Intellectual Property Office

BL O/0135/25

14 February 2025

**PATENTS ACT 1977**

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| APPLICANT | Pauline McKay |
| ISSUE | Whether patent application GB2008221.0 complies with sections 1(1)(a), 76(2), 14(3), 14(5)(b) and 14(5)(c) of the Patents Act 1977 |
| HEARING OFFICER | Dr Rowena Dinham |

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**DECISION**

**Introduction**

1 This decision relates to whether patent application GB2008221.0 ("the application") entitled "Alpha Lipoic Acid (A-ALA) and Alpha Lipoic Acid (R-ALA) as a Pharmaceutical Product for Intravenous Application to Reduce Inflammation from Infection. To repair Nerve Damage" complies with the Patents Act 1977 ("the Act").

2 The application was filed on 2 June 2020, and comprised 14 pages of description and a single claim with 3 supplementary pages attached, under the name Pauline McKay ("the applicant"), an unrepresented applicant. I note that there have been several attempts made by the applicant for a late declaration of priority under rule 6(2)[1], however it appears that these forms were both filed in error and out of time[2]. I am therefore satisfied that the earliest date of the application is the filing date of 2 June 2020.

3 Prior to the search, the applicant filed multiple abstracts[3] and provided drawings on 21 December 2020. The search report was issued on 12 January 2022, and the search was deemed by the examiner to be complete for novelty but truncated for inventive step. The search examiner also reported issues with clarity and support. The application was then published on 11 May 2022. Prior to substantive examination, a further abstract was filed[4], as well as further amendments to the description[5] and claims[6].

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

[2] See Patents Form 3 filed dated 9th January 2021, 16th February 2021 and 12th May 2021, each providing the present application number as the priority application relied upon.

[3] On 20 November 2020, 23 November 2020 and 9 December 2020

[4] On 24 February 2022

[5] On 23 February 2022 and 26 April 2022

[6] On 24 February 2022 and 26 April 2022

4 On 25 August 2023, the substantive examiner wrote to the applicant offering a refund of the substantive examination fee due to the significant issues of novelty and added matter. No response was received, and a first examination report was issued on 11 December 2023, the report being confined to the issues of added matter and novelty. In his report, the examiner identified added matter in each of the significant amendments made since the filing date and objected to the claims as lacking novelty under section 1(1)(a) of the Act.

5 There followed several rounds of correspondence in the form of examination reports, amendments (both with and without accompanying letters), emails and telephone calls. The latest claims are those filed on 12 April 2024, and the latest description on 26 April 2022. At the request of the applicant, the matter has been referred to me for a decision on the papers, and I can confirm that I have considered all of the documentation on file in coming to my decision. I was assisted by Carrie-Ann Williams.

6 The compliance period for the application ended on 2 December 2024. Given that the compliance period has expired, and it is now two months beyond that expiry, there will be no further opportunity to amend the application.

**The application**

7 The application appears to relate to alpha lipoic acid ("ALA", also known as thioctic acid and used interchangeably as such by the applicant), its anti-inflammatory effects and its potential benefits in the treatment of diseases such as COVID-19. The description provides a background into what is known about ALA, including its effects upon the inflammatory system, its metabolism and bioavailability, mostly taken from third part studies and publications. It also provides some background on the effects of COVID-19 infection. No exemplar formulations are provided in the application as filed, other than those provided in reference to published studies.

