Early Reducers are referred to in the Patent as patients who considerably reduced their alcohol consumption from high or medium DRL to below medium DRL in the observation period between screening and randomization (Patent, para. [0036]).

197. It can be concluded that the alleged invention resides in the recognition that a more pronounced effect in the reduction of alcohol consumption is achieved upon treatment with nalmefene specifically in alcohol-dependent patients having the defining characteristics of claim 1

198. On that basis, the claimed patient subgroup is, prima facie, capable of defining a distinct therapeutic use within the meaning of Article 54(5) EPC.

199. The second step is the assessment of whether any of the prior art documents submitted by the Claimant directly and unambiguously disclose the same technical teaching. In particular, it must be determined whether the prior art teaches that treatment with nalmefene produces a superior efficacy in patients having the defining characteristic of claim 1.

200. BIOGARAN submits that EP'296 lacks novelty because nalmefene had already been disclosed, before the relevant date, for reducing alcohol consumption in alcohol-dependent patients and because the patient group defined in claim 1 was not new. Since the claim concerns a known compound for a known therapeutic purpose, BIOGARAN maintains that novelty can reside only in

the allegedly specific patient subgroup, but argues that the subgroup was already disclosed, explicitly or implicitly, by the prior art.

201. BIOGARAN argues that Karhuvaara et al. disclosed a clinical study in alcohol-dependent or alcohol-problem patients treated with nalmefene to reduce alcohol consumption. The study population had an average consumption corresponding to a high DRL: 43.2 drinks per week, at 12 g of pure alcohol per drink, which equates to approximately 74 g/day. BIOGARAN further submits that an observation period occurred between screening and randomisation, during which some screened subjects were excluded, so that the patients ultimately randomised must have maintained the relevant drinking profile before treatment; in any event, it contends that such persistence is implicit in their categorisation as alcohol-dependent patients. Finally, Karhuvaara et al. disclosed as-needed administration of nalmefene when drinking was believed to be imminent, preferably 1–2 hours before alcohol intake. On that basis, BIOGARAN contends that Karhuvaara et al. discloses every feature of claim 1 and of the relevant dependent claims.

202. They further argue that the alcohol-dependent patients in Karhuvaara et al. by definition maintain a high alcohol consumption during an observation period, otherwise they would not be alcohol-dependent, and therefore that there is at the very least a strong overlap between the patient population of Karhuvaara et al. and the claimed group, precluding the group of patients that is claimed to be distinguishable from the one disclosed in Karhuvaara et al.

203. The Court is not convinced by this novelty attack.

204. Karhuvaara et al., cited at paragraph [0004] of the Patent as prior art, evaluated the efficacy and safety of targeted nalmefene taken when participants anticipated drinking ('when they believed drinking was imminent': page 1 under 'Methods'). It was a randomised, double-blind, placebo-controlled multicentre study involving 403 heavy drinkers (Karhuvaara et al., page 1182, left column, first lines), who received only minimal psychosocial support (page 1181, left column, second paragraph). 433 patients underwent screening procedures but only 403 patients were enrolled in the study after "a certain amount of time elapsed". Eligibility requirements stipulated that participants be at least 18 years old, have had at least 18 heavy drinking days during the preceding 12 weeks, and not have had more than 14 consecutive days of abstinence during that period (page 1180, right column, third and fourth paragraphs).

205. The principal findings based on this study were (p. 1179, abstract and pp. 1184-1186) that Nalmefene significantly reduced the number of heavy drinking days (HDDs) compared with placebo: *"the mean number of HDDs during the 12 weeks before inclusion was 15.5 in the nalmefene group and 16.2 in the placebo group. During treatment the mean number of HDDs were 8.6 to 9.3 in the nalmefene group and 10.6 to 12.0 in the placebo group."* It also reduced weekly alcohol consumption, drinks per drinking day, and very heavy drinking days (VHDDs) (During the randomized withdrawal period the subjects randomized to placebo apparently returned to heavier drinking).

206. Nalmefene was generally well tolerated, although adverse events (notably nausea, insomnia, dizziness and fatigue) occurred more frequently than with placebo (p.1184 and 1185).

207. In the present case, since the administration of the same therapeutic compound is not in dispute, the analysis must focus on features 2, 2.1, 2.2 and 2.2.1 of claim 1. This because feature 3 is undisputedly disclosed:

Another interesting approach is using the medication in a targeted fashion; the drug dose is taken only when there is an identified risk for heavy drinking. The latter approach

And

The primary aim of this multicenter study was to determine the efficacy and safety of targeted nalmefene, used on an "as-needed" basis, in reducing heavy drinking in a

208. Feature 2 requires a patient with alcohol dependence. Feature 2.1 requires that the patient have a specific DRL, corresponding to consumption of more than 60 g/day of pure alcohol for men and more than 40 g/day for women. Feature 2.2. requires maintenance of that DRL after an observation period following the initial assessment. Feature 2.2.1 further specifies that the observation period must be between one and two weeks.

