Intellectual Property Office

Patents Act 1977 **Opinion Number** **12/25**

OPINION UNDER SECTION 74A

Patent	EP(UK) 2608789 B2
Proprietor(s)	H. Lundbeck A/S
Exclusive Licensee	
Requester	Cleveland Scott York
Observer(s)	
Date Opinion issued	13 January 2026

The request

1. The Comptroller has received a request from Dr Adrian Bradley of Cleveland Scott York ('the requester') to issue an opinion covering the validity of EP 2608789 B2 ('the patent'). More specifically, the comptroller has been requested to issue an opinion as to whether claims 1 to 4 of the patent are valid on grounds of sufficiency, as required by s.14(3) of the Patents Act 1977 ('the Act').

2. The patent remains in force and was published on 21 August 2024. An earlier 'B1' publication was made on 12 April 2017, which is the date that the grant of the patent was mentioned in the bulletin. The patent has a date of filing of 22 August 2011, and spawns from a PCT application published as WO 2012/025123. The claimed earliest date for the patent is 23 August 2010.

The patent

3. The patent defines a compound, and salts thereof, for use in both a purpose-limited EPC 2000 format claim and a now redundant so-called 'Swiss' format. There are four claims in the granted patent, with claims 1 and 3 being independent claims. These claims are:

    1. *1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine and pharmaceutically acceptable salts thereof for use in the long-term treatment of depression or anxiety in a patient who has previously received medication for the treatment of said disease which medication was ceased due to weight gain related adverse events, wherein long-term treatment refers to a treatment period above 12 weeks.*

    2. *1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine and pharmaceutically acceptable salts thereof according to claim 1 which is the hydrobromide*

salt

3. *Use of 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine and pharmaceutically acceptable salts thereof in the manufacture of a medicament for the long-term treatment of depression or anxiety in a patient who has previously received medication for the treatment of said disease which medication was ceased due to weight gain related adverse events, wherein long-term treatment refers to a treatment period above 12 weeks.*

4. *The use according to claim 3, wherein said pharmaceutically acceptable salt is the hydrobromide salt.*

4. Whilst, as highlighted at 45 of T1021/11 by the Technical Board of Appeal, these two claims are of distinct scope[1], they are both claims comprising the purpose-limitation that 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (vortioxetine) and pharmaceutically acceptable salts thereof are suitable and intended for use in the long-term treatment of depression or anxiety in a defined patient group. Therefore, the two independent claims in the patent rely on the same data or *a priori* reasoning to provide the necessary sufficiency, and it is appropriate to consider them together.

Preliminary matters

5. Section 74A(3) of the Act states that the comptroller shall not issue an opinion "in such circumstances as may be prescribed" or "if for any reason he considers it inappropriate" to do so. Rule 94 of the Patent Rules provides for refusal of opinion requests as follows:

94 *(1) The comptroller shall not issue an opinion if –*
(a) The request appears to him to be frivolous or vexatious, or
(b) The question upon which the opinion is sought appears to him to have been sufficiently considered in any relevant proceedings.
(2) …

6. Relevant proceedings are defined in Rule 92 as "proceedings (whether pending or concluded) before the comptroller, the court or the European Patent Office". Consequently, Opposition proceedings before the EPO are understood to be relevant proceedings. As decisions coming out of the EPO are binding on the parties involved whilst opinions are not, Rules 92 and 94 serve to prevent the Opinions service offering an opinion on matters already settled. The opinion service is not intended to offer a second opinion or to require a proprietor to deal again with matters which have already been dealt with to the satisfaction of the examiner.

7. In the course of prosecution, the patent was opposed under Articles 100(a) and (b) of the EPC on the grounds that the claimed subject-matter lacked novelty and

[1] Swiss-type claims are purpose-limited process claims whereas claims pursuant to Article 54(5) EPC (i.e. in the EPC 2000 format) are purpose-limited product claims.

inventive step and was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. As is clear from even a cursory look at the 'Ground for the decision (Annex)' document dated 21 June 2019[2], sufficiency of disclosure of the patent as granted was considered. However, the Opposition Division comment only on the claim of the patent as granted and do not comment on the sufficiency of either auxiliary claim request. No heading akin to 'Sufficiency of disclosure' was used by the Board of Appeal in the decision published as T2344/19[3], wherein auxiliary request 2 was found to comprise an inventive step. It thus follows that no explicit comment as to the sufficiency of the latest allowed claims has been made by either the EPO Opposition Division or the Technical Board of Appeal.

8. Furthermore, whilst the opposition proceedings before the EPO relating to this patent did consider sufficiency of disclosure,[4] the comments that 'there is no indication that this treatment would not be possible for patients who ceased a previous treatment **due** to weight related adverse events' and 'in the absence of any proof to the contrary' implies that sufficiency of disclosure was viewed through a lens of *ab initio* implausibility. As Meade J has made clear at [341] of *Gilead Sciences v Nucana PLC* [2023] EWHC 611 (Pat), 'I am bound by *Warner-Lambert*[5], which (as the TBA said) propounds an *ab initio* plausibility test'. I also note that at [45] of *Sandoz Ltd & Teva Pharmaceuticals Industries Ltd v Bristol-Myers Squibb Holdings* [2022] EWHC 822 (Pat) Meade J indicated that 'analysis of plausibility should be firmly guided by the points in [37] of Warner-Lambert and by the principle laid out by that case that a contribution by the patentee that is in the specification is needed'. Therefore, whatever consideration of sufficiency has been made in earlier relevant proceedings, it was not within the current UK legal framework.

