Intellectual Property Office

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PATENTS ACT 1977

APPLICANT Ahmed Mahmoud Hassan Said El-Tawil

ISSUE Whether patent application number GB 0723924.7 complies with section 14(5)(c)

HEARING OFFICER C L Davies

REDACTED

DECISION

Introduction

1 This decision relates to patent application GB0723924.7 entitled "Novel agent for measurement of colonic permeability". The application was filed on 7 December 2007 and was published as GB2455342 on 10 June 2009. The applicant, Mr El-Tawil, is an unrepresented applicant.

2 There have been many rounds of correspondence between the examiner and the applicant and amendments to the claims were filed on 7th March 2013 which satisfied an added matter objection raised by the examiner in a report dated 11 February 2013. However, the applicant was not able to persuade the examiner to alter his view with regard to the outstanding matters of clarity (section 14(5)(b) of the Patents Act 1977 (hereafter as the "Act")), novelty and inventive step (sections 1(1)(a) and 1(1)(b) of the Act) and support (section 14(5)(c) of the Act) and the examiner responded in a further report of 25 April 2013 re-iterating these objections. Weighing up the case in terms of the lack of progress against the major outstanding objections, the examiner took the view that an impasse had been reached and in line with Intellectual Property Office (IPO) practice, informed the applicant in a letter of 25 April 2013, that he would be sending the application forward for a decision as to whether the application should be refused unless a hearing was requested or the application was withdrawn.

3 In a response of 20 May 2013 the applicant dismissed the examiner's objections and filed further arguments on 29 May 2013. In his final report dated 18 June 2013, the examiner acknowledged that he had taken account of the applicant's arguments and submissions including those of 22 February 2013, 20 May 2013 and 29 May 2013, but he could not see how the application could be amended to overcome the outstanding objections and re-iterated the outstanding issues to be decided.

4 A hearing was appointed for 16 September 2013 at the Intellectual Property Office (IPO) in Newport, to decide the outstanding matters. Mr El-Tawil joined by video conference from our London office. Present at the hearing were the applicant Mr El-Tawil, Dr Peter Laughton (examiner) and Dr Natalie Cole (hearing assistant).

5 Ahead of the hearing, Mr El-Tawil requested the hearing be held in private. As the Hearing Officer, I agreed in principle with the applicant's request, to exclusion of public and press.

Confidentiality

6 At the hearing Mr El-Tawil expressed that any material taken from his correspondence of 22 February 2013 or 20 May 2013 or any information he disclosed during the hearing should remain confidential.

7 In preparing my decision, I have taken this into account and confirm that Mr El-Tawil's correspondence referred to above remains not open to public inspection and that information at the hearing which he flagged up as confidential has been treated in such a way. I have taken this approach because I do not want to disadvantage the applicant in the event that he has disclosed subject matter that was not originally disclosed in the application.

The invention

8 As far as I can establish from the specification as originally filed, the invention relates to an inulin-fluorescein (hereafter InFl) conjugate as a tool for assessing colonic permeability in pathological conditions such as in inflammation of the colon. The specification describes that the conjugate can be administered rectally, preferably by enema, where it is not metabolised but is cleared in the urine allowing it to be directly determined in urine or blood samples. It is suggested that InFl is not absorbed in the gut under normal conditions but permeates the intestine in pathological conditions and is therefore an effective tool for assessing the colonic permeability in pathological conditions.

The claim

9 At the hearing Mr El-Tawil confirmed that the claim on which I should base my decision is the one and only claim filed on 7 March 2013, which reads as follows:

"Inulin-Fluorescein [InFl] conjugate in a dose between 0.001-0.005 mol/1 mol monosaccharide [2-12 mol per 1000 mol] is very safe and effective tool to be used for assessing colonic permeability under abnormal conditions. This assessment can be done by enema or other routes."

Issues to be decided

10 As set out by the examiner in his pre-hearing report of 18 June 2013, the issues to be decided are whether the claim is clear and concise as required by section 14(5)(b) of the Act; whether the invention is novel and inventive as required by sections 1(1)(a) and 1(1)(b) of the Act; and whether the claim is supported by the description as required by section 14(5)(c) of the Act.

11 It is clear from the correspondence between the examiner and the applicant that the focus of disagreement centred on the issue of clarity and claim construction. I will consider these fundamental issues first and then go on, if necessary, to consider novelty, inventive step and support.

The law

Clarity

12 Section 14(5) of the Act states:

> *The claim or claims shall –*
>
> *(a) ...;*
>
> *(b) be clear and concise*
>
> *(c) be supported by the description*
>
> *(d) ...*

Claim construction

13 It is well established in UK patent law practice that a patent specification should be given a purposive construction where the question is always what the person skilled in the art would have understood the patentee to have used the language of the claim to mean.