209. These features are not disclosed in Karhuvaara et al.

210. Karhuvaara et al. enrolled subjects on the basis of heavy drinking behaviour. Alcohol dependence (feature 2) was not an inclusion criterion, and 7 % of the study population did not meet the DSM-IV criteria for alcohol dependence. Alcohol dependence was not among the exclusionary criteria. See page 1182 of Karhuvaara et al.:

(Table 2). In both groups, 93% of the subjects met the criteria (DSM-IV) for alcohol dependence. The subjects were

211. Moreover, there was no second DRL assessment before treatment (feature 2.1.). The standard deviation of 38.4 g/day reported in Table 3 indicates that a significant proportion of participants consumed less than the claimed thresholds. Equally, an average DRL does not establish that each patient began treatment above the claimed threshold. Karhuvaara et al. discloses a Total Alcohol consumption (TAC) but not a Drinking Risk Level (DRL) (feature 2.1).

212. Nor was there a prospective observation or run-in period before treatment (feature.2.2). Subjects were excluded in Karhuvaara et al. under different conditions than those disclosed in EP'296 (observation period of one/two weeks):

for person. Prospective subjects were excluded if they (i) had any medical, psychiatric, or social problem whose treatment would be considered to have a priority over the treatment of the alcohol problem, or that would interfere with the conduct of the study or impair study treatment compliance, (ii) had a severe hepatic or renal disorder, (iii) were dependent on other drugs or used illicit drugs, (iv) had previously participated in studies with nalmefene or recently participated in other drug studies, (v) were recently treated with disulfiram or naltrexone, or (vi) were pregnant or nursing.

213. Some people have been excluded post preliminary assessment or observation, but Karhuvaara et al. does not state why the 29 screened subjects were not enrolled. They may have failed one or more eligibility criteria, but no reason-by-reason breakdown is provided. Their exclusion therefore does not show that they reduced their alcohol consumption (ERs) or failed to maintain a high DRL before treatment.

214. Therefore, Karhuvaara et al. does not directly and unambiguously disclose patients who maintain a high DRL after a 1- to 2-week observation period following initial assessment (feature 2.2.), nor does it teach that nalmefene produces superior efficacy in patients defined by that criterion. The fact that individuals volunteered for the study (page 1180, column 2) and that alcohol dependence was not an inclusion criterion (page 1186, paragraph 3) further supports that the specific patient group defined in the present claim 1 is not directly and unambiguously disclosed.

215. Even assuming that a majority of the study participants were alcohol-dependent, this does not constitute a direct and unambiguous disclosure of a treatment specifically directed to alcohol-dependent patients.

216. BIOGARAN arrives at the supposed disclosure of the feature of the observation period by artificially equating heavy drinkers with alcohol-dependent patients. Under this interpretation, the observation period would not be a limiting feature of EP'296, and would be implicit in the definition of alcohol dependence since, in their view, a drinker who was able to autonomously reduce their alcohol consumption would not be alcohol-dependent at all.

217. This interpretation circumvents features 2.2 and 2.2.1. just to arrive at the conclusion that all features in EP'296 are disclosed by Karhuvaara et al.. and is artificial. 'Alcohol dependence' is an autonomous claim-limiting feature and cannot be bypassed or replaced by analogous categories that overlap with it only in part, such as heavy drinkers or persons with alcohol-related problems, as addressed earlier under the section "claim construction".

218. It remains to be determined whether any prior-art document relied upon by BIOGARAN directly and unambiguously discloses that same technical teaching, including treatment with Nalmefene of the subgroup defined by claim 1 and the functional association between the subgroup criteria and the more pronounced therapeutic effect.

219. As established in the priority analysis, documents SmPC for Selincro, Mann et al. 2013 (Mann et al., *Biol. Psychiatry*, 73, 706–713, 2013) and EMA Assessment Report do not form part of the state of the art under Article 54(2) EPC in view of the valid priority P2. Late filed Document Van den Brink 2013 (van den Brink et al., *Alcohol Alcohol.* 2013; 48(5):570–578), is likewise not prior art. Any late-filed documents must be assessed according to their publication date and procedural admissibility. Accordingly, any remaining novelty attack based on those documents is disregarded by the Court.

220. The Court therefore considers, contrary to the Claimant's submissions, that the requirement of novelty is met in respect of Claim 1, and therefore in respect of the dependent claims incorporating the features of Claim 1.

