Intellectual Property Office

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PATENTS ACT 1977

APPLICANT	BENE AKROMAA AFOLABI
ISSUE	Whether patent application GB1902498.3 complies with section 1(1)(a), section 14(5)(b) and section 76(2) of the Patents Act 1977
HEARING OFFICER	Dr Rowena Dinham

DECISION

1 This decision concerns whether patent application GB1902498.3 entitled "Deoxycholic-bound Inulin" complies with the requirements of the Patents Act 1977 ("the Act") with regard to novelty under section 1(1)(a), the clarity of the claims under section 14(5)(b) and added subject matter under section 76(2).

2 The application, which originally comprised 33 pages of description (i.e. seven pages of text followed by figures 1-25 and tables 1-3) and one page of ten claims was filed on 25 February 2019. A combined search and examination report was issued on 9 July 2019 setting out why the claimed invention was not novel (i.e. not new). At this early stage the examiner, Dr Andrew Guy, suggested that the applicant seek the advice of a patent attorney, and also that the application be withdrawn prior to publication. There followed four amendment rounds during which the applicant, Dr Afolabi, sought to amend the claims in order to clarify the scope of her invention and amended the description in a manner which gave rise on each occasion to objections to added subject matter. The offer of a hearing was accepted on 13 December 2024, and the matter came before me on 17 March 2025. I was assisted at the hearing by Dr Graham Feeney.

3 Throughout the prosecution and at the hearing Dr Afolabi was represented by a solicitor, Mr Ezike, of Universe Solicitors Limited. At the hearing, Dr Afolabi presented the majority of her arguments and evidence herself, with Mr Ezike providing helpful legal clarifications along the way. I am grateful to Dr Afolabi for her straightforward and carefully reasoned explanations which assisted me in understanding her position and in reaching my decision.

The application

4 The application relates to a composition of a mixture of inulin (a carbohydrate/ dietary fibre/ prebiotic derived from chicory) and deoxycholic acid (one of the naturally occurring bile acids). The precise nature of the invention is not immediately clear form the specification as filed, and therefore during the early part of the hearing Dr Afolabi clarified that the application concerns the straightforward mixing of bile acids, specifically deoxycholate or deoxycholic acid with inulin[1]. As was confirmed at the hearing, the application does not disclose the manufacture of an isolated or purified complex of inulin and deoxycholate[2]. Dr Afolabi was, however, able to tell me that later crystallographic modelling confirmed that a complex can form between deoxycholate and inulin. The application further discloses the activity of a deoxycholate/inulin mixture to inhibit the proliferation of colon cancer cell lines in vitro and promote programmed cell death (apoptosis) and the molecular mechanism that underpins this effect[3]. At the hearing, Dr Afolabi placed great emphasis on these teachings, the implications of which in terms of the concept of novelty in patent law are discussed below.

5 During the prosecution of this application, the format of the independent claim(s) has been repeatedly adjusted by amendment such that a great deal of the examiner's efforts has concerned attempting to understand the scope of patent protection sought. Objections to a lack of clarity, excluded methods of treatment and unclear and/or unsupported medical use claims have arisen at various points.

6 At the hearing, Dr Afolabi clarified that she intends to seek a patent for a composition. This is consistent with the marked-up amended claims filed on 13 December 2025, and, as agreed at the hearing, are the claims that I should consider in reaching this decision. As I noted at the hearing, at present no clean copy of these claims or of the amendments to the description supplied on the same date have been received by the IPO. Therefore, at the expiry of the compliance period, the amended application did not meet the formal requirements[4] of the Rules.

7 As they stand, with the struck-out elements removed and the claims re-numbered by myself, the claims as now amended are reproduced as follows:

> *1. A composition of deoxycholic acid and inulin to form an entity/complex, to treat colorectal cancer cells.*

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[1] In the application as filed, this mixing step is conducted solely in culture medium during experiments in which the effects of the mixture of deoxycholate/inulin upon a colon cancer cell line are measured. At the hearing, Dr Afolabi was able to confirm to me that all that was required to produce a complex of deoxycholate and inulin was to simply mix the two substances. Although crystallographic modelling of the complex was not included in the application, Dr Afolabi was able to explain to me the chemistry behind predicted hydrogen bond formations between deoxycholate and inulin, which would be expected to result in the formation of a strongly linked complex.

[2] In this regard, the disclosure is limited to the mixing of ingredients and the formation of the complex in a culture medium.

