Intellectual Property Office

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16 August 2024

PATENTS ACT 1977

APPLICANT	Emulate, Inc
ISSUE	Whether patent application GB2117870.2 complies with sections 76(2), 14(3), 14(5)(b) and 1(1)(b) of the Patents Act 1977
HEARING OFFICER	Nigel Hanley

DECISION

Introduction

1 WO 2020/264303 A1 was filed on 26 June 2020, claiming a priority date of 27 June 2019. The application entered the national phase as GB 2117870.2 on 10 December 2021, and was published as GB 2599531 A on 6 April 2022.

2 Accelerated examination with amended claims was requested under the PPH programme on 26 July 2022. A first examination report was issued 12 September 2022, with an objection that the claims were not supported in the application as filed.

3 There followed several rounds of correspondence between the Patent Examiner, Miss Elizabeth Price, and the attorney for the Applicant, Patent Attorney Dr Paul Chapman of Marks and Clerk, with several sets of amended claims filed and similar objections raised against each. As no agreement has been reached, a hearing was offered, and the application has come before me for a decision on the papers as was confirmed by the attorney on 3rd June 2024..

Compliance period

4 I note that the compliance period has been extended once to 27 February 2024, and that amendments were filed on the last day of that period. No further extension of the compliance period has been requested. As a consequence, unless the application is in order with no outstanding objections, it will be refused as it will not be possible to file any further amendments.

The Application

5 The application relates to compound distribution within microfluidic devices and associated systems. Pharmaceutical and chemical compounds can absorb into, bind to, or fail to distribute well within components of *in vivo* or *in vitro* experimental setups,

introducing variability and adversely affecting results. Microfluidic devices, fabricated from gas-permeable materials, tend to absorb small molecule compounds, so that the concentration of such molecules available to contact with specimens is decreased.

6 The application is lengthy (202 pages of description and 126 figures), and various related inventive concepts are described and shown in detail. These were used as the basis for some 293 claims in the PCT application. They include methods of fabricating microfluidic devices or gas exchangers; controlling gas transport or concentration; determining, assessing or analysing compound distribution in a system; and fluidic and microfluidic devices, and systems comprising these.

7 The current claims are those filed 27 February 2024. There is just the one independent claim:

> *1. A method of determining the extent of compound absorption in a fluidic system, comprising:*
>
> *a) providing a fluidic system, said system comprising an input port configured to permit fluid input to the system and an output port configured to permit fluid output from the system;*
>
> *b) performing a first experimental protocol comprising flowing fluid comprising said compound in said system by flowing said fluid into said input port and collecting a first sample from said output port and performing a measurement of compound concentration remaining in said first sample, said fluidic system comprising one or more biological elements selected from the group consisting of cells and biological coatings, wherein said one or more biological elements are contacted by said compound;*
>
> *c) modifying said experimental protocol by excluding at least one of said one or more biological elements so as to create a first modified experimental protocol;*
>
> *d) performing said first modified experimental protocol in accordance with steps a) and b); and*
>
> *e) determining the percentage absorption of said compound in said fluidic system by comparing the concentration of said compound remaining in the first sample from the experimental protocol and the first sample from the modified experimental protocol.*

Matters to be resolved

8 The latest examination report, issued 29 April 2024, sets out the issues to be decided by the Hearing Officer:

> (1) whether claims 1 to 10 as filed 27th February 2024 contain added matter;
>
> (2) whether the invention defined in those claims is sufficiently disclosed:
>
> (3) whether it is obvious in view of what was already disclosed in the cited prior art.

9 In reaching my decision I have taken careful account of the arguments made in each of the agent's letters, particularly that filed 27 February 2024 accompanying the latest claims. No further submissions beyond this date have been received.

10 I will take each point in turn, but I will reiterate my comment earlier: should I find against the applicant on any one of the above three points, I am bound to refuse the application as no amendment is possible after the expiry of the compliance date.

Added Matter

11 I will consider the question of added matter on the basis of Section 76(2) of The Patents Act 1977 ("The Act") which states:

> *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 beyond that disclosed in the application as filed.*

Analysis

12 The application provides detailed disclosure of a wide range of technical concepts relating to different methods and devices for the measurement or control of the distribution of compounds within microfluidic or related devices and associated systems, and of practical implementations and uses for these. In, and of itself, this causes some difficulty in gaining a clear understanding of the many respective technical concepts in the specification. Furthermore, understanding is not helped by the repeated use of the phrase "in one embodiment", Several concepts are often grouped together in lengthy paragraphs as "one embodiment", and it is not always clear how these concepts interrelate.

