



PATENTS ACT 1977

APPLICANT Mohamed Fadly Abd El Ghany Elkazaz

ISSUE Whether patent application GB2300774.3 complies
with sections 1(1)(a), 1(1)(b), 14(3), 14(5) and 76(2)

HEARING OFFICER Dr Rowena Dinham

DECISION

Introduction

- 1 Patent application GB2300774.3 (“the application”) entitled “*A novel medicament for immune modulation and treating chronic or hyper inflammation*” was filed internationally on 7 July 2021 and entered the UK national phase on 3 January 2023. The application claims priority from Egyptian application EG2020060768 filed on 9 June 2020. The application was published on 16 December 2021 in the international phase as WO2021/249608 A2, and republished as GB2612481 A on 3 May 2023.
- 2 Although the first examination report was created with a date of 15 November 2023, due to an irregularity in office procedure the report was never issued. The first effective examination report was issued on 17 July 2024. In accordance with rule 30(2) of the Patents Rules 2007 (“the Rules”)¹, the period for putting this application in order under section 20 of the Patents Act 1977 (“the Act”) has been set at 17 July 2025.
- 3 There have been several rounds of correspondence between the applicant and the examiner, with numerous objections raised, in particular novelty under section 1(1)(a), inventive step under section 1(1)(b), sufficiency under section 14(3), clarity under section 14(5)(b), support under section 14(5)(c), plurality of invention under section 14(5)(d), and the presence of added matter under section 76(2) of the Act. The examiner has not fully updated the search due to the substantial objections raised during examination.
- 4 The examiner made the offer of a hearing in his letter of 4 September 2024, which was followed by the pre-hearing report dated 29 November 2024. The pre-hearing report was delivered via post to the UK address for service provided by the applicant but was returned undelivered. In an email dated 4 January 2025 the applicant confirmed that he had received the pre-hearing report, but only on the 2 January

¹ The Patents Rules 2007 (as amended) can be accessed at the following link: [The Patents Rules and Fees Rules 2007](#)

2025. The applicant then filed amended claims on 4 February 2025 in response to that report, along with 16 pages of observations. I am content that the applicant has seen the pre-hearing report and has had the opportunity to request to be heard. As no such request has been made, this decision will be based on the documents on file. I note the applicant has now provided a valid UK address for service and so has met the requirements of Rule 104.

- 5 I have based my decision on the description filed on 4 November 2024, and the claims filed in response to the pre-hearing report dated 3 February 2025. I note the correction submitted on 4 February 2025 relating to the observations filed on 3 February 2025.

The application

- 6 The application concerns the use of anabasine, or a salt thereof, for use as an immune modulator. The description as originally filed explains anabasine can activate and/or upregulate alpha-7 nicotinic acetylcholine receptors ($\alpha 7$ nAChRs) via the cholinergic anti-inflammatory pathway, thus acting as an immune modulator. A background to this pathway is provided along with some discussion on its effects on inflammatory processes, mostly taken from third party studies. The description suggests that the activation of $\alpha 7$ nAChRs may be useful in the treatment of covid-19, influenza, and other respiratory diseases caused by coronaviruses such as SARS and MERS. The use of anabasine to treat asthma, chest allergy and atopic dermatitis is also discussed; again the basis for this is taken from third party studies. Some discussion of the link between systemic inflammation and type 2 diabetes/metabolic syndrome is also present in the description as filed. One exemplar formulation is provided on page 1 of the description as filed:

“Present medicament comprises of (-)-anabasine as an active ingredient at 0.1:0.15 mg/kg of body weight and a pharmacologically acceptable excipient, diluent or carrier”.

- 7 Page 3 of the description refers to this medicament and suggests a dosage schedule:

“Current medicament at mentioned doses is described to be administered, for example by oral route twice per day for a period from 30:45 days for asthmatics and patients of chest allergy according to severity and condition development and from 21:40 days for patients of atopic dermatitis according to severity and condition development. Herein medication is one course only”.