[3] In terms of a mechanism of action, the *a priori* reasoning and data presented in the application indicate that inulin may sequester intracellular deoxycholate, with the formation of a complex inulin/deoxycholate. It seems that this complex may promote apoptosis by causing up-regulation of pro-apoptotic protein caspase-3 and an inhibition of the pro-inflammatory signal TNF-α.

[4] See the Patents Rules 2007 at rule 14 and schedule 2 Part 2.

2. The composition of claim 1, wherein the composition comprises inulin which is a polysaccharides.

3. The composition of claim 1 wherein the said composition comprises deoxycholic acid which is selected from the group of steroids which are apoptotic.

4. The composition of claim 1 where in the composition comprises inulin (3 mg/ml) and deoxycholic acids (300 µM). F is fructose-sucrose group R represents a steroid group N is a number ~36.

5. Deoxycholic-bound inulin down regulates β-catenin in normal human colon and colorectal cancer cells.

6. Deoxycholic-bound inulin down regulates vimentin in normal human colon and colorectal cancer cells.

7. Deoxycholic-bound inulin down regulates E-cadherin in normal human colon and colorectal cancer cells (Figure 14, 15).

The Law

8 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

9 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

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

Issues for decision

10 There are several 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 their pre-hearing report, the examiner sets out that the application fails to meet the requirements for novelty[5], added matter[6] and clarity[7], and defers matters relating to sufficiency[8] and support[9].

11 I note that the extended compliance period for this application expired on 16 May 2025.

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[5] Section 1(1)(a)
[6] Section 76(2)
[7] Section 14(5)(c)
[8] Section 14(3)
[9] Section 14(5)(b)

Claim construction and clarity

12 The claims are construed 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[10]. During the prosecution of this application, there does not appear to have been a clear identification of the identity of the skilled person. At the hearing Dr Afolabi indicated that in her view the skilled person would have knowledge of the art of biomedical science and medicinal chemistry and some expertise in molecular crystallography. I cannot agree with this because, for the purposes of patent law, the notional skilled person is an unimaginative legal fiction[11] and "not a highly skilled expert…"[12]. Instead, I consider that the skilled person would in fact be a skilled team comprising a competent biomedical laboratory technician capable of following instructions to make up culture media with added components (i.e. deoxycholate and inulin), and a chemist capable of making some predictions based upon the chemistry of biological polymers.

13 Turning to the understanding of the claims, the scope of claim 1, as now amended in manuscript form, is not entirely clear, and there is little in the description that would help the skilled person with this understanding. It is clear that the description discloses the mixing of inulin and deoxycholic acid in solution, and that this mixing appears to allow for inulin to bind to deoxycholic acid, however, there is no disclosure of the isolation of the complex. As such the skilled person would understand that the composition of deoxycholic acid and inulin has to be *capable of* forming an entity/ complex. This composition may then be further limited as being either suitable for use "to treat colorectal cancer cells" or it might be regarded as unclearly seeking to define the second medical use of the composition.

14 At the hearing, Dr Afolabi confirmed that the claim is intended to define the composition *per se* when suitable for use. Whilst, arguably, claim 1 remains of ambiguous scope, for the purposes of this decision I will adopt the construction as intended by the applicant. As such, claim 1 is construed when suitable for use as follows:

"A composition of deoxycholic acid and inulin capable of forming an entity/complex when suitable to treat colorectal cancer cells either in vitro or in vivo."

15 In view of the present claim 1, claims 2 and 3 now appear to be superfluous. In any case, they are not taken as further limiting claim 1. Claims 5-7 do not add any technical features to the invention defined by claim 1 and, at least for the purposes of novelty and inventive step, they also do not place any additional limitations beyond claim 1. Accordingly, any documents found to show that claim 1 is not novel will also inherently anticipate claims 2, 3 & 5-7.

16 Turning to claim 4, which further defines the composition of claim 1 in terms of the concentrations of inulin and deoxycholic acid. I can construe this claim in two

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

[11] As Jacob LJ put it in Technip France SA's Patent [2004] RPC 46 at paragraph 7: "It is settled that this man [the skilled person], if real, could be very boring—a nerd"

[12] Manual of Patent Practice at 3.20

different ways. The claim can be taken to define to the concentrations of inulin and deoxycholic acid ingredients to be used in the production of the complex. If this construction is correct, then, at least for the analysis of novelty, claim 4 is not limiting over claim 1. Alternatively, claim 4 may be construed as defining the concentrations of inulin and deoxycholic acid that appear within the final product, i.e. the complex, however at reaction equilibrium[13] this definition at best implies the presence of unbound inulin or deoxycholate, in addition to that present in the stable inulin/deoxycholate complex. Therefore, claim 4 is unclear and the limitations, if any, that it places upon the invention, i.e. the complex per se, remain ambiguous.