Arguments

Clarity and claim construction

14 I note from the reports/correspondence on file that the examiner clearly found construing the claim problematic, providing within the report dated 18 June 2013, three possible options based on different ways of construing the claim with regard to the information provided in the specification as originally filed. The three constructions are as follows:

"i) The invention relates to an Inulin – Fluorescein conjugate (0.001-0.005mol/mol) per se (that is suitable for assessing colonic permeability); or

ii) The invention relates to a method of assessing colonic permeability using an Inulin – Fluorescein conjugate (0.001-0.005mol/mol); or

iii) The invention relates to a second medical use of an Inulin – Fluorescein conjugate (0.001-0.005 mol/mol) for diagnosing inflammation of the colon(or other pathological conditions of the intestine)"

15 In a response dated 23 August 2012 Mr El-Tawil stated:

"we have to link the permeation of the InFl conjugate to another tool that is 100% absorbable by the bowel (monosaccharide) so, at identifying the dose we have to refer to this link"

16 Mr El-Tawil explained this further in his correspondence submitted on 22 February 2013, in response to the examination report dated 11 February 2013. He made reference to page 1 paragraph 3 of the application as filed, which referred to the use of different carbohydrates for assessing intestinal permeability. He went on to explain more about the monosaccharide dose, divulging information that is not in his application as originally filed.

17 At the hearing I asked Mr El-Tawil to explain the meaning of the wording "[InFl] conjugate in a dose between 0.001-0.005 mol/1 mol monosaccharide [2-12 mol per 1000 mol]", which he did.

18 He then went on to explain further the feature of "...0.001-0.005 mol/1 mol monosaccharide..."

19 However within his explanations, Mr El-Tawil referred to information that is not in the application as originally filed and whilst I have heard Mr El-Tawil on these points, it does not help with the clarity issue I need to decide.

20 Mr El-Tawil did assert however that the claim should not be construed as a composition *per se*.

21 He also explained more about what he considered constituted the "abnormal conditions".

Analysis

22 Taking into consideration the arguments raised in the correspondence between the examiner and Mr El-Tawil plus Mr El-Tawil's observations at the hearing, I will now consider claim 1 afresh.

Clarity and claim construction

23 In my opinion, the particular elements of claim 1 which need careful consideration with regard to clarity and claim construction are: (a) the defined doses of the InFl conjugate in accordance with the invention; and (b) the use of the conjugate in assessing colonic permeability under pathological conditions. These features are defined in the claim as:

(i) "Inulin-Fluorescein [InFl] conjugate in a dose between 0.001-0.005 mol/1 mol monosaccharide";

(ii) "[2-12 mol per 1000 mol]"; and

(iii) "used for assessing colonic permeability under abnormal conditions"

24 I have to first ascertain who the person skilled in the art is and then determine what that person would have understood the language of the claim to mean with regard to each of the key elements of the claim as defined above.

The person skilled in the art:

25 In my opinion, the person skilled in the art is a team of physicians, pharmacologists and chemists working in collaboration with an interest in assessing colonic permeability in pathological conditions. It is also my belief that such a team would be aware of the current methods and practices utilised in the assessment of gut permeability in pathological conditions and would also be aware of commonly used permeability markers including mannitol and lactulose etc. used in such methods.

What would the person skilled in the art have understood the language of the claim to mean?

26 At the hearing, Mr El-Tawil offered his construction of the claim which included information not divulged in the application as filed.

27 After careful consideration of the comments and arguments presented by Mr El-Tawil in his correspondence and at the hearing, I am not convinced that the person skilled in the art would arrive at Mr El-Tawil's proposed construction when giving the claim a purposive construction. It is my view that Mr El-Tawil has confused claim construction with identifying the technical contribution as it is clear that his construction is not a purposive construction of the claim in question. At the hearing Mr El-Tawil asserted that the specification contained enough information to support his construction of the claim. However I do not accept this argument.

28 I will now consider what the person skilled in the art would have understood the language of the claim to mean with regard to each of the key elements of the claim as defined above.

(i) "Inulin-Fluorescein [InFl] conjugate in a dose between 0.001-0.005 mol/1 mol monosaccharide"

29 Again, the information provided by Mr El-Tawil at the hearing does not help here because that information is not in the application as originally filed.

30 Whilst I have considered Mr El-Tawil's submissions, it is nevertheless my opinion that the wording *"Inulin –Fluorescein InFl conjugate in a dose of 0.001-0.005 mol/1 mol monosaccharide"* is lacking in clarity as I can find no basis within the specification (claim, description), as originally filed, to enable the person skilled in the art to clearly interpret its meaning. Furthermore, with regard to the feature of ".../1 mol monosaccharide", it is my belief that the person skilled in the art would not understand the function of the monosaccharide within the context of the invention as I can find no reference to the monosaccharide within the description bar mention of mannitol and its use as a known permeability marker.