INVENTIVE STEP

221. The benchmark for assessing inventive step was set by the Court of Appeal in Meril Italy a.o. v. Edwards Lifesciences Co., UPC_CoA_464/2024 et al., decision of 25 November 2025 (headnotes 8-12); Amgen v Sanofi/ Regeneron, UPC_CoA_528/2024 and 529/2024, decision of 25 November 2025 (headnotes 10-22)

a. It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the person skilled in the art, with their common general knowledge, as at the application or priority date (also referred to as the effective date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the person skilled in the art, on the basis of the application, understands is (are) achieved with the claimed invention.

b. In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution.

c. The claimed solution is obvious when at the effective date the person skilled in the art, starting from a realistic starting point in the state of the art in the relevant field of technology and wishing to solve the objective problem, would (and not only “could”) have arrived at the claimed solution.

d. A starting point is realistic if the teaching thereof would have been of interest to a person skilled in the art who, at the effective date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention.

e. The person skilled in the art has no inventive skills and no imagination and requires a pointer or motivation (in German: “Anlass”) that, starting from a realistic starting point, directs them to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be considered not inventive/obvious when the person skilled in the art would take the next step, prompted by the pointer or as a matter of routine, and arrive at the claimed invention.

222. As asserted above, in the Court’s view, the objective problem is to identify, within the population of alcohol-dependent patients, a subgroup in which nalmefene produces a more pronounced reduction in alcohol consumption.

223. The Court’s assessment on inventive step is confined to documents forming part of the state of the art before the valid priority date. Also here, later documents will not be considered i.e. Selincro 2013, Mann 2013, published online on 12 December 2012, and the EMA Assessment Report of 13

December 2012 cannot be relied upon for inventive step because they post-date the relevant priority date.

224. The Court further considers that the EPO Board of Appeal's decision T 0963/20 concerning parent patent EP'564 does not have *res judicata* effect before the UPC. This argument of BIOGARAN will also be disregarded. Although, as a matter of law and principle, this issue concerns admissibility, the Court will address it here, in the section dedicated to inventive step, in accordance with the order in which it has been presented by the Claimant.

225. In fact, although EP'564 and EP'296 are closely related patents with similar subject-matter, they are legally distinct patents. *Res judicata* applies between the same parties on the same legal subject-matter (*petitum* and *causa petendi*). Moreover, the EPO Boards of Appeal and the UPC belong to distinct legal systems and exercise jurisdiction under different legal frameworks. An EPO decision may therefore be persuasive as to the arguments conveyed therein, but it does not bind this Court, which must carry out its own assessment of the facts and the applicable law.

226. BIOGARAN relies principally on Karhuvaara et al. as a realistic starting point, alone and in combination with:

- Lundbeck's 2011 corporate release (Lundbeck, Corporate Release No. 442, 15 June 2011),
- EMA Guidelines ("Guideline on the development of medicinal products for the treatment of alcohol dependence", EMA/CHMP/EWP/20097/2008, 18 February 2010),
- and in combination with additional papers such as
- Soyka et al. (Soyka & Rosner, *Expert Opin. Investig. Drugs* 2010; 19(11):1451–1459),
- Mann P59 (Mann et al., P-59, 20th European Congress of Psychiatry, March 2012),
- Schuckit et al. (Schuckit et al., *Am. J. Psychiatry*, 155, 733–740, 1998),
- Lejoyeux et al. (Lejoyeux et al., *Eur. Addict. Res.*, 7, 198–201, 2001),
- Pablo-Mendez et al. (Pablos-Mendez A, et al. *JAMA*. 1998;279:222–225.),
- Franciosa et al. (Franciosa JA. *Am J Cardiol*. 1999;83:942–944),
- Bisaga et al. (Bisaga A, et al. *Drug Alcohol Depend*. 2005;77:7–11),
- Nature Reviews Drug Discovery (Nalmefene reduces alcohol use in Phase III trial", *Nat. Rev. Drug Discov*. 2011; 10:566),
- Mitchell et al. (Mitchell et al., *Sci. Transl. Med*. 2012; 4(116):116ra6), and
- Saxon et al. (Saxon et al., "Further Validation of the Alcohol Dependence Scale as an Index of Severity", *J. Stud. Alcohol Drugs*, 68, 149–156, 2007).

227. BIOGARAN submits that Karhuvaara et al. already disclosed nalmefene for heavy drinkers, reduction rather than abstinence as the treatment objective, and as-needed administration.

228. The Court considers both Karhuvaara et al. and LUNDBECK's corporate press release of 15 June 2011 to be realistic starting points. As the Court of Appeal clarified in *Edwards Lifesciences v. Meril*, UPC_CoA_464/2024 et al., and *Amgen v. Sanofi/Regeneron*, UPC_CoA_528/2024 and UPC_CoA_529/2024, both decisions of 25 November 2025, inventive step does not depend on identifying a single closest prior-art document. A starting point is realistic where its teaching would have interested the skilled person seeking to solve the objective problem.