Novelty

17 The requirement for novelty is set out in section 1(1)(a) of the Act which states:

A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –

(a) the invention is new;

Section 2(1) goes on to further state:

An invention shall be taken to be new if it does not form part of the state of the art.

And, excepting the provisions concerning the "first-to-file" rule, section 2(2) defines the state of the art as follows:

The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

18 In order for a prior art document to be shown to anticipate an invention (i.e. show that it is not new), that document must make a prior disclosure which must disclose subject matter which, if performed, would necessarily[14] result in infringement of the patent as set out by the Court of Appeal in *General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited*[15], the so-called post-infringement test. The same prior art must enable the notional skilled person, at the date of the prior art disclosure, to perform the invention, as held by the House of Lords in *SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent*[16]. Only when both requirements, those of prior disclosure and of enablement, are fulfilled does a prior art document anticipate.

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[13] https://en.wikipedia.org/wiki/Law_of_mass_action

[14] To paraphrase Lord Hoffman in SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10, the flag must be planted on the claimed invention.

[15] General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited, [1972] RPC 457

[16] Ibid, SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10, where Lord Hoffmann summarised the disclosure requirement as follows: "anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention".

How the invention works and the relevance of a new mechanisms of action

19 At the hearing it became apparent to me that much of Dr Afolabi's arguments, asserting that the cited prior art is irrelevant to the novelty of her invention, centred upon her new findings concerning the molecular mechanisms by which the composition of deoxycholate and inulin has its effects to inhibit the proliferation of colon cancer cells.

20 Under UK law and practice, it has been a very long-standing principle that novelty cannot be conferred to a claim to a material or composition merely by discovering new properties[17]; a newly discovered technical effect or molecular mechanism cannot confer novelty to an already known invention. In *Tate & Lyle Technology v Roquette Frères [2009]*[18], the High Court found that a claim to "the use of maltotriitol to modify or control the form of maltitol crystals", was held to lack novelty over a number of prior art documents which disclosed crystallisation of maltitol merely in the presence of maltotriitol at levels at which it would inherently control crystal formation, even though this effect was not recognised at the time. In other words, as long as the requirements for prior disclosure and enablement are met, any additional underlying mechanistic details are not pertinent to the assessment for novelty. It is to this end that the examiner has referenced the judgment of the House of Lords in *Merrell Dow* [19], in which the inevitable result of carrying out the directions given in the prior art necessarily resulted in anticipation of the claimed invention[20]. However, I do note that, whilst, unfortunately not indicative of the novelty of the claimed invention, at least from the prior art identified during the prosecution, it would appear that Dr Afolabi's mechanistic findings have not been made before.

21 In passing, although claim 1 does not relate to an asserted new medical use, I further note that the approach set out above is also consistent with the case law relating to medical inventions where a new piece of information about how a treatment worked does not constitute an invention if it does not lead to a new use[21].

Analysis

22 In order to determine whether an invention as defined by a claim is novel, the first step must inevitably be to construe the claims. For the avoidance of doubt, the claims have been construed as set out above.

23 Next, I must consider each piece of prior art separately and determine what has been disclosed to the skilled team at the date of the disclosure[22].

24 During my preparations ahead of this hearing, I identified an additional relevant prior disclosure made by the applicant in 2015:

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[17] In I.G. Farbenindustrie A.G.'s Patents, 47 RPC at page 322, it was stated that "no man can have a patent merely for ascertaining the properties of a known substance".
[18] Tate & Lyle Technology v Roquette Frères [2009] EWHC 1312; [2010] FSR 1
[19] Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76
[20] See also the Manual of Patent Practice at Section 2: Novelty
[21] Bristol-Myers Squibb v Baker Norton Pharmaceuticals [1998] EWHC 300, paragraph 66
[22] SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10

D1 Abstract LB-271: *"Inulin inhibits free radical species in HCT 116 adenoma carcinoma and normal human HK (keratinocyte) cell line"* Ekine-Afolabi *et al Cancer Research (2015) 75:15* Supplement LB-271 presented at the AACR Annual Meeting in Philadelphia, 2015[23]