8 The most recent claims on file read as follows:

> *"1. Thioctic acid and its reduced form dihydrolipoic acid, works synergistically with adenin, thiamin, riboflavin, pantothenic acid and pyroxidine and has efficacy to attenuate the effects on the central nervous system, the respiratory, arterial and cardiovascular systems in severely affected Covid-19 patients and patients with T2DM.*
>
> *2. Thioctic acid and its reduced form dihydrolipoic acid, works synergistically with adenin thiamin, riboflavin, pantothenic acid and inositol and has efficacy to attenuate the inflammatory effects on damage to the cardiovascular, arterial and central nervous system. Repurposing of thioctic and dihydrolipoic acid for use in the prevention of severe inflammatory cytokine response in the lungs of severely affected Covid-19 patients, Sars cov-2 patients and patients with type 2 Diabetic mellitus and obese patients, promotes vaccine efficacy.*
>
> *3. Thioctic acid and its reduced form dihydrolipoic acid, works synergistically with vitamin B complexes to attenuate the inflammatory and associated responses in the lungs, respiratory and cardiovascular system in Covid-19, Sars Cov2 associated illnesses including arterial thrombosis, and some*

*cancers such as HIV and immunodeficiency illnesses. Repurposing vitamin B complex and both forms of thioctic acid promotes inhibition and prevention of the severity of the symptoms "*

9 This differs from claim 1 as originally filed, which read:

*"1. A natural powerful anti-oxidant, and anti-inflammatory aid to have access to every cell and organ in the body. The third party studies seen here conclude that (ALA)-may reduce inflammation in a COVID-19 infected patient"*

I note that appended to this claim 1 as originally filed was a table outlining the symptoms of COVID-19 as well as a summary of what is known about ALA.

**The Law**

10 The relevant law is defined in the Patents Act 1977 (as amended) 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.

**Disclosure unlawfully obtained**

13 I am aware of the applicant's claim that their mobile phone was stolen in February 2020. In their emails of 17 January 2024 and 6 September 2024, the applicant asks the examiner to consider two issues: (i) that the present application would have been filed in February 2020 had the phone theft not occurred; and (ii) the documents cited by the examiner and dated between February 2020 and June 2020 should be disregarded as there are 'discrepancies' within them that likely arise from the theft of the phone.

14 There is no basis in the Act or rules that allow for an earlier filing date in the circumstances of point (i) and so I cannot consider this any further. As such the filing date of 2 June 2020 stands.

15 In relation to point (ii), although unclear, it appears the applicant is alleging that the authors of the cited documents obtained information from their stolen phone unlawfully, and therefore these documents should be disregarded under section 2(4)(a) of the Act. The examiner has explained to the applicant that evidence would need to be submitted to substantiate this serious allegation[7]. No evidence has been

[7] See telephone report dated 9 September 2024 and examination report dated 29 October 2024.

provided, and therefore I agree with the examiner that these documents remain citeable as prior art under section 2(2), and I will consider their relevance below.

**Issues for decision**

16 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 matter[8], novelty[9], clarity[10], sufficiency[11] and support[12].

17 I have carefully considered the documents on file, and I shall address the objections set out in the detailed pre-hearing 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**

18 My starting point for assessing this invention lies in construing the claims. As is the case with many unrepresented applicants, a patent professional is not used to draft their application. This is perfectly acceptable, however without the benefit of experience of drafting claims they may not be as clear as they could be, which is the case here.

19 Nevertheless, I have attempted to construe the claims in a purposive manner, through the eyes of the skilled person, 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 law[13]. In this case, the examiner has considered the skilled person to be someone in the art of pharmacy, and the applicant has provided no alternative. I agree with this, but consider that they would also have a knowledge of infectious diseases and their impacts upon the immune and inflammatory system. The examiner has argued that the claims are unclear in scope and comprise desirable results to be achieved (as well as added matter, which I will consider later). If I take claim 1 as an example, which reads:

> "*Thioctic acid and its reduced form dihydrolipoic acid, works synergistically with adenin, thiamin, riboflavin, pantothenic acid and pyroxidine and has efficacy to attenuate the effects on the central nervous system, the respiratory, arterial and cardiovascular systems in severely affected Covid-19 patients and patients with T2DM*".

