Intellectual Property Office

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PATENTS ACT 1977

APPLICANT	California Institute of Technology and Thermo Fischer Scientific (Bremen) GmbH
ISSUE	Whether patent application GB1811529.5 is entitled to its claimed priority date
HEARING OFFICER	B Micklewright

DECISION

Introduction

1 This decision relates to patent application GB1811529.5, a divisional of earlier application GB1507362.0. GB1811529.5 was lodged on 13 July 2018, and has been treated as having been filed on the same date as the earlier application i.e. 10 October 2013. The application claims priority from two earlier US applications, the earlier of which, US 61/712,022, is dated 10 October 2012. The application was published on 31 October 2018 as GB2561998 A.

2 The examiner considers the claimed invention to be obvious based primarily upon a piece of prior art which was published after the claimed priority date, but before the filing date. The examiner is of the view that the claimed invention is not entitled to the priority date due to a lack of enabling disclosure in the priority document. The applicant and examiner have been unable to resolve this issue. The matter therefore came before me at video hearing held on 6 March 2019. The applicant was represented by Mrs Elspeth Doyle and Dr Elaine Taylor-Shaw of Murgitroyd and Company.

3 In addition to the submissions made at the hearing I am also grateful to Mrs Doyle for providing me with a set of written skeleton arguments prior to the hearing. I confirm that I have carefully considered these and reviewed the other correspondence on file.

4 There are two linked issues here: priority and inventive step. At the outset of the hearing I made it clear to Mrs Doyle and Dr Taylor-Shaw that that it would be very difficult for me to consider inventive step. The skeleton arguments propose a number of possible amendments that the applicant might be prepared to make in order to address inventive step objections in the event that I find that the claimed invention is not entitled to the declared priority date, and also propose an amendment in the event that I find that the priority claim is valid. Mrs Doyle clarified that it was the applicant's intention to amend the claims to overcome any inventive

step objection regardless of my decision on priority. The examiner has not had an opportunity to consider the proposed amendments, and furthermore stated at the hearing that those amendments are likely to prompt further searching. It was therefore agreed that my decision would relate solely to the issue of priority and that the application would then be referred back to the examiner for further consideration of inventive step, and any other issues that might arise as a consequence.

The Invention

5 The application is rather a long one; there are 85 pages of description and 48 pages of drawings. So before looking at the specific issue to be considered it is perhaps helpful to give a general overview of the technical background of the application. The application relates to mass spectrometry. Conventional mass spectrometry generally determines the overall concentration of an isotope irrespective of its location in the molecule or the proportions of multiple isotopic substitutions in the same molecule, and therefore does not distinguish among different isotopologues of the same molecule. An isotopologue is a chemical that differs from its parent chemical in that at least one atom has a different number of neutrons. The application is therefore directed towards apparatus, systems and methods for the quantitative analysis of the isotopologues of compounds of interest. The system may use a combination of two mass spectrometers, one of which is multi-collector low resolution spectrometer and the other of which is a single-collector high resolution spectrometer. A complete quantitative analysis of all the isotopologues present in a sample compound may enable determination of useful information, such as the geographic origin of the molecule, its temperature of origin, or the parent molecule from which the molecule was derived. The application points to a number of different fields in which this might be useful, including hydrocarbon exploration, chemical forensics, biomedical research, and diagnosis and treatment of diseases.

The claims

6 The application contains a single independent claim which reads:

> *1. A method for determining the isotopic composition of an analyte in a sample, the method comprising:*
>
> *converting a first portion of the analyte to first molecular analyte ions using a first ion source of a first mass spectrometer;*
>
> *filtering out second molecular analyte ions from the first molecular analyte ions according to their momenta;*
>
> *filtering out third molecular analyte ions from the second analyte ions according to their energy levels;*
>
> *detecting two or more of the third molecular analyte ions at a mass resolution of 30,000 or greater to produce first molecular analyte data;*
>
> *analyzing the first molecular analyte data to determine an isotopic composition of a least a portion of the analyte; and*

the analyzing further comprises determining a molecular position of at least one isotope in an analyte isotopologue comprised in the analyte.

7 On the day of the hearing three sets of auxiliary claims were submitted for my consideration. They differ from the above only in the value given for the mass resolution. The relevant portions of these three claims are:

a) *detecting two or more of the third molecular analyte ions at a mass resolution from 30,000 to 100,000 to produce first molecular analyte data;*

b) detecting two or more of the third molecular analyte ions at a mass resolution of greater than 27,000 to produce first molecular analyte data;

c) detecting two or more of the third molecular analyte ions at a mass resolution of 49,000 or greater to produce first molecular analyte data.