- 8 There are no experiments disclosed demonstrating the effectiveness of the treatments at all, let alone at the dosage regimes disclosed. The assertions made appear to be reliant upon what the applicant has discovered from his analysis of third party studies.
- 9 The most recent claims have not been examined, as they were filed after the pre-hearing report was issued. There are two independent claims:

1. Anabasine or its salts for use in curing asthma types, chest allergy and atopic dermatitis, all in humans.

2. Anabesine or its salts for use in curing certain atopic and allergic diseases i.g. food allergies, skin allergies and anaphylaxis, all in humans.

These claims differ from originally filed claims 1 and 2, which read:

- 1. Use of anabesine in the preparation of a human medicament for immune modulation and treating chronic or hyper inflammation.*
- 2. Use of anabesine in the preparation of a human medicament for the innate immune modulation and treating chronic or hyper inflammation”*

The Law

- 10 The relevant law is defined in the Patents Act 1977 (as amended) (“the Act”) and can be viewed online at the IPO’s website:

[The Patents Act 1977 \(as amended\) - Guidance - GOV.UK](#)

- 11 The Manual of Patent Practice (MOPP) explains the IPO’s practice under the Act and makes helpful references to relevant case law. The Manual can be viewed online at the IPO’s website:

[Manual of Patent Practice - Guidance - GOV.UK](#)

- 12 I have indicated below the sections of the Act which apply to each of the examiner’s objections.

Issues for decision

- 13 There are many issues of contention between the applicant and the examiner, each relating to substantive requirements of the Act that need to be satisfied before the patent may be granted. Specifically, in his pre-hearing report, the examiner sets out that the application fails to meet the requirements for added matter², novelty³, inventive step⁴, clarity⁵, sufficiency⁶, support⁷ and plurality⁸. I have carefully considered the documents on file, including the most recent claims filed after the pre-hearing report was issued, and I shall address the objections set out in that report to the extent necessary to resolve the question of whether the application meets the requirements and conditions for grant of a patent.

Claim construction and clarity

- 14 My starting point for assessing this invention lies in construing the claims. The applicant is unrepresented and I can appreciate he has made genuine efforts to meet the examiner’s objections and ensure the claims are clear. I will attempt to construe the claims in a purposive manner through the eyes of the skilled person

² Section 76(2)

³ Section 1(1)(a)

⁴ Section 1(1)(b)

⁵ Section 14(5)(b)

⁶ Section 14(3)

⁷ Section 14(5)(c)

⁸ Section 14(5)(d)

and in light of the disclosure of the description, as set out in section 125 of the Act and following the established principles of UK patent law⁹. In this case, when considering inventive step, the examiner considered the skilled person to be someone involved in finding new therapeutic treatments for disorders associated with inflammation. I agree that this would be one aspect of the skilled person, but I consider that the skilled person would in fact be a team, not only comprising a physician who would explore therapeutic treatments for inflammatory diseases, but would also comprise a pharmacologist who would have a knowledge of existing therapies for inflammatory diseases, including asthma and allergic diseases. I note that the applicant has not provided an alternative.