20 I agree that the claim is unclear, and on the face of it is merely a statement of an apparent mechanism of action of ALA. Claims 2 and 3 face the same issue. I

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[8] Section 76(2)
[9] Section 1(1)(a)
[10] Section 14(5)(c)
[11] Section 14(3)
[12] Section 14(5)(b)
[13] See MOPP Section 14.111-14.116 and 125.13-125.14; and Kirin-Amgen Inc v Hoescht Marion Roussel Ltd [2005] RPC9

acknowledge that the applicant may not be familiar with claim structure (despite significant guidance from the examiner), and this may lead to wording that may not be what they are seeking protection for. Therefore, I will bear in mind what it appears that the underlying inventive concept is when attempting to construe the claims. Nevertheless, I am constrained by what the skilled person would understand **from the specification as filed** as being the subject of the invention, and consequently the meaning of the words of the claims.

21 For ease of understanding I will address each problematic section of the claim in turn, and its impact upon how the claim can be construed.

"..works synergistically with adenin, thiamin, riboflavin, pantothenic acid and pyroxidine…"

22 It is unclear from the wording of the claim whether a combined use of ALA with one or more of adenine, thiamine etc. is intended, or whether the claim is merely defining a mechanism of how ALA interacts with these compounds *in vivo*. However, taking guidance from the description as filed, the skilled person would understand that the invention lies in the anti-oxidant and anti-inflammatory effects of ALA, and that it may have beneficial effects in the treatment of various diseases, including COVID-19 and type-2 diabetes mellitus ("T2DM"). Furthermore, there is no mention of a combined use with any other compound, including adenine, thiamine etc as listed in claim 1, and therefore they would not understand that the intention of the claim was to provide a composition of ALA with one or more of adenine, thiamine etc. It therefore appears that the claim merely describes how ALA may interact with the listed compounds.

"…and has efficacy to attenuate the effects on the central nervous system, the respiratory, arterial and cardiovascular systems in severely affected Covid-19 patients and patients with T2DM"

23 There is no use provision in this part of the claim, either as a method of treatment or as a second medical use, and the examiner contends that it merely provides for a desired result of ALA. I *prima facie* agree with this; the claim does not limit the use of ALA to the treatment of COVID-1 or T2DM and would merely appear to define ALA in a composition suitable for pharmaceutical or nutraceutical use. However, as noted above, I am aware that the applicant may be unclear on the required format for second medical use claim, and have to wonder whether the intention is to claim ALA for use in the treatment of COVID-19 or T2DM. In particular, looking at claim 1 as originally filed, the claim defines "…*ALA may reduce inflammation in a COVID-19 patient*". Taking this into account, and the disclosure of the specification as filed, it appears to me that an alternative inventive concept may lie in the use of ALA in the treatment of COVID-19[14].

[14] I do not believe that the intention is to claim a use for T2DM as (a) it was not claimed in the application as filed, and (b) all references in the description of the benefits of ALA in T2DM patients are to third party studies presented in the prior art referenced therein. This is in line with Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd [2010] RPC where the Court of Appeal held that the patentee would not be expected to have claimed what they had expressly acknowledged as old.

24 In light of this it appears that there are two possible interpretations of the inventive concept defined by claim 1:

(i) ALA and/ or its reduced form dihydrolipoic acid suitable for pharmaceutical or nutraceutical use; or

(ii) ALA and/ or its reduced form dihydrolipoic acid for use in the treatment of COVID-19

25 From reading the specification as filed, and particularly what is disclosed therein, I arrive at the same two possible constructions for the inventive concepts of claims 2 and 3, in light of the inherent lack of clarity also present in those claims. The claims therefore lack clarity and do not meet the requirements of section 14(5)(b). However, whilst unconventional, I will consider both possible constructions below in my assessment of novelty.

**Novelty**

26 In his assessment of novelty, the examiner has cited the following documents:

D1 MedRxiv, 21st April 2020, Zhong et al, "*A randomized, single blind, group sequential, active-controlled study to evaluate the clinical efficacy and safety of alpha lipoic acid for critically ill patients with coronavirus disease 2019 (COVID-19)"*.