229. LUNDBECK's press release reported that nalmefene reduced heavy drinking days and total alcohol consumption, was safe and well tolerated, and described its pharmacological profile as a selective opioid receptor ligand with antagonist activity at μ - and δ -opioid receptors and partial agonist activity at κ -opioid receptors.

230. Furthermore, these two documents are strongly related and do not contradict each other.

231. Relying on the known action of nalmefene on the opioid system, the 2011 LUNDBECK Corporate release and Soyka 2010, BIOGARAN argues that stronger opioidergic involvement in physiological alcohol dependence would have suggested a greater therapeutic response. The skilled person would therefore have stratified Karhuvaara et al.'s population by alcohol dependence, identified the relevant patients through persistent high consumption measured by DRL, and used an observation period to select those expected to respond best. BIOGARAN also relies on Pablos-Méndez, Bisaga and Franciosa as evidence that observation or run-in periods were broadly known trial-design tools.

232. The decisive question is whether Karhuvaara et al., alone or in combination with the common general knowledge and the cited documents, would have prompted the skilled person to select alcohol-dependent patients who maintain a high DRL after an observation period as a subgroup expected to derive a more pronounced benefit from nalmefene.

233. As already said in the section dedicated to novelty, Karhuvaara et al. disclosed targeted nalmefene treatment in heavy drinkers, but assessed efficacy only in the overall randomised population. Its statistical plan expressly states that no subgroup analyses were performed (page 1181, left column, final paragraph), and the authors found that family history, alcohol-dependence diagnosis and treatment-centre type had no significant impact on response. Although dependence severity was measured by ADS and SCID, it was not used to select patients or allocate treatment.

234. Karhuvaara et al. therefore contained no pointer towards the teaching of EP'296: it neither identified a subgroup before treatment, nor suggested that nalmefene would be more effective in patients who maintained a high DRL after an observation period.

235. Additionally, BIOGARAN has not identified any neurological or other technical consideration that would have prompted the skilled person to introduce an observation period into Karhuvaara et al.'s teaching and to use persistence of a high DRL as a predictive selection criterion. Nor does any cited document disclose that prospective DRL-based stratification.

236. The same conclusion is reached after examining the LUNDBECK's Corporate Press release. The LUNDBECK press release announced completion of the Phase III programme and the intended

European marketing-authorisation application. It described completion of ESENSE1, ESENSE2 and SENSE, involving approximately 2000 alcohol-dependent participants; as-needed oral nalmefene at 20 mg; reduction rather than abstinence as the therapeutic objective; and efficacy assessed through heavy drinking days, total alcohol consumption, responder rates, dependence symptoms, clinical status, liver function and other laboratory parameters.

237. It reported an effect emerging within the first month, a reduction in alcohol consumption exceeding 50 %, and maintenance of the effect throughout the study periods, although not every endpoint was statistically significant at every time point. The release also defined heavy drinking as five or more drinks per day for men and four or more for women. It confirms that as-needed nalmefene, drinking-intensity thresholds and reduction in consumption were known, but neither suggests selecting patients who have a high DRL at baseline and maintain that level after an observation period nor provides any specific pointer that persistence of high consumption predicts a more pronounced response.

238. Treating those steps as implicit assumes the very features that had to be demonstrated, instead, without hindsight, and does not establish a linear path from a realistic starting point to the claimed solution.

239. In the following sections, the other documents will be examined individually.

240. The EMA Guidelines recognise that alcohol-dependent patients are highly heterogeneous in terms of dependence severity, psychiatric comorbidity, genetic factors, cognitive impairment, age of onset, sex, motivation, social support and craving. It recommends thorough baseline characterisation and stratification by dependence severity, using validated instruments such as the Severity of Alcohol Dependence Questionnaire (SDAQ), the Alcohol Dependence Scale (ADS) or the Addiction Severity Index (ASI), and, where relevant, by prior treatment history. Those recommendations concern trial methodology; they neither use DRL as a patient-selection criterion nor propose an observation period or suggest that nalmefene is more effective in the subgroup defined by claim 1. Furthermore, contrary to BIOGARAN's assertion, the EMA Guidelines disclose that the opioidergic system, comprising the three main G-protein-coupled receptors κ , δ and μ , is not the only one involved in alcohol dependence; several other pathways are involved:

Current research suggests several pathways which are involved in the development and maintenance of alcohol dependence. One pathway involves the opioidergic and the mesolimbic dopaminergic system, which seems to cause alcohol craving and relapse due to positive reinforcing effects of alcohol consumption, especially in earlier stages of the disease. A second pathway involves several components of the glutamatergic and the GABAergic system, which seems to induce alcohol craving and relapse due to a hyperglutamatergic state. A further pathway seems to be a hypodopaminergic state, especially during alcohol withdrawal after chronic alcohol intake, which is associated with a state of dysphoria that promotes resumption of alcohol intake. However, since it is currently recognised that

241. That means that the person skilled in the art, starting from Karhuvaara et al. and bearing the EMA Guidelines in mind, would not have obviously identified or validated a specific patient subgroup expected to derive greater therapeutic benefit from nalmefene, nor would they have obviously

proposed a pre-treatment selection criterion based on physiological alcohol dependence, DRL, or opioid receptor function or dysfunction.