The law

8 The relevant provision relating to declaration of priority is Section 5(2) of the Patents Act 1977, which reads:

5(2) If in or in connection with an application for a patent (the application in suit) a declaration is made, whether by the applicant or any predecessor in title of his, complying with the relevant requirements of rules and specifying one or more earlier relevant applications for the purposes of this section made by the applicant or a predecessor in title of his and the application in suit has a date of filing during the period allowed under subsection (2A)(a) or (b) below, then-

(a) if an invention to which the application in suit relates is supported by matter disclosed in the earlier relevant application or applications, the priority date of that invention shall instead of being the date of filing the application in suit be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them;

(b) the priority date of any matter contained in the application in suit which was also disclosed in the earlier relevant application or applications shall be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them.

9 The courts have provided some guidance on how to interpret this. In particular, in *Asahi Kasei Kogyo KK's application*[1], the court held that:

[1] *Asahi Kasei Kogyo KK's application* [1991] RPC 485

"…a description in an earlier application which contains no enabling disclosure will not "support" the invention so as to enable it, as an invention, to claim priority from the date of that application under section 5(2)(a)…"

10 And in *Biogen Inc. v Medeva plc*[2] it was held that

"the test of support in section 5(2)(a) of the 1977 Act contains within it both a formal requirement (that there should be descriptive words there which provide support for the claim) and a substantive requirement (that the description should allow the invention to be performed)."

Arguments and analysis

11 There are two separate aspects to the priority date issue. The first relates to the numerical limit(s) associated with the mass resolution. The second relates to the step of determining the molecular position of at least one isotope in an analyte isotopologue comprised in the analyte. I will consider these two aspects in turn.

1. Mass resolution

12 Mrs Doyle stated that the applicant's preference is the claim as it currently stands, i.e. the claim which recites that the mass resolution is 30,000 or greater. It is common ground that the value of 30,000 is not explicitly disclosed in the priority document. Mrs Doyle argued at some length that the value of 30,000 is implicitly disclosed. To briefly summarise she submitted that since the priority document discloses that the mass resolution is within the range of 27,000 to 100,000 then a value of 30,000 is implicitly disclosed because it falls within that range and is not far removed from the value of 27,000. Mrs Doyle's argument here is akin to a novelty test. In other words she argues that if the claim in the application in question is anticipated by the priority document then the priority document must provide the necessary support. I am not sure that the issue is necessarily so black and white but in any case the argument presupposes that there is a disclosure of a mass resolution of 27,000 to 100,000. If that is not the case then Mrs Doyle's arguments regarding 30,000 are moot and I need not consider them further.

13 So does the priority document provide an enabling disclose of a mass resolution of 27,000 to 100,000? I should point out that the priority document is not a typical patent application. It takes the form of a proposal for a schedule of research; it is just six pages long and does not contain a claim or a consistory clause. It does not automatically follow from this that there is no enabling disclosure as Mrs Doyle quite correctly pointed out with reference to some relevant case law. In *Unilin Beheer BV v Berry Floor NV*[3], Jacob LJ held that

"The approach is not formulaic: priority is a question about technical disclosure, explicit or implicit. Is there enough in the priority document to give the skilled man essentially the same information as forms the subject of the claim and enables him to work the invention in accordance with that claim?"

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[2] *Biogen Inc. v Medeva plc* [1997] RPC

[3] In *Unilin Beheer BV v Berry Floor NV* [2004] EWCA (Civ) 1021

And in *Abbot Laboratories*[4] it was held

> *"So the important thing is not the consistory clause or the claims of the priority document but whether the disclosure as a whole is enabling and effectively gives the skilled person what is in the claim whose priority is in question. I would add that it must 'give' it directly and unambiguously. It is not sufficient that it may be an obvious development of what is disclosed."*

14 One of the underlying ideas of the application is that data from a first low resolution multi collector spectrometer is combined with data from a second high resolution single collector spectrometer. It is to the method of using this second spectrometer that the claims are directed. The priority document is certainly very clear about the idea of combining measurements from two spectrometers. It refers to the first device as the "Thermo IRMS 253 Ultra", or more simply "The Ultra", and states that it is capable of analysing isotopologues of organic molecules up to mass resolutions of 27,000. It refers to the second device as the "Thermo DFS". There are two explicit references to the mass resolution of the second device. The first says that the Thermo DFS is used

> *"to make a separate measurement of the same sample at very high mass resolving power (up to 100,000)"*

and the second says that the second device is

> *"capable of achieving extremely high mass resolutions (~100,000; we will use the Thermo DFS mass spectrometer)".*

I do not think there can be any doubt from this that the priority document teaches the skilled addressee that the high resolution single collector spectrometer may have a mass resolving power as high as 100,000, but as Mrs Doyle readily conceded at the hearing there is no explicit disclosure that it might have a mass resolving power of 27,000 as a lower limit.