D2 Respiratory Medicine Case Reports, Vol 30, 21st April 2020, Horowitz et al, "*Efficacy of glutathione therapy in relieving dyspnea associated with COVID-19 pneumonia: A report of 2 cases*"

D3 US 2013/0034632 A1 (CUOMO et al.)

D4 US 2007/0072937 A1 (PARK et al.)

D5 EP 2386552 A1 (CBB NET S A)

27 I will consider the novelty of both possible constructions of the claim in light of these documents.

(i) <u>ALA and/ or its reduced form dihydrolipoic acid suitable for pharmaceutical or nutraceutical use</u>

28 The examiner considers that the invention is not new in light of D3-D5 above, which disclose ALA for pharmaceutical or nutraceutical use in various dosage forms[15]. Specifically, D3 discloses nutritional supplements comprising ALA in tablet, capsule or powder form. Paragraph [0002] of the description discusses that nutritional supplements containing ALA are known in the art. D4 discloses formulations of oral or parenteral preparations containing ALA, for the treatment of endotoxemia. I note that page 6 of this document references several other documents. One reference dated 2003 relates to the use of ALA to treat complications of diabetes; one dated 2002 relates to its use in the treatment of neurodegeneration; and one dated 2004

[15] See examination report dated 29 October 2024 and pre-hearing report dated 16 December 2024

relates to its use in the treatment of hepatic disorders. D5 also provides for pharmaceutical tablets containing ALA salts (of the R-enantiomer form). This document also makes several references to other documents when discussing what is already known on pages 1 and 2; these other earlier documents show that injectable and oral forms of alpha lipoic acid were already well known before 2011[16].

29 The only argument that appears to have been put forward by the applicant in relation to these documents is that they do not "*appear relevant to these claims, which do not include a claim about glutathione"*[17]. I acknowledge that the wording of the claims does not require the presence of glutathione, however the construction of the claims is such that glutathione is not explicitly excluded. Moreover, none of D3-D5 above require glutathione as part of their composition; the closest here is D3 which requires N-acetyl cysteine, a glutathione precursor. Therefore, taking all of the above sources of disclosure into account, I am of no doubt that the use of ALA as a pharmaceutical/ nutraceutical has been well known for several years, well before the earliest date of this application. If claim 1 is attempting to claim ALA in a composition suitable for nutraceutical or pharmaceutical use then it is not novel.

(ii) <u>ALA and/ or its reduced form dihydrolipoic acid for use in the treatment of COVID-19</u>

30 None of the disclosures above relate to the use of ALA to treat COVID-19. However, the examiner has cited two additional documents in this regard:

> D1 *MedRxiv*, 21st April 2020, Zhong *et al, "A randomized, single blind, group sequential, active controlled study to evaluate the clinical efficacy and safety of alpha lipoic acid for critically ill patients with coronavirus disease 2019 (COVID-19)*";
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> D2 *Respiratory Medicine Case Reports*, Vol 30, 21st April 2020, Horowitz *et al*, *"Efficacy of glutathione therapy in relieving dyspnea associated with COVID-19 pneumonia; a report of two case*".

31 D1 documents a study carried out in Wuhan, China between February 2020 and March 2020, where ALA was administered to patients critically ill with COVID-19. D2 discloses a trial where ALA was given to patients suffering from dyspnea associated with COVID-19 infection, along with glutathione and/or its precursors. These two documents clearly show that the use of ALA to treat COVID-19 patients was known before the filing date of the present invention.

32 The applicant's submissions on the relevance of these documents are focussed upon their dates of publication as being following the theft of their phone in February 2020, and how they may result from unlawful disclosure of the application[18]. This I have addressed above. There are some comments in this letter that state that the present application is distinguished from these documents, but aside from the inclusion of glutathione in the studies of D2, no other specifics are provided of what

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[16] I also note here that page 9 at least of the present application as filed is a reproduction of an article found at Lipoic Acid | Linus Pauling Institute | Oregon State University, written in 2002 and last updated in 2018.