31 I am also not convinced that the person skilled in the art would necessarily link the permeation of the InFl conjugate with that of the monosaccharide and consider this link to be used to assess the severity of a disease as asserted by Mr El-Tawil. The skilled man will be looking at this with the view to understanding what is meant. Thus from the supporting statements within the specification, as highlighted by Mr El-Tawil above, I consider that the person skilled in the art, would not link the permeation of the InFl conjugate with that of the monosaccharide and that this link is

used in assessing colonic permeability under pathological conditions. In this regard I can find no basis within the specification to direct the skilled worker to reach this conclusion.

32 Furthermore, as the specification does not contain any explanation or worked examples regarding the method of the invention it is not clear how the dose of 0.001-0.005 mol InFl conjugate per 1 mol of a monosaccharide as outlined by Mr El-Tawil is used in assessing the colonic permeability of an abnormal condition.

33 It is therefore my opinion that the feature of *"Inulin –Fluorescein [InFl] conjugate in a dose of 0.001-0.005 mol/1 mol monosaccharide"* is lacking clarity and I am not able to construe it in any meaningful way.

(ii) "[2-12 mol per 1000 mol]"

34 At the hearing Mr El-Tawil discussed what he considered this term to mean but again, this doesn't help him as the information he divulged in his explanation is not present in the application as originally filed.

35 Whilst I have heard Mr El-Tawil, his arguments simply don't help address this clarity issue and again there is nothing helpful in the application as filed. It is therefore my opinion that the term "[2-12 mol per 1000 mol]" is also lacking clarity and so I am not able to construe this term in any meaningful way.

(iii) "used for assessing colonic permeability under abnormal conditions"

36 At the hearing Mr El-Tawil explained what conditions he believed were covered by the term "abnormal conditions". However, there is no disclosure or suggestion within the specification as originally filed that those conditions may be assessed by the invention. Indeed the only condition expressly indicated is inflammation of the colon. Whilst I acknowledge that the application states "As InFl is not absorbed in the gut under normal conditions, but permeates the intestine in pathological conditions", I believe that this is not enough information to direct the person skilled in the art to determine what "pathological conditions" are necessarily encompassed by this wording.

37 Nevertheless, I am of the opinion that a person skilled in the art would consider the invention is to be used as some sort of a tool for assessing colonic permeability in pathological conditions, in particular, in inflammation of the colon as outlined within the specification as originally filed. However, given the fact that I have been unable to give any useful meaning to (i) and (ii) above, I am left unable to put any meaningful construction on the claim as a whole.

38 I have given consideration to Mr El-Tawil's arguments at the hearing and also to the correspondence on file. What is clear to me from the discussions at the hearing is that Mr El-Tawil has not provided in the application as originally filed, enough information to enable a person skilled in the art to interpret the claim.

39 Unfortunately, I have been unable to put any meaningful construction/interpretation on the claim and I therefore find the claim lacking clarity under section 14(5)(b) of the Act.

Novelty/Inventive step/Support/Sufficiency

40 Since I have not been able to put any meaningful construction on the claim, I am not in a position to consider novelty and inventive step. I have also not considered sufficiency under section 14(3) or support under section 14(5)(c).

Conclusion

41 I find that patent application GB0723924.7 does not comply with the requirement of section 14(5)(b) of the Act as the claim has not been defined in a manner which is clear. I therefore refuse the application under section 18(3).

42 I have given careful consideration to the specification and I can see nothing which would form the basis of an allowable amendment.

Other matters

43 From our discussions at the hearing, it is clear that Mr El-Tawil divulged information which may well have been very useful if provided in the application as originally filed, in understanding the invention and in interpreting the claim and it is most unfortunate that information of this nature was not disclosed in the application when originally filed. Section 76 prevents any further information being introduced within the specification after filing.

Complaints

44 On reviewing the case file, it is evident that Mr El-Tawil has provided a lot of correspondence including letters of complaint to John Alty (CEO). To me it seems that the complaints and concerns expressed by Mr El-Tawil before, during and after the hearing have arisen from his lack of familiarity with the patent system and the procedures involved, and this is a common problem amongst unrepresented applicants. Since the complaints are not related to the issue of clarity which I have needed to decide, I will not consider them any further.

45 I appreciate that the patent system, laws and procedures are extremely complex and it is for this reason that IPO encourages applicants to seek professional advice from legal patent representatives such as attorneys.

Appeal

46 Any appeal must be lodged within 28 days.

C L Davies
Deputy Director acting for the Comptroller