242. Soyka et al. discusses the endogenous opioid system, the different receptor subtypes and nalmefene's distinct pharmacological profile, including its activity at κ -opioid receptors. However, its conclusions remain tentative: it leaves the clinical relevance of patient and treatment characteristics unresolved, expressly calls for further research, and provides no guidance on stratifying patients by μ -opioid receptor characteristics or by persistence of a high DRL after an observation period. It therefore offers no technically credible basis for expecting that the claimed subgroup would derive a more pronounced benefit from nalmefene; deriving that subgroup from Soyka in combination either with Karhuvaara et al. or with the Lundbeck Press Release would be speculative.

The central question is whether nalmefene has substantial advantages over naltrexone in treatment of alcohol dependence. Since no studies have directly compared the two drugs it remains unclear whether nalmefene offers advantages over naltrexone in efficacy or side-effect profile. Nevertheless, the drug is one of the very few novel developments in the pharmacotherapy of alcoholism that is likely to enter clinical use [6,9] and thus deserves much further attention.

243. In fact, the prior art (see UPC_CoA_528/2024 and 529/2024, decision of 25 November 2025, headlines 18 et sequi – Amgen v Sanofi) must provide, in combination with a reasonable starting point, more than a hypothesis for further investigation: it must offer a technically credible basis on which the skilled person could reasonably predict that the proposed therapeutic approach would succeed. Decisive for the inventive step assessment is, in fact, not what the skilled person could have arrived at, but rather what he/she would have considered to solve the technical problem.

244. This distinction involves the difference between hope of success (what the skilled person could simply do) and reasonable expectation of success (what the skilled person would do).

245. In UPC_CFI 552/25 (CD Milan's decision of 4 May 2026, headnote 3) this Central Division has already clarified that in a second medical use: *"There is a reasonable expectation of success when the scientific data or experiments indicate that the tested solution can yield a positive result, despite the general uncertainty arising from the necessary experimentation and the application of the scientific method. A reasonable expectation of success is therefore based on reason and knowledge of scientific data, even though the expert knows that the outcome is never certain until it is the subject of clinical trials. Therefore, it can be said that the greater the realism or reasonableness of the starting point, the greater the expectation of success. Hope for success, on the other hand, arises when the result is based on sheer assumptions or there is a contradiction in the sources, so that the outcome is considered possible but not reasonable"*.

246. Applying this principle to the combination Karhuvaara et al. /Soyka et al. and Lundbeck PR/Soyka, the Court notes that Soyka yields uncertain and contradictory information about the role of the opioid receptors; it acknowledges superior knowledge about acamprosate and naltrexone and

leaves open a future use of nalmefene in the domain of alcohol reduction. This starting point is weak and would not reliably prompt the skilled person to proceed any particular direction.

247. The same applies to Mann P59, which reported a randomised, double-blind, placebo-controlled trial of as-needed nalmefene 18 mg in 604 alcohol-dependent patients over 24 weeks, using HDD and TAC as endpoints. It reported results only for the overall population and neither selected nor evaluated any subgroup corresponding to claim 1. As a starting point, Mann P59 is therefore weak and provides no indication pointing towards the patented solution, in particular the prospective selection of patients who maintain a high DRL after an observation period.

248. As to Schuckit et al., this document provides evidence supporting the clinical relevance of subtyping alcohol dependence according to the presence or absence of a physiological component, defined by the DSM-IV as alcohol tolerance and/or alcohol withdrawal. The authors concluded that physiological alcohol dependence is associated with greater alcohol involvement and a more severe clinical profile, supporting the clinical validity of this distinction, and further suggested that alcohol withdrawal may be a more clinically relevant indicator of severity than alcohol tolerance alone (p. 739, right column, last paragraph).

249. Lejoyeux et al. corroborated these findings in an independent cohort, confirming that physiological alcohol dependence is associated with a more severe alcohol dependence syndrome and providing additional evidence supporting the distinction between alcohol dependence with and without a physiological component (p. 200, left column).

250. Schuckit et al. and Lejoyeux et al. disclose, however, that alcohol dependence and physiological dependence are not synonymous:

- Alcohol dependence is the overall clinical diagnosis, and may occur with or without a physiological component,
- whereas physiological dependence refers to the physiological component of alcohol dependence characterized by the development of tolerance and/or the emergence of withdrawal symptoms.