13 Against this background, the examiner has identified clause e) of the claim as being problematic, as it claims added matter. Specifically, they find no support in any embodiment or in the specification that relates to:

> "*comparing the concentration of said compound remaining in the first sample from the experimental protocol and the first sample from the modified experimental protocol"*

14 The attorney in their letter of 27th February 2024 directs me to the specification from the bottom of Page 77 to the top of page 79. In their view, the method of pages 77-79 clearly "*includes analysing compound absorption"*. Furthermore, A further point to note from their submission is the reference "*that although the initial supporting text refers to compound distribution, it is clear that this includes analysing compound absorption*".

15 In relying on this specific embodiment, the attorney notes that amendments have been made to the claims, specifically "*to avoid any added-subject matter concerns and/or intermediate generalisations".* This would appear to be very relevant to any discussion on added matter as the embodiment the attorney relies upon is clearly framed as a method of determining distribution of a compound.

16 This is in addition to their letter of 5th December which directs me to the embodiment set out in pages 79-81 of the specification. Of particular relevance, is the text near the

bottom of page 80 which provides a clear statement that the *"first modified experimental protocol further quantifies the percentage of said compound that is absorbed into said system".*

17 In conducting my analysis, I need to be aware of the guidance on the application of Section 76 found in *Richardson-Vicks Inc's Patent*[i] where Jacob J (as he was then) noted:

> *"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."*

and in *Bonzel Schneider*[ii], where Aldous J (as he was then) stated:

> *"The decision as to whether there was extension of disclosure must be made on a comparison of the two documents read through the eyes of a skilled addressee. The task of the court is threefold:*
>
> > *(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."*

18 Firstly, I need to consider whether the issue of absorption and distribution is relevant to the discussion on added matter. There is undoubtedly a question of construction in what the terms mean, but I am not sure it is relevant at this point. Put simply, it appears to me that the terms are a different way of looking at the same answer – they are inextricably linked in so far that if the distribution of a known compound differs in the outlet port from the input port it is because of absorption between the input and output port.

19 It is my understanding of the claim that this method is done twice, with a "remaining concentration" of a compound collected in a first experimental protocol in which a biological coating or element is present and in a modified experimental protocol in which they are not. However, as the Examiner has noted there does not appear to be a comparison of the two values. This is the key issue in determining whether the amended claim relates to added matter.

20 It is clear to me that there is no explicit statement of the comparison of the results of the original and modified experimental protocols. As I have said before, there are multiple embodiments set out in the specification and none, so far as I am aware, presents or identifies a comparison step.

22. Given there appears to be no explicit "comparison step", I now need to decide if one is implicitly disclosed. The applicant has clearly drafted the specification in such a way as to endeavour to reflect multiple embodiments within a wide ranging long and

voluminous specification. There can only be one purpose for this: they are endeavouring to provide specific support for as many concepts as they can in some detail. Despite all this, they still do not have an embodiment that specifically shows a comparison step: I can only come to one conclusion from this state of affairs. It was never intended to cover the comparison step and it would be wrong to conclude that it was implicitly supported in the absence of a specific reference.

23. The amended claims are therefore considered to add matter contrary to Section 76(2) of the Act.

Sufficiency and inventive step

24. Having determined that claim 1 contains added matter, it is not necessary for me to go on to consider whether there is sufficient disclosure for the skilled person to work the invention or whether the defined invention would have been obvious to the skilled person. Specifically, the application is not in order due to the presence of added matter and as the Section 20 compliance date has expired no amendment is possible.

Conclusion

25. I have found that claim 1 adds matter to the application as filed contrary to section 76 of the Act.

26. As noted above, the compliance period has now expired, so there is no opportunity remaining to file any amendments to overcome the issue of added matter. Consequently, I have not considered the issues of sufficiency or inventive step.

27. I therefore refuse the application under Section 18(3)

Appeal

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

NIGEL HANLEY

Patent Examination Group Head

[i] Richardson-Vicks Inc.'s Patent [1995] RPC 568
[ii] Bonzel and Schneider (Europe) AG v Intervention Ltd [1991] RPC 553