Intellectual Property Office

BL O/305/15

01 July 2015

PATENTS ACT 1977

APPLICANT	Genapsys Inc.
ISSUE	Whether patent application GB1308138.5 complies with section 76(2) and 1(1)(b)
HEARING OFFICER	Mr Peter Slater

DECISION

1 Patent application GB 1308138.5 entitled *"Systems and methods for automated reusable parallel biological reactions"* is derived from the corresponding PCT application filed by Genapsys Inc on 4 October 2011 and published as WO 2012/047889. The application claims an earliest priority date of 4 October 2010 and was republished on 14 August 2013 as GB2499340.

2 Though there have been several of rounds of examination and amendment, and a number of telephone discussions, the examiner and applicant have been unable to reach agreement on the issues of added matter and inventive step. The matter therefore came before me at a hearing on 30 April 2015.

3 The applicants were represented by Alex Turnbull, assisted by David McNeight, both of TLIP Ltd. The examiner, Jeremy Kaye, and my assistant, Stephen Jennings, were also present.

The application

4 The application as a whole describes various method steps and system components useful in extracting, amplifying and sequencing polynucleotides. The description comprises a number of sections, identified by sub-headings, which relate to these various aspects. The originally filed claims, of which seven were independent, were apparently directed towards a number of these individual aspects.

5 On entry to the national phase an entirely new set of claims was filed, the first of which was directed towards a method for sequencing a nucleic acid sample. That claim has since been subject to a number of amendments, but the underlying nature of the claimed method remains much the same. In short, particles or 'beads' which carry nucleic acid molecules are subjected to an electric field in order to enhance amplification reactions, following which the amplified nucleic acid molecules are subject to an extension reaction which is monitored with a sensor array. Each sensor

of the array comprises a pair of electrodes, and the sensors detect changes in impedance of the particles as a result of the extension reactions. The recorded impedance measurements allow for the sequencing of the nucleic acid sample.

6 Further amended claims were provided in advance of the hearing, along with skeleton arguments. There are two subtly different versions of the main claim – a 'main request' and a 'first auxiliary request'. The main request reads as follows:

> *1. A method for sequencing a nucleic acid sample, the method comprising:*
>
> *a) providing a plurality of particles, wherein each particle of said plurality is coupled to on average at most one nucleic acid molecule from said nucleic acid sample;*
>
> *b) performing simultaneous nucleic acid amplification reactions on said nucleic acid molecules coupled to said particles, wherein said nucleic acid amplification reactions are performed while subjecting the particles to an electric field, thereby producing isolated, clonally-amplified nucleic acid molecules coupled to at least a subset of said plurality of particles;*
>
> *c) performing a nucleic acid extension reaction using primers that hybridize to said clonally-amplified nucleic acid molecules;*
>
> *d)* ***measuring local impedance change*** *of each* ***of said particles*** *using a sensor array comprising a plurality of sensors to determine a sequence of each of said clonally-amplified nucleic acid molecules,* ***when an individual sensor*** *among said plurality of sensors* ***comprises a pair of electrodes that are within the Debye length of a surface of the particle****; and*
>
> *e) based on the measured local impedance change, sequencing the nucleic acid sample.*

7 The 'first auxiliary request' differs from the 'main request' only in that section d) of the claim further recites that the sensor array forms part of an 'electronic sensing subsystem'.

8 Whilst both the 'main request' and 'first auxiliary request' contain a series of identical dependent claims Dr. Turnbull in his submissions at the hearing and in the skeleton arguments chose to focus only upon the independent claim.

9 I have emphasised the portion of the claim that was the focus of the hearing. This is the portion of the claim that the examiner considers to constitute added matter. It is also the portion of the claim that Dr Turnbull contends is novel over any of the prior art and therefore central to the inventiveness of the claim.