- 15 Claims 1 and 2 (reproduced above) are now written in the format of second medical use claims. They both contain the word “*curing*”. There has been some discussion between the examiner and the applicant as to whether the inclusion of this word alters the scope of the claims as it was not in the application as filed¹⁰, and I will consider the implications for added subject matter separately below. The applicant believes that claims 1 and 2 are clear and define a second medical use for the permanent eradication of the disease state in relation to asthma, chest allergy and atopic dermatitis. I note that page 5 of the description as filed suggests a dosage schedule and the wording “*..medication is one course only*”. Page 5 then goes on to state that treating asthma, chest allergy and atopic dermatitis with anabesine “*terminates them permanently*”, and that one course is required; original claim 8 also included the word “*permanently*”.
- 16 The examiner, on the other hand argues that it cannot be clear what constitutes curing an inflammatory disorder caused by an allergen, and that the description does not clearly explain the mechanism of such a cure. He also refers to T24/91¹¹ and the definition of therapy provided therein:
- “...any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the animal body”*
- 17 I note that the passages from the description above are the only ones that suggest a *permanent* curing of the disease states. There is no disclosure of how this may be achieved, or even a clear statement that this is the inventive concept. There is also no indication of how this is monitored throughout a patient’s life. I am therefore not convinced that the term “curing” would be read by the skilled person to be anything other than “treating”, when trying to understand the meaning of the claim in light of the description.
- 18 If the claims are construed instead as a standard second medical use claim, and assuming the word “*curing*” is analogous to “*treatment*”, then claim 1 defines the second medical use of anabesine for treating asthma “types”, chest allergy and atopic dermatitis. I note that asthma “types” is unclear and consider that the skilled person would understand this to mean asthma in any form, such as allergic asthma

⁹ See MOPP section 14.111-14.116 and 125.13-125.14; and Kirin-Amgen Inc v Hoescht Marion Roussel Ltd [2005] RPC9

¹⁰ See Applicant’s letter dated 4 November 2024 and pre-hearing report.

¹¹ T 0024/91 (Cornea) 05-05-1994

and non-allergic asthma. Similarly, “chest allergy” is unclear as it does not define a specific disease, and instead I consider that this would be understood to be synonymous with allergic asthma. Claim 2 defines the second medical use of anabasine for the treatment of “certain atopic and allergic diseases i.g [sic] food allergies, skin allergies and anaphylaxis”. Again these definitions of the diseases to be treated are unclear, and I consider that, taken in its broadest sense and in light of the description, the skilled person would understand this to refer to any allergic reaction. Given these ambiguities in the wording of the claims, I do not consider them to meet the requirements of section 14(5)(b), and construe claims 1 and 2, to the best of my ability as follows:

1. *Anabasine or its salts or its use in treating asthma and atopic dermatitis in humans*

2. *Anabasine or its salts or its use in treating allergic diseases in humans.*

Added matter

- 19 Objections to added matter have been raised throughout the prosecution of this application. It is worth reiterating here that under UK law the presence of added matter is a very clear and unambiguous ground for the revocation of a granted patent. A patent containing added matter is invalid, and amendments which add matter to an application for a patent are not allowable under section 76(2). As summarised by Jacob J. (as he then was) in *Richardson-Vicks Inc.’s Patent*, (at page 576 line 34-37):

“the test of added matter is whether a skilled man would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification.”

- 20 Numerous amendments have been filed to both the description and claims. The original application comprised 5 pages of description, 14 claims and one drawing. The application as currently amended comprises 32 pages of description, 7 claims and one drawing. The examiner has provided significant detail of examples of the added matter in his pre-hearing report and in his earlier examination reports.
- 21 The applicant has disagreed with this assessment in his responses. In his view, although new *information* has been added to the specification by amendment, this is not prohibited by s.76(2) of the Act, which instead refers to *matter*. The applicant submits the information that has been added to the specification is essential for a complete understanding of the originally filed matter; it provides an illustration of what was originally filed. He maintains the advantage of the invention was not clear at filing, but the added information has allowed a skilled reader to now understand it. He refers to *Merrell Dow Pharmaceutical Inc v NH Norton & Co Ltd*¹², *T344/189*¹³, *Flexible Direction Indicators Ltd’s Application*¹⁴, and *DSM NV’s Patent*¹⁵.