251. Accordingly, not all alcohol-dependent patients exhibit physiological dependence, as recognized in both Lejoyeux et al. and Schuckit et al.. These documents support the clinical relevance of subtyping alcohol dependence according to the presence or absence of a physiological component. However, neither study evaluated any pharmacological treatment demonstrating that this subtype predicts differential treatment response or suggested that it should be used to guide therapeutic targeting of patient subgroups. Furthermore, nalmefene is not mentioned in either document. The Court therefore sees no reason why the skilled person, seeking to improve the therapeutic use of nalmefene, would have consulted those documents.

252. BIOGARAN's proposed chain of reasoning is therefore not supported by these pieces of prior art, when considered together. Knowledge that nalmefene modulates the opioid system, that the opioid system is involved in alcohol dependence, that physiological dependence may mark greater

clinical severity, that DRL may quantify drinking, and that run-in periods may be used in trials does not establish that persistent high DRL after an observation period identifies patients who will respond better to nalmefene.

253. Nor does it provide a motivation to use DRL, rather than validated dependence-severity scales, as the predictive selection criterion. Even if excluding early reducers were routine, which seems to be contradicted by the high number of early reducers disclosed in the Patent at Table n. 5 (more than 50 %) the response of the remaining high-DRL patients was not thereby predictable.

254. Actually, the relevance of these documents might become apparent only by already knowing the proposed solution.

255. The mere fact that relevant features are disclosed separately and in different contexts, and could in principle be combined, is insufficient: absent a pointer, the skilled person has no reason to combine them. An inventive-step objection cannot therefore be sustained by reconstructing the claimed solution with knowledge of the patent.

256. The fact that this attack relies on the combination of such a large number of prior-art documents suggests hindsight. Where an obviousness attack can be constructed only by selecting and combining numerous (more than 10) disclosures addressing different technical questions, none of which supplies the missing pointer or gives the skilled person a reason to consult the others, the resulting mosaic is indicative of an ex post facto analysis rather than the course the skilled person would have followed at the effective date.

257. Accordingly, starting from either Karhuvaara et al. or the LUNDBECK corporate release, whether alone or in combination with the cited common general knowledge, the skilled person would not have been prompted to select the subgroup defined in claim 1 with a reasonable expectation of success.

258. The inventive-step objection must therefore be dismissed.

259. That conclusion is further confirmed by the documents relied upon by BIOGARAN concerning observation periods.

260. Pablos-Méndez et al. treats run-in periods as a trial-design tool that may be used to exclude non-adherent patients, placebo responders, or patients who do not tolerate or respond to the active drug. Its approach is cautious: run-in periods do not necessarily affect the internal validity of a randomised trial, but they may reduce the applicability of the results to ordinary clinical practice because the randomised population becomes a selected subgroup. The run-in periods are described in the field of depression (fluoxetine), Alzheimer's disease (tacrine), chronic-heart failure (carvedilol), aspirin and beta-carotene in the domain of cardiac arrhythmia.

261. Franciosa et al., by contrast, considers run-in periods to be legitimate and often useful elements of clinical-trial design, especially for assessing tolerability, compliance, safety and the benefit-risk profile of a treatment. In his view, run-in periods may reflect ordinary clinical practice, where physicians monitor patients carefully when starting a new therapy. This document, therefore, does

not address alcohol dependence or nalmefene. The study focuses on carvedilol and enalapril (a compound active in the domain of cardiology).

262. Bisaga et al., a document specifically referring to the studies by Pablos-Méndez and Franciosa, uses a two-week lead-in period in the field of substance dependence, specifically cocaine use, to assess whether pre-treatment cocaine use predicts subsequent treatment outcomes. The study suggests that patients with higher levels of cocaine use during the lead-in period were more likely to continue using cocaine during the following twelve weeks of treatment. It thus indicates that persistence of substance use during a short lead-in period may have predictive value beyond self-reported consumption and may help identify a more suitable or informative population for treatment-efficacy analysis. Nevertheless, the document shows the inconsistencies of the research outcome and appears strongly related to the specific domain of cocaine addiction.

The results of the study should be considered in light of the methods used. This was a preliminary data analysis with a small sample. The population of patients selected for this study was not representative of the general populations applying for cocaine dependence treatment since participants with several psychiatric disorders were excluded from participation. Finally, due to the small sample size we did not have adequate power to conclusively rule out the interaction

between treatment assignment and outcome. Replication and extension of this research is clearly in order, both for the complete sample of this study, and also for other patients treated for cocaine dependence or other drugs of abuse. Regardless

263. Taken together, these documents show that observation or run-in periods were known methodological tools in clinical trials and could serve purposes including selection, compliance, tolerability and prediction of subsequent outcomes. They do not concern alcohol dependence or nalmefene and do not suggest using persistence of a high DRL after an observation period as a prospective criterion for selecting patients expected to derive a more pronounced therapeutic benefit.