15 Mrs Doyle's argument is that the mass resolving power of the second device must be viewed through the lens of the described prior art. The priority document explains, by way of example, that the "Ultra" cannot distinguish ^{13}C-substituted decane from D-substituted or H-substituted versions as this would require a mass resolving power of 49,000 (which is beyond the 27,000 limit of the "Ultra"). Mrs Doyle argued that since the clear intention is to improve upon the prior art "Ultra" device then the second device must implicitly have a higher mass resolution greater than the 27,000, and that this is derivable unambiguously from the priority document.

16 Whilst *Unilin* says that the implicit disclosure of the priority document may be taken into account *Abbot* makes clear that obvious developments may not. It is trite law[5] that matter regarded as obvious to add is not the same thing as matter implicitly disclosed. What certainly is implicit from the priority document is that the combination of the two mass spectrometers should <u>together</u> be able to overcome the limit to the maximum size of compounds that can be analysed using the "Ultra"

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[4] *Abbott Laboratories Ltd v Evysio Medical Devices ULC* [2008] EWHC 800 (Pat)
[5] See for instance *Flexible Direction Indicators Ltd's Application* [1994] RPC 207

alone. It may well be obvious to the skilled person, very obvious even, that the high resolution single collector spectrometer could have a mass resolving power of greater than 27,000. However I do not consider that this would have to be the case not least because there are other options that would present themselves to the skilled reader. Firstly, as the priority document at face value suggests to the skilled reader, the mass resolution should be very high, or extremely high, of the order of 100,000. Secondly, the mass resolution could conceivably have a range which overlaps that of the Ultra. I am therefore not persuaded by the argument that a lower limit of 27,000 on the mass resolution of the high resolution single collector spectrometer is implicitly disclosed.

17 I do not need to address Mrs Doyle's arguments regarding the two alternative claims which specify limits of greater than 30,000 and 30,000-100,000 respectively, since those arguments rely upon the lower limit of 27,000 being implicit and I have decided that it is not.

18 There is one further alternative claim to consider, in which the limit is given as 49,000 or greater. Mrs Doyle argues that there is an explicit disclosure of 49,000 in the priority document. It is certainly the case that the value of 49,000 is mentioned, but I am not at all persuaded that this amounts to an enabling disclosure of a lower limit for the mass resolution of the spectrometer. As I have already mentioned above, the reference to 49,000 is in relation to discussion of a particular problem (distinguishing ^{13}C-substituted decane from D-substituted or H-substituted versions) that cannot be solved using the prior art Ultra device. To my mind it is quite clear that this portion of the priority document simply explains to the skilled reader, by way of a suitable example, why the applicant was motivated to consider combining data from the Ultra with data from a high resolution single collector spectrometer. It does not explicitly teach the skilled addressee that a resolution of greater than 49,000 is a necessary requirement for that spectrometer. Again, it may well be obvious that a value of 49,000 could be a lower limit which would be appropriate not just for analysis of decane but also for other high-mass compounds, but that does not mean that there is an implicit disclosure of a spectrometer having a mass resolution of 49,000 or greater.

19 To summarise, there is no explicit nor implicit disclosure in the priority document of the mass resolutions specified in either the claim on file or any of the three auxiliary claims.

2. Determining a molecular position

20 The examiner is of the opinion that the priority document contains insufficient information to enable the skilled person to perform the "analysing" step in the claim, i.e. determining a molecular position of at least one isotope in an analyte isotopologue comprised in the analyte. The priority document discusses an example application in which a 'map' may be constructed of ^{13}C substitutions in high molecular weight components of oils, but the examiner considers that insufficient indication is provided as to how to actually carry out this reconstruction.

21 During the examination procedure the applicant pointed out that the priority document clearly teaches that in order to determine a molecular position of at least one isotope in an analyte isotopologue fragments of the analyte isotopologue have to

be analysed and from the detected proportions the position of the isotope can be reconstructed. The applicant argued this reconstruction would be just a statistical standard problem for a person skilled in the art. Furthermore the applicant provided two documents (a paper from a scientific journal and a Wikipedia webpage) as evidence that appropriate techniques were well known to those skilled in the art at the priority date. Both document relate to the technique known as “position specific isotope analysis”, or PSIA.

22 In her pre-hearing report the examiner addressed the applicant’s arguments in some detail. In simple terms the examiner considered that the webpage did not provide sufficient specific information and that an isolated disclosure in one scientific paper was not persuasive evidence that something was common general knowledge. Moreover the examiner was not persuaded that the PSIA technique, even if it was common general knowledge, was actually suitable for performing the analysis step required by the claim. She considers that the PSIA technique allows for determining the isotopic composition of a specific position in a molecule and that this is quite different to the claimed invention which requires determining an unknown molecular position of an isotope in an analyte isotopologue.