25 Dr Afolabi was made aware of the relevance of her own prior disclosure before the hearing, which was delayed allowing Dr Afolabi to further prepare her arguments. She was thus able to address me during the hearing about this conference abstract. Briefly, this abstract discloses how HCT116 colon cancer cells were treated *in vitro* with inulin (5-40 %) in the presence of deoxycholic acids (100 µM-500 µM). At the hearing Dr Afolabi was able to confirm that, in substance, her prior disclosure concerned the mixing of inulin and deoxycholate in a culture medium which would result in the formation of the same deoxycholate/inulin complex as that referred to by claim 1. At this point, I can readily determine that the meeting abstract, alone, fulfils the requirements for an enabling prior disclosure of the composition of claim 1 simply because if the teaching of the abstract is followed, inulin and deoxycholate would be mixed such that the composition of claims 1 would necessarily be produced. As noted above, there is nothing in claims 2,3 & 5-7 that add any further limitation to claim 1.

26 Assessing the novelty of the invention defined by claim 4 is problematic because the limitations it imposes are ambiguous. If the claim 4 merely refers to the concentrations of ingredients used, then for the assessment of novelty, Dr Afolabi's prior disclosure in D1 anticipates the claim. This conclusion is less clear if claim 4 is taken to define concentrations found in the product, however at the hearing, Dr Afolabi explained to me that the complex of inulin and deoxycholate she produced in 2015 is the same as that disclosed in the present application (the advances in the present application being in the characterisation of the same complex) such that D1 anticipates claim 4.

27 Unfortunately, contrary to Dr Afolabi's expectations, as I have explained above, the teaching of new scientific details about the complex cannot confer novelty upon a claim to the complex *per se*. It is regrettable both that this prior art was not identified at the search stage and that, in the knowledge of her own previous publications, the applicant did not realise that the disclosure was pertinent to the assessment of the novelty of her invention.

28 In his prehearing report the examiner assessed the novelty of the latest amendments to the claims and cited the following journal article:

D2 "*Nasal drug delivery: An in vitro characterization of transepithelial electrical properties and fluxes in the presence or absence of enhancers*" Wheatley *et al; Journal of Controlled Release* 8 (1988) 167-177[24]

29 As can be seen in this article, at figure 6 and its associated legend on p172, inulin (0.01 nM) flux across an isolated sheep nasal mucosa was measured in the absence and then the presence of 0.1% deoxycholate. Thus, there is an incidental disclosure

[23] https://doi.org/10.1158/1538-7445.AM2015-LB-271

[24] https://doi.org/10.1016/0168-3659(88)90043-0

that inulin and deoxycholate were mixed in an aqueous serosal bathing solution such that the complex of claim 1 was inevitably formed. During the hearing, Dr Afolabi confirmed that in her view the complex of inulin and deoxycholate would inevitably form upon mixing. It is therefore my conclusion that this document also meets the requirements for prior disclosure and enablement such that the invention defined by claims 1-3, 5-7 are anticipated. In my assessment, D2 anticipates claim 4 if that claim is taken to define the concentrations of ingredients used to produce the complex. Should claim 4 be construed as defining the concentrations of inulin and deoxycholate in the product, then D2 is at least relevant to inventive step, any distinction being wholly arbitrary. I further note that even had D1 never been published, the application would still not meet the requirements of section 1(1)(a) of the Act.

30 Throughout much of the prosecution of the application[25] and at the hearing, the question has featured prominently as to whether claim 1 is anticipated by the prior reports of the use of oral inulin, alone, as a pharmaceutical or nutraceutical which may reduce the risk of colorectal cancers. This line of argument follows the reasoning set down in *Merrell Dow*[26]. Having already decided that claims 1-7 are not novel, I will not set out detailed analysis here beyond saying that having read the application as filed, wherein the complex of the invention is produced by mixing of inulin and deoxycholate, and taking into account Dr Afolabi's confirmation that mixing is all that is required to produce the complex, I agree with the examiner's analysis that the commonplace prior art oral ingestion of inulin would inevitably result in the *in vivo* formation of a complex that anticipates claims 1-7. This would also mean that, in the event claim 1 could be amended to a second medical use format, for use in the treatment of colorectal cancer, (and for argument's sake ignoring any issues arising due to lack of disclosure, enablement or support in the application as filed), the claim would lack novelty in light of at least those documents cited by the examiner in their report of 9 July 2019.

31 Claims 1-7 as now amended in manuscript form are not novel, and as such the application does not meet the requirements of section 1(1)(a) of the Act.