¹² Merrell Dow Pharmaceutical Inc v NH Norton & Co Ltd BL C/089/96

¹³ EPO Decision T344/189; [1993] EPOR 209

¹⁴ Flexible Direction Indicators Ltd’s Application [1994] RPC 20

¹⁵ DSM NV’s Patent [2001] RPC 35

22 It would be helpful here to address some of the applicant's interpretations of the law. I am not convinced there is a difference between the meaning of the terms *information* and *matter* insofar as it relates to section 76 of the Act. The test I must apply is that set out by Aldous J in *Bonzel and Schneider*¹⁶:

- (1) *To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application;*
- (2) *To do the same in respect of the patent as granted;*
- (3) *To compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition. The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly.*

I note the strictness of the third step, with no allowance whatsoever for adding details that may be merely obvious.

23 In his reliance on the case law he has cited, I believe the applicant has overlooked that those judgements must be interpreted alongside the test set out in *Bonzel*. In *Merrell Dow*, the judge held that where cited documents showed that certain aspects of the alleged development were already known, a reference to those documents would not contravene section 76, although any such additions must also satisfy the *Bonzel* test. EPO decision *T344/189* was concerned with the specific situation of amending the application to set out disadvantages of the prior art in order to put the claimed invention in its proper perspective in the art. This also does not seem to be relevant to the amendments the applicant has made to this application.

24 In *Flexible Direction Indicators* Aldous J held that matter which was not disclosed, but the skilled reader would find it obvious to add, will constitute added matter, so I do not think this reference helps the applicant's arguments. In *DSM Neuberger J* gave an example of pH values being implicitly disclosed where only acidity is referred to. Again, this judgement lies alongside the *Bonzel* test and does not contradict it. Therefore, there is nothing in the applicant's arguments that indicate to me that, when considering whether there is added subject matter, the *Bonzel* test can be disregarded.

25 Notwithstanding the entire content of the many pages of description that have been added since the application was filed, there are two main additions to the specification that the examiner deems to be sufficiently significant to specifically object to as added subject matter. For ease of argument, I will address these additions separately, following the three step test set out in *Bonzel*, and ascertaining what is disclosed in the specification through the eyes of the skilled person that I identified above.

26 The first addition that the examiner has raised an objection to is the amendment of the specification to include the words "cure" and "curative". I have already touched upon this wording above in my construction of the claims, deeming "cure" and

¹⁶ *Bonzel and Schneider (Europe) AG V Intervention Ltd* [1991] RPC 553

“curative” to be synonymous with “treatment”. However, for arguments sake I will also consider whether the terms “cure” or “curative” could be seen to be added subject matter, when given their ordinary meaning.

Step 1: to ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application [as filed]

- 27 The description as filed does not contain the words “cure”, “curing” “cured” or “curative”. Neither do the originally filed claims. Page 5 of the description as filed suggests a dosage schedule and the wording “..medication is one course only”. Page 5 then goes on state that treating asthma, chest allergy and atopic dermatitis with anabesine “*terminates them permanently*”, and that one course is required. I note that original claim 8 also included the word “*permanently*”.

Step 2: to do the same in respect of the patent [application as amended]

- 28 Present claims 1 and 2 include the phrase “*Anabesine or its salts for use in curing...*”. Page 17 of the amended description includes the text “*has the potential to cure..*”, and page 20 “*potential curative effect*”.

Step 3: to compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition

- 29 The words “*cure*” or “*curative*” were not in the application as filed. In the amended specification, the skilled person learns that anabesine may be used to cure the disease states defined in the claims. This is not taught in the specification as filed. However, I note that the specification as filed does state that anabesine “terminates [the diseases] permanently”; would the skilled person understand that this is intended to mean that they cure the patient of diseases such as asthma? Without straying into the realms of sufficiency and support, it is clear there is no experimental data in the specification as filed that indicates how the diseases could be cured, or how this is monitored in patients who have been treated with anabesine. Therefore, in my opinion, whilst the skilled person would understand from the specification as filed that a single dose of anabesine could be used to treat a particular instance of allergic asthma or dermatitis, I do not think that they would expand this to curing all causes of allergic asthma or dermatitis in that patient and eradicating it completely. As such, I consider that the term “curing” in claims 1 and 2, and corresponding references in the description, if intended to mean eradicating completely such that no other reaction to any allergen would occur, amounts to added subject matter.
- 30 The second area of added subject matter referred to by the examiner is the dosage regime defined by claim 4.