9. In a letter of 10 November 2025, filed by the respondent's representative, Potter Clarkson, paragraph 3.3.2 of T2344/19 is highlighted as showing that the Technical Board of Appeal considered if data within the patent supported the assertion that long-term treatment of depression or anxiety with vortioxetine is associated with weight gain and if the claimed patient population was exemplified in the test data in the patent. While this paragraph does discuss the data filed as part of the patent, it does so only in the sense of ascertaining the 'problem' part of the problem-solution approach and does not determine if the patent discloses the invention in a manner which is clear and complete enough for the invention to be performed by one skilled in the art.

10. In conclusion I consider neither R.94(1)(a) or R.94(1)(b) apply and therefore I will issue an opinion. Concluding this section, the request that an opinion be issued is not being refused. Additionally, the purpose of the Opinions service is to help parties focus on the key issues in a dispute and to resolve potential disputes over validity. I consider that, in this case, issuing an opinion helps serve this purpose.

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[2] See https://register.epo.org/application?documentId=E3GRPKCY5534DSU&number=EP11749331&lng=en&npl=false, or Annex 5 to the respondents letter of 10 November 2025

[3] See https://www.epo.org/boards-of-appeal/decisions/pdf/t192344eu1.pdf

[4] See 4.1 and 4.2 of https://register.epo.org/application?documentId=E3GRPKCY5534DSU&number=EP11749331&lng=en&npl=false

[5] By '*Warner-Lambert*' Meade J is referring to *Warner-Lambert v Generics* [2018] UKSC 56

Claim construction

11. Before I can determine an opinion as to the validity of the patent, I must construe the claims. This means interpreting them in light of the description and drawings as instructed by Section 125(1) of the Act:

> *(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.*

12. I must interpret the claims in context, through the eyes of the person skilled in the art. Ultimately, the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the decisions of the High Court in *Mylan v Yeda*[6] and the Court of Appeal in *Actavis v ICOS*[7]. Furthermore, it is long standing practice of the UK courts that 'a patent specification should be given a purposive construction rather than a purely literal one'[8]. This principle of 'purposive construction' has been affirmed many times, not least when this approach was summarised in [182] of *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWHC 26 (Pat).

13. Claim 1 of the patent, given at paragraph 3 of this report, is a medical use claim in the EPC2000 format, where the relevant drug is 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine, or pharmaceutically acceptable salt thereof, and the disease to be treated is anxiety or depression. As is now standard, the 'for' in an EPC2000 format is construed as meaning 'suitable and intended for'.[9] Claim 1 is further limited by specification of the patient group and in that the treatment is of at least 12 weeks duration.

14. As the claim defines a limitation of the patient group, I wish to briefly discuss two pertinent decisions of the EPO Technical Board of Appeal. At 8.7 of T233/96, the Board of Appeal interpreted earlier decisions of the EPO and came to the conclusion that, notwithstanding that the use of a compound was known in the treatment of a disease, the treatment of the same disease with the same compound could nevertheless represent a novel therapeutic application provided that; the treatment was carried out on a novel patient group that was clearly distinguishable with respect to either physiological or pathological status from the earlier group treated and that there is no overlap of the two patient groups, and that the choice of the new patient group must not be arbitrary, by which there must exist a functional relationship between the particular physiological or pathological status of the new group and the therapeutic effect obtained.

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[6] *Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor* [2017] EWHC 2629 (Pat)
[7] *Actavis Group & Ors v ICOS Corp & Eli Lilly & Co.* [2017] EWCA Civ 1671
[8] *Catnic Components Ltd and another v Hill and Smith Ltd* [1982] RPC 183
[9] See [58] of Hospira v Genentech [2014] EWHC 1094

15. The patent discussed in T108/09 comprised claims with a patient group limitation, namely that the patient group comprised patients with breast cancer who had previously been unsuccessfully treated with an aromatase inhibitor and tamoxifen. As the Board noted at 2.3.1, this caveat was not merely the presentation of information relating to the patient's medical history but constituted a relevant technical feature, with the technical feature seemingly linked to physiological changes in the tumour arising from the administration of one of the earlier drugs.

16. While a purely literal interpretation of the claims would result in construing claim 1 as defining 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (vortioxetine) that is both suitable and intended for the treatment of depression and/or anxiety over a period of at least 12-weeks duration, and wherein the patient has previously been treated with medication for the treatment of depression and/or anxiety but has ceased said previous medication due to weight gain related adverse events, I do not believe this would be correct. It would set the necessary outcome as the treatment of depression and/or anxiety in the patient group, and not as the treatment of depression and/or anxiety without causing weight gain.