Added Matter

32 Objections to added matter have been raised throughout the prosecution of this application and it is worthwhile reiterating that under s.72(1)(d), the presence of added matter is a very clear and unambiguous grounds for the revocation of a granted patent. A patent containing added matter is invalid, therefore, under the Act, amendments which add matter to an application for a patent are not allowable under s.76(2). As summarised by Jacob J. (as he then was) in *Richardson-Vicks Inc.'s Patent [1995] RPC 568*[27]*:*

> *"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."*

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[25] See the combined search and examination report dated 9 July 2019 and the subsequent examination reports. https://www.search-for-intellectual-property.service.gov.uk/GB2581531
[26] Ibid, Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76
[27] Hereafter *Richardson-Vicks*, see page 576 lines 34-37.

33 In *Bonzel and Schneider (Europe) AG v Intervention Ltd [1991] RPC 553*[28] Aldous J (as he then was) described a three-step analysis to determining whether there was added matter in a patent:

> *(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~~ [the application as amended];*
>
> *(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.*

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

Analysis

35 In the prehearing report, the examiner identified additional subject matter **at least** at amended paragraphs 012, 013, 015, 017, 021 and 022 of the description[29].

36 I have applied the three-step test from *Bonzel* as follows:

37 *Step 1:* I consider skilled team (as set out above under Novelty) is taught how to produce the invention of claim 1 by mixing inulin with deoxycholate in cell culture medium. The medium containing the inulin/deoxycholate composition is then used to culture CRL-1790 (immortalised normal colon) cells and HCT116 (colorectal cancer) cell lines, control cultures being performed using media containing deoxycholate but no inulin. From these experiments, it was deduced that inulin can inhibit the proliferation of colon cancer cells via the induction of apoptosis, with experimental evidence of the molecular mechanism that may deliver this effect. Further, whilst the details remain unclear, there is a brief line of *a priori* reasoning that the invention (i.e. a complex of inulin and deoxycholate) may bind and eliminate deoxycholate to "yield a better prognosis for colorectal cancer patients".

38 *Step 2:* The examiner explains that paragraph 013 relates to what appears to be original research relating to the structure of such a complex and the interactions between inulin and various bile acids. Paragraphs 012, 015, 017, 021 and 022 relate to reasoning and predictions on the structure of the complex of the invention and further include subject matter relating to inulin/deoxycholate micelle formation, synergy between the activities of inulin and deoxycholate. In addition, paragraphs 005-010 mention the manufacture/formulation of medications, the association of colorectal cancer with a high-fat diet, 'fat dissolver' activity related to bile acids, the

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[28] Hereafter *Bonzel*, see page 574.

[29] Presently these pages have been received on 13 December 2024 in marked form only, though the new paragraphs were first identified with the amendments filed with the letter of 15 February 2024. The paragraph numbering referred to above is as per the marked-up numbering of the latest amendments.

structural flexibility of the polyethylene oxide backbone of inulin, and what is known about the structure of steroids. I agree with this.

39 *Step 3:* Some of the amendments listed above simply present details of what is known in the prior art in relation to the function of bile acids, their role in fatty acid metabolism, and their structure, along with the structure of steroids. Such references or summaries of what is known in the art does not necessarily contravene section 76(2). However, when these references or summaries are used to demonstrate advantages of the invention, then this may result in unallowable added subject matter. In the present case, it is clear that the amendments to paragraphs 005-010, 012, 015, 017, 021 and 022, at least, where they relate directly to the original research and the objects of the invention, extend the disclosure to the skilled team beyond that of the application as originally filed. As such, I find that the application, as now amended, fails to meet the requirements of section 76(2).

40 Nevertheless, I note that the applicant has not relied upon this added matter as basis for claims 1-7, such that my finding that the claims are not novel does not turn on the removal of the added subject matter.

Further matters

41 I note that the examiner has further identified that the claims are unclear, and as such do not meet the requirements of section 14(5)(b) and has deferred consideration of sufficiency under section 14(3) and support under section 14(5)(c). As I have found that the application fails to meet the requirements of section 1(1)(a) and section 76(2) I see no merit in considering these additional matters.

Conclusion

42 I have found that the application does not meet the requirements of the Act for novelty and added subject matter. I therefore refuse this application for a patent under section 18(3) of the Act.

Appeal

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

DR ROWENA DINHAM

Patent Examination Group Head acting for the Comptroller