Step 1: to ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application [as filed]

- 31 The description as filed disclosed (-)-anabesine is present in a medicament at 0.1: 0.15 mg/kg of body weight. Claim 12 as filed disclosed medical methods using a medicament comprising anabesine in a concentration of 0.01 mg/kg: 3.5 mg/kg of body weight.

Step 2: to do the same in respect of the patent [application as amended]

- 32 Present claim 4 defines a medicament comprising anabasine as an active ingredient at a concentration of 0.000001 mg/kg: 2.5 mg/kg of body weight.

Step 3: to compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition

- 33 In the amended specification, the skilled person learns that the effective amount of anabasine may be as low as 0.000001 mg/kg, and that the maximum of 2.5 mg/kg has inventive significance. This is not taught in the specification as filed. As such, I consider that this new range of dosage regime relates to unallowable added subject matter.
- 34 As noted above, there have been numerous additions to the description throughout the prosecution of this application. As far as I am able to substantiate, and in addition to the two specific instances above, I cannot find any other amendment to the description as it stands that does not constitute some degree of added matter. The examiner has set out, in detail, in his examination and pre-hearing reports the objections to the substantial amendments, and I am in agreement with them. I therefore find that the application fails to meet the requirements of section 76(2).

Novelty

- 35 In my consideration of novelty, I have construed claims 1 and 2 as defining the second medical use of anabasine in the treatment of the specified conditions, in line with my construction of the claim, and my assessment of added subject matter above. For a document to anticipate a claim, there is a requirement that there is a prior disclosure of subject matter which, if performed, would necessarily result in infringement of the patent¹⁷, and the same prior art must also enable the skilled person to perform the invention¹⁸.
- 36 In his assessment of novelty, the examiner has cited the following document in the pre-hearing report:

WO2016/161055 A2 (SRQ PATENT)

- 37 The examiner considers that the invention defined in claims 1-3 and 5-7¹⁹ is not new in light of WO2016/161055, as it discloses that anabasine acts as an MAO-A and MAO-B inhibitor, and that MAO inhibitors may be used in the treatment of asthma, and atopic dermatitis, and extends to the use of MAO inhibitors to treat chronic inflammation caused by allergic reactions. In reference to figures 1 and 2 of WO2016/161055, the examiner acknowledges that whilst it can be seen that *in vitro* isomyosmine is more effective than anabasine at inhibiting MAO-A and MAO-B activity, anabasine can still be seen to also have a significant effect on MAO activity, and as such is clearly an MAO inhibitor. Given the experimental evidence provided of anabasine as a MAO inhibitor, and the clear disclosure of the use of MAO inhibitors in the treatment of asthma, atopic dermatitis and allergic reactions, the

¹⁷ General Tire & Rubber Company v Firestone Tyre & Rubber Company Ltd [1972] RPC 457

¹⁸ SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10

¹⁹ Of the claims filed 4 November 2024

examiner considered the disclosure enabling in light of the plausibility aspect discussed by Birss J at 175 of *Merck Sharp & Dohme v Ono*²⁰.