Added matter – the law

10 The examiner has raised an objection under section 76(2) of the Patents Act 1977 that the claims contain added matter and therefore cannot be allowed; this provision of the Act reads as follows:

76(2) 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.

11 Dr Turnbull directed my attention to a number of precedent cases at the hearing in order to establish the correct basis for assessing added matter.

12 He turned first to *AP Racing Ltd v Alcon Components Ltd*[1]. The main point that Dr Turnbull drew out from this case was that it may well be possible to derive an allowable amendment to a claim based upon just a couple of brief mentions of a feature, in a different context to the claim, in different places within a description. The situation is somewhat similar in this case as we shall go on to see. In principle I cannot disagree with Dr Turnbull's submission, but it will clearly depend on the circumstances. It is not reasonable to take *AP Racing* to suggest that a couple of vague references will always be adequate to support a claim.

13 Dr Turnbull also referred to *Vector Corporation v Glatt Air Techniques Ltd*[2]. Referring back to one of his earlier judgments[3], Jacob LJ summarised the *Bonzel*[4] test for added matter thus:

I think 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

I have no dispute with this, and I will adopt this test when reaching my decision.

14 Dr Turnbull also addressed the issue of intermediate generalisations, with reference to a decision of the Board of Appeal of the European Patent Office[5]. What Dr Turnbull sought to establish from this decision was that there is no separate test in the case of an intermediate generalisation. Rather, as the Board observed, the overriding requirement is that an amendment can be made only within the limits of what a skilled person would derive directly and unambiguously from the application as filed, which is very much in accord with Jacob LJ's summary above. Again, I have no dispute with Dr Turnbull's submission.

Intermediate generalisation

15 The examiner has argued that the claim contains an intermediate generalisation, in that a feature not presented as having a general significance to the invention has been taken from one embodiment and introduced into a claim relating to another embodiment. In simple terms the examiner observes that whilst paragraph [1078] of the description refers to a sensor which can detect a change in conductivity due to moieties within the Debye length of the surface of the sensor, there is no reference in this paragraph to a pair of electrodes. On the other hand, whilst paragraphs [1089]

[1] AP Racing Ltd v Alcon Components Ltd [2013] EWPCC3, at first instance, and [2014] EWCA Civ 20 on appeal
[2] Vector Corporation v Glatt Air Techniques Ltd [2007] EWCA Civ 805
[3] Richardson Vick's Patent [1995] RPC 568, at 576
[4] Bonzel v Intervention Ltd. (No 3) [1991] R.P.C. 553
[5] T 0248/12

and [1091] of the description refer to pairs of electrodes, with particular spacing between the electrodes, there is no reference to the Debye length.

16 Dr Turnbull appeared to accept that the specification was somewhat disjointed in its presentation, but set out his understanding of how the skilled addressee would read it. His explanation is as follows. Paragraph [1078] falls within a section of the description headed 'Sequencing', and this section, at paragraph [1078], makes clear that an electronic sensing subsystem (i.e. a detector) is necessary in order to monitor incorporation reactions. Paragraph [1078] does not say much about the detector, so the skilled reader would realise that he needed to read the section of the description headed 'Detector' (paragraphs [1087]-[1095]), and it would be well within the capabilities of the skilled person to put these two bits of the description together in order to work the invention. I am grateful to Dr Turnbull for this explanation, and I am inclined to agree with his analysis.

17 Having decided that it is reasonable to read paragraph [1078] in conjunction with [1089] and [1091] I am of the opinion that the issue of intermediate generalisation does not arise; these paragraphs do not, in my view, constitute separate embodiments. That is not to say, however, that I have resolved the issue of added matter in favour of the applicant. Some further analysis of the claims and the description is necessary.