23 The skeleton arguments provided by Mrs Doyle prior to the hearing go some way to addressing the examiner’s concerns. Another two documents were provided as further evidence that PSIA is a technology of common knowledge in the art. Both documents take the form of technical reviews, as opposed to scientific papers detailing specific techniques. These documents may well advance the applicant’s argument that PSIA is common general knowledge in the art, but what Mrs Doyle’s skeleton arguments did not address was the examiner’s view that knowledge of PSIA would still not enable the skilled person to bridge the gap between the priority document and the claim. I addressed this point with Mrs Doyle at the hearing, inviting further submissions in writing.

24 Mrs Doyle duly provided further arguments in writing, for which I am grateful. The argument, in a nutshell, is that the essential feature of PSIA is the mass balance equations which provide a correlation between the isotope ratios of the complete molecule and the isotope ratio at a position of the molecule, and that the skilled person would be able to solve these equations using the data obtained from the mass spectrometry detailed in the claim and so determine the molecular position of the isotopes.

25 It cannot be denied that the priority document provides very little detail on the necessary technique to analyse the molecular analyte data so as to determine the isotopic composition and the molecular position of the isotope. What I have to decide is whether the omission of further detail means that there is a lack of an enabling disclosure in the priority document such that it cannot be said to provide support for the claimed invention in the application in suit.

26 Whether or not a priority document provides sufficient information to allow an invention claimed in a later application to be performed will depend upon the facts of the case and may be highly sensitive to the nature of the invention. The skilled person must be able to perform the invention but they need not be provided every detail necessary. Rather the skilled person, in attempting to make the invention work, must use their skill and knowledge. Whether or not they have the knowledge

and skill to do so in this case is a question of fact. This invention lies in a highly complex technical field, and to determine precisely what the common general knowledge of the skilled person might be is far from straightforward.

27 There are two questions for me to decide here. Firstly, would the person skilled in the art be familiar with PSIA techniques? And secondly, if that is the case, then does the combination of his knowledge of PSIA with the teaching of the priority document equip the skilled person to perform the invention?

28 The courts have provided guidance for dealing with such questions of fact which are difficult to conclusively answer at the application stage. The Court of Appeal in *Aerotel/Macrossan*[6], though addressing an issue of excluded matter rather than enabling disclosure, commented:

> *"Of course if a debatable question of pure fact is or may be involved at the application stage, things are different - one cannot then say that the decision at that point must be the last word on the subject. Then the applicant must be given the benefit of any reasonable doubt."*

And the Patents Court in *Blacklight Power*[7] noted:

> *"It is not the law that any doubt, however small, on an issue of fact would force the Comptroller to allow the application to proceed to grant. Rather he should examine the material before him and attempt to come to a conclusion on the balance of probabilities. If he considers that there is a substantial doubt about an issue of fact which could lead to patentability at that stage, he should consider whether there is a reasonable prospect that matters will turn out differently if the matter is fully investigated at a trial. If so he should allow the application to proceed."*

29 I have carefully considered Mrs Doyle's detailed arguments and the various evidence she has provided. I have also considered the examiner's point of view, though I note that I have not had the benefit of her opinion on the most recent submissions from Mrs Doyle on the issue. I am of the view that the arguments on the subject of determining the molecular position are finely balanced. I consider it likely that the person skilled in the art would indeed be familiar with the technique known as PSIA but whether, in light of that knowledge, they would understand how to perform the invention is rather more difficult to say. Without the possibility to call upon evidence from expert witnesses, which could quite possibly prove persuasive, I am inclined to conclude that the applicant is entitled to the benefit of the doubt on this point.

Conclusion

30 I have decided that the priority document, when read by the skilled reader having amongst their common general knowledge an understanding of PSIA techniques, and giving the applicant the benefit of the doubt on the facts, does provide an enabling disclosure of the analysis step at the end of the claimed invention. However, there is neither explicit nor implicit disclosure of the lower limits of mass

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[6] *Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1* [2007] RPC 7

[7] *Blacklight Power Inc.'s Application)* [2009] RPC 6

resolution as defined in the claims currently on file or in the three auxiliary claims submitted prior to the hearing. Accordingly the invention claimed in claim 1 is not entitled to the declared priority date of 10 October 2012.

31 I will refer this application back to the examiner to consider amendments and arguments on the substantive issue of inventive step, should the applicant decide to file any. The compliance period has already been extended four times. Given that the applicant has already had ample opportunity to submit amendments to distinguish their invention from the cited prior art the applicant should not expect to readily obtain multiple further extensions of the compliance period.

Appeal

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

B Micklewright
Deputy Director, acting for the Comptroller