[17] See Applicant's letter of 22 November 2024

[18] See Applicant's letter of 9 February 2024

these distinguishing features might be. As pointed out above, glutathione is not excluded as part of the therapeutic regime of this application.

33 As D1 and D2 both disclose the use of ALA as part of a therapy to treat COVID-19 then if the claims were construed as ALA for use in the treatment of COVD-19 then they are not new.

34 I therefore conclude that claims 1-3 are not novel in light of any one of D1-D5 listed above and therefore I find that the application fails to meet the requirements of section 1(1)(a).

**Added matter**

35 Section 76(2) of the Act prohibits the amendment of an application to add matter:

> *"No amendment of an application for a patent shall be allowed under section 15A(6), 18(3) or 19(1) if it results in the application disclosing matter extending beyond that disclosed in the application as filed."*

As outlined above, numerous amendments have been filed; some were filed with a covering letter setting out the amendments made and arguments for their allowability, and some were filed alone. The case file is somewhat muddled as a result. I also note that numerous abstracts have been filed. Each abstract was submitted after the original filing date of the application, and each contains significant amounts of matter which was not present in the description, claims or drawings. However, in *Abbott v Medinol*[19], Arnold J held that section 14(7) should be interpreted as meaning that the purpose of the abstract is to give technical information only (by reference to the similar Article 85 EPC and associated EPO case law), and so is irrelevant for the purpose of determining the disclosure of the application as filed. Consequently, the specification cannot be amended to incorporate matter from the abstract into the description or claims, whether or not the abstract was filed on the day of filing. As such, I will disregard the contents of all abstracts filed.

36 I will now turn to the specification. The original application comprised 18 pages, with page 15 comprising a single claim. There were no figures. The application as currently amended comprises 44 pages of description, 2 pages of figures and 3 claims. The examiner has provided significant detail of the added matter in his pre-hearing report and in his earlier examination reports, and I note that minimal, if any, attempt has been made by the applicant to address this. The applicant has put forward a number of arguments explaining why they deem this additional matter to not be contrary to section 76(2). However, there appears to be a misunderstanding on the part of the applicant of the requirements of section 76(2) and its association with the ability to make amendments to a patent application. From their letter of 9 February 2024, it appears that the applicant believes that amendments made of their own volition[20] that are "part of the invention steps" are not deemed to be added matter. Unfortunately that is not the case. Any amendments made to an application

[19] Abbott Laboratories Ltd. v Medinol Ltd [2010] EWHC 2865 (Pat)
[20] In this case, between the issue of the search report under section 17 and the first examination report under section 18 (see section 19(1)).

after it has been filed is subject to the requirements of s76(2), regardless of whether they were made of the applicant's own volition or in response to an examination report. The examiner was therefore correct in assessing the amendments for added matter, and there are no submissions from the applicant that indicate the basis for any of the amendments in the application as filed.

37 As far as I am able to substantiate, I cannot find any amendment to the application as it stands that does not constitute some degree of added matter. This includes all of the figures and significant parts of the description and claims, and I do not consider it proportionate to identify each instance individually. Whilst I have assessed the inventive concept of the claims as currently amended for the requirements of novelty, my finding that the claims are not novel does not turn on the removal of the added subject matter, or the reversion of the claims to the wording of the claim as filed.

38 I therefore find that the application fails to meet the requirements of section 76(2).

**Sufficiency and Support**

39 Given that I have found that the claims are not new in light of the documents listed above, and that the application comprises significant amounts of added matter, I am minded not to make a definitive finding with respect to sufficiency and support. However, I will note that the application as filed comprises no detail in the form of experimental data supporting any therapeutic use of ALA for any therapeutic treatment, let alone COVID-19, and so will provide a brief assessment of sufficiency and support.

40 I have considered what is disclosed in the application as filed and summarised it below:

- Facts about ALA, including its physical properties and alternate names
- Lists of benefits of ALA, limited to statements with no associated evidence
- Incomplete discussions of third party prior art studies, some involving ALA
- Discussion of biochemical pathways that may involve lipoic acid
- Discussion of COVID-19 and a suggestion that it originated in bats.