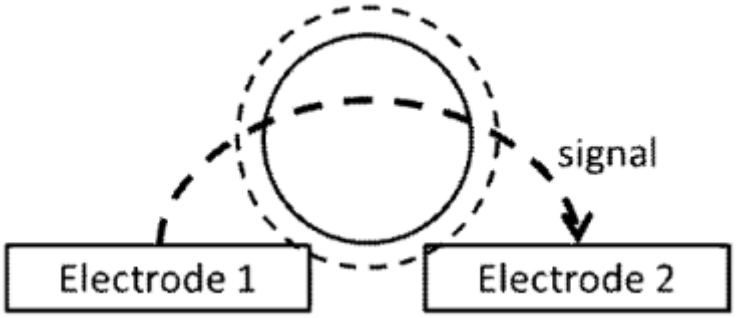
18 This is an appropriate point to briefly mention the 'first auxiliary request'. Dr Turnbull explained that the reason for adding the phrase 'electronic sensing subsystem' into the auxiliary claim was to try to emphasise the connection between the two sections of the description discussed above. In the event, this does not seem necessary, and I need say no more about the auxiliary request since in all other respects it is identical to the main request.

Claim construction

19 Having determined in general terms how the skilled reader would read the description, I must now turn to the claim and address a more specific point of claim construction. In order that I can properly determine whether the claim includes added matter and/or is obvious I need to decide what the skilled addressee would understand by "measuring a local impedance change...when an individual sensor...comprises a pair of electrodes that are within the Debye length of a surface of the particle".

20 Two slightly different strands to Dr Turnbull's submissions at the hearing and in his skeleton arguments caused me to question his construction of this portion of the claim, as I shall now explain.

21 On the one hand, there was some discussion of the "electrode-to-particle spacing". The skeleton argument contains the sentence "Out of the various possibilities of the electrode-to-particle spacing...we have claimed a very specific spacing such that the electrodes are within the Debye layer [of the particle]". The skeleton argument also contains the following illustrative sketch (which is not present in the application). The solid circle shows the particle and the dotted circle represents the Debye length.



The sketch is intended to show both electrodes [at least partially] within the dashed circle.

22 On the other hand there was also some discussion at the hearing of the importance of the "electrode spacing", i.e. the distance between the two electrodes of the pair. Dr Turnbull commented that the "key to achieving the advantages of the invention is to know that your electrode spacing must be within the Debye length of the particle", and also "there is no point having a wide electrode spacing for particle A and then putting a smaller particle in; there will be no measurements". The skeleton argument makes a similar point – "if [the electrodes] are too far apart, there will be no effective measurement. The person skilled in the art will determine what the Debye length is likely to be, given the task in hand, and make sure he has an appropriate spacing so that he will pick up signals".

23 In view of this inconsistency I sought to clarify how Dr Turnbull and Mr McNeight were construing the phrase "pair of electrodes that are within the Debye length of a surface of the particle", i.e. whether this phrase was intended to specify that the distance apart of the two electrodes was less than the Debye length of the particle, or alternatively that the electrodes were both within the Debye length of the particle. Dr Turnbull and Mr McNeight were quite clear that it was the former.

24 So which interpretation is correct? What is actually meant by "measuring a local impedance change...when an individual sensor...comprises a pair of electrodes that are within the Debye length of a surface of the particle"? Whilst this portion of the claim is by no means a model of clarity, in my view the plain reading is that the claim is seeking to define the distance of the electrodes from the surface of the particle, and this distance is said to be less than 'the Debye length'. This does of course raise the question of what is meant by the term 'Debye length'?

25 Dr Turnbull, at the hearing, directed me towards Wikipedia, where the following definition may be found:

> *The Debye length (also called Debye radius), named after the Dutch physicist and physical chemist Peter Debye, is the measure of a charge carrier's net electrostatic effect in solution, and how far those electrostatic effects persist. A Debye sphere is a volume whose radius is the Debye length, in which there is a sphere of influence, and outside of which charges are electrically screened.*

26 Applying this definition, in terms of the current application, I understand the 'charge carrier' to be the 'particle' defined in the claim and the 'Debye length' to be the radius of the sphere of electrostatic influence encompassing the particle.