- 38 The applicant disagrees with this assessment. He argues that WO2016/161055 does not show the use of anabasine to treat chronic inflammation. Instead, he interprets the disclosure as presenting research which shows anabasine is not as effective an MAO inhibitor as isomyosmine, such that it is not immediately apparent how effectively anabasine may treat the symptoms *in vivo*. He asserts that the use of anabasine to reduce the inflammation associated with these diseases is not known, and that it would be implausible to the skilled person that such an anti-inflammatory could be used to this effect. However, these arguments are based around the mechanism of action of the drug in the treatment of the disease, which is not considered to impart novelty to the claim²¹. There is also much emphasis put on the fact that the use of the anti-inflammatory was not shown to *cure* asthma and atopic/ allergic diseases. However, as discussed when construing the claim above, the skilled person, reading the claims in light of what is disclosed in the specification, and in the absence of any evidence to the contrary, would read the term “cure” as synonymous with “treat”.
- 39 The results shown in the figures of WO2016/161055 clearly point to an inhibitory effect of anabasine on MAO-A and MAO-B, and the document as a discusses how MAO-A and MAO-B inhibition can be effective in the treatment of chronic inflammatory conditions, including asthma, atopic dermatitis, and allergies. I am satisfied that, for the skilled person, this disclosure would indicate a therapeutic application, and to use anabasine for the treatment of chronic inflammation in the form of allergy is entirely plausible. I therefore conclude that claims 1 and 2 are not new in light of this document. Dependent claims 3 and 5-7 all disclose features clearly disclosed in WO2016/161055 and so are also not considered new. I have found that claim 4 relates to unallowable subject matter, and as such will not assess the novelty of this claim

Inventive Step

- 40 In his pre-hearing report, the examiner has referenced a number of documents which he considered to render obvious the claims. I have already found the claims to not be novel in light of WO2016/161055. Nevertheless, I do consider it worthwhile to comment on the inventive step of the claims in light of this document, in the event that I am wrong in my assessment of novelty, especially with regards to the enablement aspect, and whether the disclosure in WO2016/161055 makes it plausible to the skilled person that anabasine could be used to treat asthma and allergic disorders. In this regard, even if it is not clear that WO2016/161055 enables the skilled person to use anabasine in the treatment of asthma, allergies and dermatitis, in my opinion there is a strong direction pointing towards its use in these disorders. The skilled person reading this document would therefore at least consider testing anabasine as a therapeutic for chronic inflammatory disorders including asthma, allergies and dermatitis, and they would do so with a reasonable expectation of success in light of the results shown in the figures. Therefore, even if I

²⁰ *Merck Sharp & Dohme v Ono* [2015] EWHC 2973.

²¹ See especially paragraphs 188-189 of the [Examination Guidelines for Patent Applications Relating to Medical Inventions in the Intellectual Property Office](#) (“IPO Medical Guidelines”)

am wrong and WO2016/161055 does not meet the enablement requirement for anticipation, then there is sufficient disclosure in this document to direct the skilled person to try the use of anabasine in these diseases. The claims therefore lack an inventive step.

41 The examiner also cited the following additional documents under inventive step:

RU 2541312 C2 (IVASHCHENKO)

European Respiratory Journal, Vol. 48 (suppl 60), 2016 Santana *et al* “Alpha-7 nicotinic acid receptor stimulation reduces airway inflammation in a murine model of asthma”, PA 5066

Nature Communications, Vol.7, 2016, L Galle-Treger *et al*, “Nicotinic acetylcholine receptor agonist attenuates ILC2-dependent airway hyperreactivity”, 13202

Immunity, Vol. 46, 2017, S Chavan *et al*, “Mechanisms and Therapeutic Relevance of Neuroimmune Communication”, pages 927-942.

42 From a cursory inspection of RU 2541312 and Chavan *et al*, I cannot see any clear indication that nicotinic acetylcholine receptor agonists (or anabasine in particular) are considered to be useful in the treatment of allergic airway inflammation. Whilst RU 2541312 exemplifies anabasine, it is for use to aid smoking cessation, and Chavan *et al* merely reviews the interplay between peripheral neuronal function and immunity and inflammation. There is nothing that points to the use of anabasine in allergic airway inflammatory disorders. I will therefore not consider these documents any further.

43 I consider the remaining two documents to have enough relevance that it is worthwhile for me to assess the claims for inventive step in light of them. The examiner has assessed the claims following the test as set out in *Windsurfing*²², and reformulated as the “Windsurfing/Pozzoli” test in *Pozzoli*²³, although the applicant has not responded to the objections using the steps of this test. I am bound to assess the claims using the same approach.