41 Following the judgment of the Supreme Court in *Warner Lambert*[21] the **specification as filed** must make the claimed use plausible; data filed after the filing date of the patent can only be used to confirm an effect made plausible in the specification or to refute a contention that the treatment does not actually work; it cannot be a substitute for sufficient disclosure in the specification. Whilst the specification as filed (notably from third party studies) suggests a role for ALA in certain therapies, there is nothing conclusive. Even if there were sufficient disclosure to make plausible the use of ALA in any therapeutic method, it is clear that this disclosure is in light of the third party studies disclosed within the application itself and therefore any claimed invention limited in this regard would inherently lack

[21] Warner-Lambert Company LLC v Generics (UK) Ltd (t.a. Mylan) & Anor., [2018] UKSC 56

novelty. If the intention is for the more limited use of ALA in the treatment of COVID-19 then there is nothing in the specification as filed that would make this assertion plausible. Therefore, it appears that the application does not meet the requirements of section 14(3).

42 It also follows that there is not enough material to enable the skilled person to conclude that ALA would in fact treat COVID-19, as required by *Prendergast*[22]*.* Whilst I acknowledge that data supporting any therapeutic use need only be rudimentary, I cannot identify any such data in the specification as filed, and as such the specification as filed would also not appear to meet the requirements of s14(5)(c).

**Other issues of concern to the applicant**

43 Records of name changes for the applicant are on file. The first name change to "Pauline Salakov" was made before A publication, and then on 6 October 2023 a request was made to change the name to "Pauline McKay". The applicant has queried why the A document shows the applicant as "Pauline Salakov". I can confirm that the application is proceeding in the name of "Pauline McKay" but as the name provided on the Form 1 was correct at the time of filing, the name change has been actioned under Rule 49(6)(b) and so no changes have been made to the A publication document retrospectively.

44 The applicant has made several requests to update the title of the invention. The title of the invention as requested on Patents Form 1 forms part of the specification under section 14(1)) and rule 12(4), and has formal requirements as set out under rule 12(6). The first request to change the title was made via email on 19 November 2020, to "Anti Inflammatory effects of Thioctic acid on SARS-COV2 Respiratory and Cardiovascular Associated Illnesses, T2DM and the central nervous system". A second request to change the title was then made on 18 May 2022, to "Kushimore AI AO". As the title of the invention forms part of the specification, a request to amend the title is generally allowable, although any amendment is subject to the requirements of s.76(2) in that it must not add matter. Both of these amendment requests contain matter that extends beyond what was originally disclosed and so the requests cannot be accepted. These change requests cannot alternatively be considered as corrections under s.117 rather than amendments, as there was not an immediately obvious error in the original title provided. Therefore, the title remains as the title originally provided on the Form 1.

45 In their email of 22 November 2022, the applicant refers to a trade mark application that she made in error. The trade mark in question is UK00003486432, and consists of the text "Alpha Lipoic Acid (ALA) and R-ALA for use for treatment of coronaviruses and viral infections". This application was filed on 3 May 2020, i.e. before the earliest date of the present application. However, I have no need to consider the relevance of this any further in relation to the novelty and/or inventive step of the claim in light of the other issues discussed above.

[22] Prendergast's Applications [2000] RPC 446

## Conclusion

46 I have concluded that the invention is not new as is required by section 1(1)(b), and that it also includes subject matter extending beyond that disclosed in the application as filed, as prohibited by section 76(2). Furthermore, it would appear that the specification does not disclose the invention in a manner which is clear enough or complete enough for it to be performed by a person skilled in the art, as is required by section 14(3) and also that the invention as claimed is not supported by the description as filed as is required by section 14(5)(c).

47 I therefore refuse the application under section 18(3) of the Act.

## Appeal

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

Dr Rowena Dinham

Patent Examination Group Head