27 It is evident from this that the electrodes of the invention (or of any similar sensor, for that matter) will only sense a charge associated with a particle when they are within the particle's Debye sphere, and this is precisely what I consider the claim to say.

28 As an aside I might add that I am not convinced that the application uses the term 'Debye length' in precisely the same manner as Wikipedia (in view of the references to the surface of the particle as opposed to its centre), but I do not think this is of much significance here. The crucial point here is that the claim is not about the inter-electrode spacing, but rather it is about the distance between the particle and the electrodes when an impedance change is measured.

29 In summary, the claim recites that the sensor comprises a pair of electrodes, and that the sensor measures a change in impedance of the particle. The claim further says that the sensor only measures an impedance change when the distance between the electrodes and the surface of the particle is less than the 'Debye length' (i.e. the distance from the surface of the particle over which the effect of the particle's charge continues to persist).

30 Accordingly I am not at all persuaded that the claim, as currently presented, is consistent with the construction proffered by Dr Turnbull and Mr McNeight, but I agreed at the hearing that I would take into consideration their interpretation of the claim in my decision. However I will also consider the interpretation I have set out above, which is more correct in my view.

Added matter - analysis

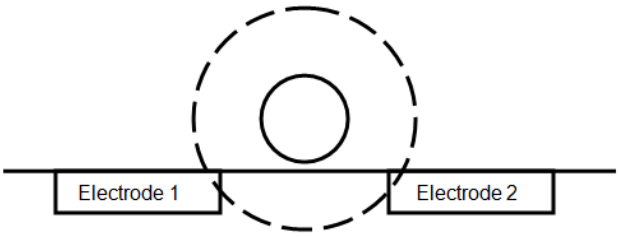
31 So, having analysed the claim, and set out two potential interpretations, I must now ask whether the skilled person would learn anything about the invention from the amended claim which he or she could not learn from the unamended specification.

32 Paragraph [1091] quite clearly teaches the skilled person that impedance changes due to incorporation events can be detected by a sensor having a pair of electrodes. Similarly paragraph [1089] refers to detecting impedance changes due to incorporation events with pairs of electrodes, and further provides some indication of how far apart the electrodes of the pair should be from each other. Paragraph [1078], though somewhat vague, teaches the skilled reader no more than that the sensor detects changes in conductivity/impedance of a particle when either a) the particle is bound to the sensor or b) the particle is near enough to the sensor in order for its charge to be detected which is by definition the Debye length even if not specifically referred to as such. In other words paragraph [1078] simply explains to the skilled person something of how the sensor actually works in practice.

33 Put simply, then, the combined teaching of these portions of the unamended specification is that a sensor, comprising a pair of spaced electrodes, can measure impedance changes of a particle when the distance between the electrodes and the surface of the particle is less than the 'Debye length'. As I have construed it above, this is exactly what the amended claim says, and as such it teaches the skilled

person nothing more than he would learn from the unamended specification. Given this construction, the claim i, to my mind, supported by the description and as such there is no added matter.

34 However, if the claim is construed to mean that the spacing between the two electrodes is less than the Debye length of the particle, as Dr Turnbull and Mr McNeight appeared to suggest, then I would reach a different conclusion. I have no doubt that the spacing of the electrodes is not arbitrary, and that the relative position of two electrodes in a functioning sensor must in some sense be defined by the Debye length of the particle, but there is no teaching in paragraph [1078], or elsewhere, that the distance between the electrodes must be less than the Debye length. As I have explained above, paragraph [1078] is all about the distance between the sensor and the particle, and not about the distance between the electrodes. For the sake of completeness I should also say that I do not consider there to be any implicit disclosure of the electrode spacing being less than the Debye length. In fact, one can readily conceive of electrode arrangements in which both electrodes are within the Debye sphere of a particular particle, and yet are spaced apart by more than the Debye length – as illustrated below, for example.