264. It is therefore unclear, here too, why the skilled person, seeking to improve the therapeutic use of nalmefene, would have had any reason to consult those documents. The CoA has recently reaffirmed the principle whereas (UPC_CoA 312/25 Kodak v. Fujifilm, Decision of 2 June 2026, para. 183) *'the mere fact that the necessary parameters are present (separately and in different context) and could be combined is not sufficient, since failing a pointer there is no reason for the skilled person to actually combine these separate parameters'*.

265. Neither Karhuvaara et al. nor the LUNDBECK corporate press release gives the skilled person any reason to consult the different fields addressed by Pablos-Méndez, Franciosa and Bisaga. Those documents likewise contain no pointer towards alcohol dependence, nalmefene treatment or the use of persistence of a high DRL after a two-week observation period as a predictive selection criterion. As clarified in Fujifilm v. Kodak, UPC_CoA_473/2025 et al., decision of 13 July 2026,

Headnote 6, a reason to combine cannot be derived solely from the document with which the realistic starting point is retrospectively combined.

266. Against this background, it cannot be established that the skilled person would have consulted documents Bisaga et al., Franciosa et al. or Pablos-Méndez et al. and regarded a two-week observation period as a predictable means of selecting patients expected to benefit particularly from nalmefene.

267. Obviousness requires that, at the priority date and on the basis of the known facts, the skilled person would—not merely could—have arrived at the claimed solution from a realistic starting point through a specific pointer or as a matter of routine.

268. Conclusively, although Bisaga et al. concerned a comparable field of substance dependence, it remained specific to cocaine use and did not address alcohol dependence or treatment with nalmefene. Nothing in Bisaga et al. or in the parallel documents showed that the same predictive logic could be transferred to alcohol-dependent patients treated with an opioid-system modulator. At the priority date, the outcome of such a transfer was technically uncertain and not reasonably predictable. The skilled person would therefore have had, at most, a general methodological indication that a short lead-in period might be used in some opioid addiction studies, but no reasonable expectation that such an approach would be applicable to alcohol consumption, let alone that it would improve the efficacy of a pharmacological treatment for alcohol consumption.

269. Nor does the remaining scientific literature supply the missing pointer.

270. Nature Reviews Drug Discovery's document reported preliminary Phase III results for as-needed nalmefene, described its opioid-receptor profile and observed that response might differ between patient groups, but did not identify or validate the claimed subgroup or any selection criterion based on DRL, physiological dependence or opioid-receptor function.

271. Mitchell et al. investigated endogenous opioid release after alcohol consumption using PET imaging in heavy drinkers and healthy controls. The authors found that alcohol consumption induced endogenous opioid release in the orbitofrontal cortex and nucleus accumbens and discussed the implications of those findings for the mechanism of action of opioid antagonists such as naltrexone. However, the study excluded alcohol-dependent subjects, did not mention nalmefene, neither selected any patient subgroup for treatment, nor evaluated treatment efficacy according to any patient subgroup.

272. Saxon et al. assessed whether the Alcohol Dependence Scale was a valid measure of dependence severity and could identify DSM-IV physiological dependence, defined by tolerance and/or withdrawal, in treatment-seeking alcohol-dependent patients. It found the scale valid for measuring severity but insufficiently accurate for identifying physiological dependence. The study did not evaluate nalmefene, DRL, an observation period or differential treatment response.

273. BIOGARAN's inventive-step attacks are therefore unfounded.

VALUE OF PROCEEDINGS

274. During the IC the parties agreed to set the value of proceedings at EUR 2 000 000.

275. The Court agrees with this value. In fact, following point 3 of the Guidelines for the determination of Court fees and the ceiling of recoverable costs of the successful party “Where the parties agree on a valuation the Court should in principle base its valuation on their estimate”.

COSTS OF PROCEEDINGS

276. Pursuant to Article 69(1) UPCA, the unsuccessful party must bear the reasonable and proportionate legal costs and other expenses incurred by the successful party, unless equity requires otherwise. Since BIOGARAN is the unsuccessful party in the present proceedings, it must bear the costs incurred by LUNDBECK.

277. LUNDBECK’s application for an interim award of costs may also be granted.

278. An interim award of damages, including the costs of any subsequent merits proceedings (R. 119), is designed to streamline the process and promote settlement by avoiding further ancillary applications. The assessment of damages is, therefore, entrusted to the panel’s equitable discretion and must be based on the criteria set out in Art. 68.2 UPCA, which reproduces almost verbatim Art. 13 of the Enforcement Directive (Directive 2004/48/EC).

279. Having regard to the value of the proceedings, the Court assesses the recoverable costs on an equitable basis at 50 % of the applicable ceiling for recoverable costs.

FOR THESE REASONS

BIOGARAN’s revocation action is dismissed in so far as the Patent is maintained in the amended form set out below.