(1)(a) Identify the notional “person skilled in the art” and (b) Identify the relevant common general knowledge of that person

44 I will proceed with my earlier identification of the skilled person as a team comprising a physician who would explore therapeutic treatments for inflammatory diseases, and a pharmacologist who would have a knowledge of existing therapies for inflammatory diseases. The skilled team would know that asthma²⁴, atopic dermatitis²⁵ and allergic diseases²⁶ are examples of inflammatory diseases, and would be aware of inhibitors of the inflammatory process and their potential as therapeutic targets. The applicant has not disputed the identification of the skilled

²² *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*

²³ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

²⁴ [Asthma - Wikipedia](#)

²⁵ [Atopic dermatitis - Wikipedia](#)

²⁶ [Allergy - Wikipedia](#)

person, although in his letter of 4 November 2024 he sets out further details of what is considered to be the common general knowledge. This includes the immune response, via IgE-sensitised mast cells, to an allergen, and the various factors (such as environmental and genetic) that can influence this.

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

45 There are two independent claims, claims 1 and 2. At the time the examiner wrote his pre-hearing report, the claims were in the Swiss claim format, and the examiner construed the claims in light of this. I have construed the present claims in light of my earlier construction of them, and my assessment of added matter above, as follows:

1. *Anabasine or its salts or its use in treating asthma and atopic dermatitis in humans*

2. *Anabasine or its salts or its use in treating allergic diseases in humans.*

(3) Identify what, if any, differences exist between the matter cited as being “known or used” and the alleged invention

46 Santana *et al* is an abstract from conference proceedings, disclosing that the cholinergic anti-inflammatory pathway has been described as controlling inflammation in several organs and that this pathway links the brain and immune system through effects at $\alpha 7$ nAChR receptors. The experiments recorded utilised PNU282987 (PNU) at 0.05 mg.kg^{-1} as an $\alpha 7$ nAChR agonist *in vivo*, and results showed the $\alpha 7$ nAChR stimulation reduced inflammation. The article concludes that $\alpha 7$ nAChR receptors may be a new target to be explored in asthma. This differs from present claims 1 and 2 in that it does not disclose the use of anabasine as a treatment for asthma, atopic dermatitis or allergic disease, instead disclosing that the use of an alternative $\alpha 7$ nAChR agonist in the form of PNU at 0.05 mg.kg^{-1} may be used to treat asthma.

47 Similarly, Galle-Treger *et al* discloses that $\alpha 7$ nAChR receptors are thought to have an anti-inflammatory role in several inflammatory diseases and that use of an $\alpha 7$ nAChR agonist leads to a reduction in ILC2 receptor function, ILC2-dependant airway hyperactivity and NF- κ B. As such $\alpha 7$ nAChR agonism is a potential therapeutic target for treatment of ILC2-mediated asthma. The first column of page 2 also discloses that an $\alpha 7$ nAChR agonist mediates inflammatory diseases. The experiments recorded utilised GTS-21 (3-(2,4-dimethoxy-benzylidene) anabasine) as an $\alpha 7$ nAChR agonist. Such disclosure differs from what is claimed in present claims 1 and 2 as it discloses the treatment of asthma with an $\alpha 7$ nAChR agonist, but not with, specifically, anabasine.

(4) Decide, without any knowledge of the alleged invention, whether these differences constitute steps which would have been obvious to the skilled person or whether they require any degree of invention

48 The arguments from the applicant, similar to his arguments in relation to the novelty of the claims, are all based around the lack of disclosure of the mechanism of action of the $\alpha 7$ nAChR agonists in the reduction of inflammation that arises in response to

certain atopic and allergic diseases. The lack of this disclosed link between inflammation and the diseases treated means, in the applicant's mind, that the use of these agonist would not be with the intention to cure these atopic and allergic diseases. However, as noted above, I consider the term "cure" to be synonymous with "treat", and even if the skilled person were intending to treat the diseases without the knowledge that they would "cure" the patient, the outcome would be the same: the underlying disease would be treated and "cured". Therefore, the consideration of obviousness lies in whether the skilled person would use an $\alpha 7$ nAChR agonist to treat an allergic or atopic disease or asthma.