In my opinion, it would be unreasonable to adopt this construction as it would appear to be incorrect, has no apparent support within the specification as filed, and as such would appear to add matter beyond that which was was originally disclosed.

Inventive step – the law

35 The examiner has also objected that the claims lack an inventive step. Section 1(1) states that:

> *1(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –*
>
> *(a) ...*
>
> *(b) it involves an inventive step*
>
> *(c) ...*
>
> *(d) ...*

Section 3 explains that:

3 An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

36 I do not propose to quote sections 2(2) and 2(3) here, but it follows from these that the state of the art for inventive step purposes comprises all matter which has at any time before the priority date of the invention been made available to the public, whether in the UK or elsewhere.

37 There was no debate at the hearing over the correct approach for assessing inventive step. It is well established that inventive step should be assessed on the basis of the well-known *Windsurfing*[6] approach as reformulated by Jacob LJ in *Pozzoli*[7]. The four steps of the test are:

(1)(a) Identify the notional "person skilled in the art"

(1)(b) Identify the relevant common general knowledge of that person;

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

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Inventive Step - analysis

38 The claim when construed to relate to electrode-particle spacing does not contain any added matter, but is it inventive? To decide this I should adopt the *Windsurfing/Pozzoli* approach, but it is very clear that the second step in the test presents me with a problem, and in view of this I do not propose to work through the four steps of the test.

39 The problem I have is that the examiner and the applicant have largely focussed their attention on the portion of the claim that recites "measuring a local impedance change...when an individual sensor...comprises a pair of electrodes that are within the Debye length of a surface of the particle". Moreover, Dr Turnbull's submission on obviousness at the hearing was based entirely on this portion of the claim. As set out above there has been some confusion over this portion of the claim and I do not believe that it has been properly construed, until now. As a result the inventive concept cannot have been properly identified, as step 2 of Windsurfing requires. It would be wrong for me to reach a decision based on the arguments put forward thus far since these arguments are in no small part based upon a misunderstanding of the invention. Furthermore, I am unsure whether the focus on this portion of the claim

[6] Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 59
[7] Pozzoli SPA v BDMO SA [2007] EWCA Civ 588

means that insufficient attention has been given to the remainder of the claim and the relevance of the cited prior art to the particular combination of method steps claimed.

40 The question of obviousness needs careful reconsideration in the light of my decision on added matter, particularly taking into account a correct construction of the claims. Since the applicant must have an opportunity to respond to any new objection made I consider that the most appropriate course of action is to remit the application to the examiner for re-examination. The examiner is in the best position to further consider the issue of inventive step, which will involve a fresh assessment of the inventive concept and reconsideration of the relevance of the cited prior art. It may conceivably require some further searching.

41 Having found the alternative construction of the claim to be unsupported there is no need for me to consider it in relation to inventive step.

Conclusion

42 If I were to construe the claims as Dr Turnbull and Mr McNeight suggest then I would conclude that the claims add matter, and I would refuse the application accordingly. However, in the light of my findings I conclude that the claims, construed as I consider they should be, do not add matter.

43 I also conclude that the issue of inventive step has not yet been properly considered. I therefore remit the case back to the examiner so that the claims can be re-examined for obviousness in the light of this decision, and so that the applicant may have the opportunity to offer further amendments and/or observations in light of any new objections raised.

44 I note that the examiner has deferred certain aspects of his examination, and that the applicant has deferred making any amendments to the description in view of amendments to the claims. These can now be considered.

45 The original compliance period prescribed by Rule 30 of the Patents Rules expired on 4 April 2015. The applicant had already extended the period until 4 June 2015 at the time of the hearing and has since extended the period by a further two months to 4 August 2015. Further extensions may be required if the application is to proceed. Any such extensions are at the discretion of the Comptroller.

Appeal

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

PETER SLATER
Deputy Director, acting for the Comptroller