BIOGARAN will bear the costs of proceedings incurred by the Defendant pursuant to Art. 69.1 UPCA.

The value of the proceedings is set at EUR 2 million.

BIOGARAN shall pay to LUNDBECK an interim award of costs and legal expenses in the amount of EUR 100 000. Payment must be made within 3 weeks.

Issued in Milan on 09 October 2026

Judge-Rapporteur and presiding Judge Andrea Postiglione	ANDREA POSTIGLIONE Firmato digitalmente da ANDREA POSTIGLIONE ID: email=andrea.postiglione@giustizia.it, c=IT, cn=ANDREA POSTIGLIONE, sn=POSTIGLIONE, givenName=ANDREA, serialNumber=10103130965559390318, title=Private Person Data: 2026.10.09 09:54:26 +02'00'
Legally qualified Judge Anna-Lena Klein	ANNA-LENA KLEIN Firmato digitalmente da ANNA-LENA KLEIN Data: 2026.10.09 10:08:31 +02'00'
Technically qualified judge Eric André Enderlin	Enderlin Eric André Signature numérique de Enderlin Eric André Date : 2026.10.09 11:43:14 +02'00'
For the Deputy-Registrar	Digitally signed Ginestro Marco 2026-10-09 09:59:24 +0200 Unified Patent Court Einheitsliches Patentgericht Jurisdiction unified du brevet

INFORMATION ABOUT APPEAL

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of service of the decision (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

INFORMATION ABOUT ENFORCEMENT

Art. 82 UPCA, Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP: An authentic copy of the enforceable decision will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

INSTRUCTION TO THE REGISTRY

A certified copy of the decision shall be sent to the European Patent Office as soon as the decision on the revocation action has become legally binding.

SUBMITTED 20.09.2025

Claims

1. Nalmefene for use in reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;
 - a) identifying a patient with alcohol dependence
 - i) who has a Drinking Risk Level (DRL) corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women, and
 - ii) who maintains the DRL of alcohol consumption after an observation period following initial assessment, wherein said observation period following initial assessment is 1-2 weeks, and
 - b) administering nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.
2. Nalmefene for use according to claim 1, wherein said patient does not require immediate detoxification.
3. Nalmefene for use according to any of claims 1 or 2, wherein said patient is subject to ongoing motivational support.
4. Nalmefene for use according to any of claims 1-3, wherein said patient is subject to counseling focused on enhanced treatment adherence and reduced alcohol consumption.
5. Nalmefene for use according to claim 4, wherein said counseling is performed according to the BRENDA model.
6. Nalmefene for use according to any of claims 1-5, wherein said patient is a patient for whom immediate abstinence is not a treatment goal.
- ~~7. Nalmefene for use according to any of claims 1-6, wherein said nalmefene is to be used for a treatment period of 6-12 months, such as 6 months.~~

- ~~87.~~ Nalmefene for use according to any of claims 1-~~76~~, wherein patient is an adult or an adolescent.
- ~~9.~~ ~~Nalmefene for use according to any of claims 1-8, wherein said patient is 12 years or older, such as 14 years or older, such as 16 years or older, such as 18 years or older.~~
- ~~408.~~ Nalmefene for use according to any of claims 1-~~97~~, wherein said nalmefene is used in a dose of 10-20 mg such as 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg or 20 mg.
- ~~449.~~ Nalmefene for use according to any of claims 1-~~408~~, wherein said nalmefene is used in a dose of 18 mg.
- ~~4210.~~ Nalmefene for use according to any of claims 1-~~449~~, wherein said nalmefene is used in the form of a pharmaceutically acceptable acid addition salt.
- ~~4311.~~ Nalmefene for use according to any of claims 1-~~4210~~, wherein said nalmefene is used in the form of the hydrochloride salt.
- ~~4412.~~ Nalmefene for use according to any of claims 1-~~4311~~, wherein said nalmefene is used in the form of the hydrochloride dihydrate.
- ~~4513.~~ Nalmefene for use according to any of claims 1-~~4412~~, wherein said nalmefene is used in a crystalline form.
- ~~4614.~~ Nalmefene for use according to any of claims 1-~~4513~~, wherein said nalmefene is used in an oral dose form such as tablets or capsules.
- ~~4715.~~ Nalmefene for use according to any of claims 1-~~4614~~, wherein said nalmefene is used in combination with a further active ingredient.
- ~~4816.~~ Nalmefene for use according to any of claims 1-~~4715~~, wherein said patient does not fall into one or more of the following categories: patients taking opioid analgesics, opioid-addicted patients without successful withdrawal, patients with acute symptoms of opioid withdrawal, patients for whom recent use of opioids is suspected, patients with moderate or severe hepatic impairment, patients with moderate or severe renal impairment.