17. Purposively construing the claims, taking into account the specification as a whole, most notably [0015], [0016] and [0025], brings me to construing claim 1 as defining 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (vortioxetine) that is both suitable and intended for the treatment of depression and/or anxiety over a period of at least 12-weeks duration *free of weight gain related adverse effects as determined by patient compliance*, and wherein the patient has previously been treated with medication for the treatment of depression and/or anxiety but has ceased said previous medication due to weight gain related adverse events.

Sufficiency

18. As set out in the first paragraph of this report, the opinion requester has requested an opinion as to if the patent as a whole lacks sufficiency. Section 14 of the Act governs the making of an application while section 72 covers powers to revoke patents.

> *14 (3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.*
>
> *72 (1) Subject to the following provisions of this Act, the court or the comptroller may by order revoke a patent for an invention on the application of any person (including the proprietor of the patent) on (but only on) any of the following grounds, that is to say—*
>
> *(a)…*
> *(b)…*
> *(c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;*
> *(d)…*
> *(e)…*

19. It is clear, from both sections 14 and 72 of the Act, that an application must disclose the invention in a manner which is clear enough and complete enough for the invention to be worked by one skilled in the art and that the absence of such disclosure is grounds for revocation. This is what is meant by the catchword 'sufficiency'. It is important to note that disclosure that is clear enough and complete enough does not necessitate that experimental data is present.

20. In *Warner-Lambert v Generics* [2018] UKSC 56 ('*Warner-Lambert*'), the UKSC affirm both T1437/07 and T578/06 as being authority 'for the proposition that experimental data are not essential to sufficiency… But this does not mean that the specification is sufficient if there is neither experimental data nor any other reason to deduce from the specification that the claim to therapeutic efficacy is plausible'[10]. Having introduced the term plausibility to the discussion as to the law of sufficiency, Lord Sumption goes on to posit that 'the proposition that a product is efficacious for the treatment of a given condition must be plausible… it is not made plausible by a bare assertion to that effect… the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, ie not just because there was an abstract possibility that it would work, but because reasonable scientific grounds were disclosed for expecting that it might well work'[11].

21. There are two points which the requester seeks to highlight in the request; that the data obtained from the examples does, itself, show that the claims lack sufficiency, and that the patient group defined within the claims is not exemplified in the examples.

22. Example 1 of the patent discloses data from patients presenting with major depressive disorder who received 12-week treatment with either 5 mg or 10 mg of the hydrobromide salt of 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine, before then being randomised into a continuation group or a placebo group. There is no mention of any of the people in the initial cohort having been previously treated with any drug. Example 2 is similar, but with patients presenting with generalised anxiety disorder. Example 2 does not disclose that any patients had previously been administered any drug. Neither example discloses any data, or makes any comment, as to the efficacy of the treatment, relative to the placebo, on the symptoms of the relevant diseases, namely major depressive disorder and generalised anxiety disorder, and instead focus solely on weight gain within the patient group.

23. From the data in Table 2, the per centage of patients with major depressive disorder displaying ≥7 % weight gain is greater for patients taking the hydrobromide salt of 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine relative to patients taking the unspecified placebo at 36, 48, and 60 weeks (i.e. at three out of the six provided time points). From data in table 4, the per centage of patients with generalised anxiety disorder displaying ≥7 % weight gain is greater for patients taking the hydrobromide salt of 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine relative to patients taking the unspecified placebo at 56 and 68 weeks, while identical amounts of patients displaying ≥7 % weight gain are seen at 76 weeks, the final data point. Such data, if

[10] *Warner-Lambert v Generics* [2018] UKSC 56 [33]
[11] *Warner-Lambert v Generics* [2018] UKSC 56 [37]

statistically significant, shows that the desired technical effect cannot be achieved over the full scope of the claim, which defines long-term treatment as treatment of ≥12 weeks duration. As such, the claims are insufficient as they are not made plausible, as is required. It appears that not only are the claims not made plausible by the examples in the patent, but that the examples of the patent explicitly disclose that the technical effect of achieving treatment free of adverse weight gain related effects cannot be achieved across the full scope of the claims, at least for the patient group used in the examples of the patent.

24. Taking the second point raised by the requestor, the question is best understood as asking if the patient group is arbitrary by application of the reasoning in T233/96 and/or T108/09. This question is one of novelty and/or inventive step, neither of which form part of the opinion request. However, it is worth noting that one cannot reasonably extrapolate from data showing an effect (e.g. weight gain during long-term treatment with the hydrobromide salt of 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine) in a specific patient group and plausibly assert that a different effect (e.g. lack of weight gain) will be observed in an alternate patient group.

Opinion

25. In my opinion, the specification of the patent does not disclose the invention, as construed, clearly enough and completely enough for it to be performed by a person skilled in the art. That is, the claims of the patent are insufficient.

Application for Review

26. Under section 74B of the Act and Rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion

Robert Goodwill
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.