- 49 Both Santana *et al* and Galle-Treger *et al* disclose that $\alpha 7$ nAChR agonists are a target for asthma, which is a known chronic inflammatory disease. The skilled team would appreciate that alternative $\alpha 7$ nAChR agonists could be tried as a therapeutic regime against asthma and other chronic inflammatory diseases, including atopic and allergic diseases, with anabasine as one such $\alpha 7$ nAChR agonist. In his letter of 4 November 2024, the applicant pointed out that the examiner did not indicate that there was any reasonable expectation of success in such a trial, and as such, this did not satisfy the standard required for demonstrating a lack of inventive step. He went on²⁷ to refer to the decision of the Supreme Court in *Actavis v Icos*²⁸, with reference to the principles set out therein and as set out in paragraph 148 of the Medical Guidelines.
- 50 I agree that *Actavis v Icos* does help in the assessment of the inventive step of new therapeutic uses, but I do not see how this helps the applicant's arguments. The Supreme Court emphasised that the invention has to be obvious to try with a reasonable expectation of success, but that there is no requirement that it should be manifest that the trial ought to work. The nature of the research, especially if it is routine in nature, and the role of the skilled person is also significant. Given that both Santana *et al* and Galle- Treger *et al* both suggest that $\alpha 7$ nAChR agonists may be useful for the treatment of asthma, then the skilled person would consider alternative agonists for such a therapeutic use, with a reasonable expectation of success. They would also appreciate the potential for other chronic inflammatory conditions, including other allergic diseases. The work that they would undertake to test such alternative agonists would be routine.
- 51 I further note that the present application specifically selects anabasine as the $\alpha 7$ nAChR agonist for use in these treatments. However, there is nothing in the specification as filed that demonstrates that anabasine has any special effect over any other $\alpha 7$ nAChR agonist. In the absence of any experimental data, the selection of anabasine appears to me to be no more than arbitrary. Therefore, there are no surprising results to indicate inventiveness of the use of anabasine. Furthermore, as I have discussed previously, the reduction of inflammation that arises in response to these atopic and allergic diseases is merely a mechanism of action proposed by the applicant, akin to the "bonus effect" discussed in *Actavis v Icos*.
- 52 Therefore, I consider that the invention as defined in claims 1 and 2 would be obvious to the skilled person, in light of either of Santana *et al* or Galle-Treger *et al*. In the absence of any evidence to the contrary, claims 3 and 5-7 also appear to be

²⁷ In the applicant letter dated 3 February 2025

²⁸ *Actavis v Icos* [2019] UKSC 15

routine and lack inventive step. Again I will not assess claim 4 as it encompasses unallowable added subject matter.

Other issues

- 53 The examiner has raised further objections to plurality, sufficiency and support, which I consider to be justified from a cursory view. However, having already found that the application does not comply with the requirements of section 76(2), section 1(1)(a) and section 1(1)(b), I do not consider it necessary or proportionate for me to consider any other issues identified by the substantive examiner, or arising from the newly amended claims.

Conclusion

- 54 I have concluded that the invention is not new as is required by section 1(1)(a), and does not involve an inventive step as required by section 1(1)(b). I have also concluded the amended application includes subject matter extending beyond that disclosed in the application as filed, as prohibited by section 76(2). Furthermore, it would appear that the claims are not clear as required by section 14(5)(b). The application is therefore refused under section 18(3).

Appeal

- 55 Any appeal must be lodged within 28 days after the date of this decision.

DR ROWENA DINHAM

Patent Examination Group Head