

OPINION UNDER SECTION 74A

Patent	EP(UK) 0854911
Proprietor(s)	Government of the United States of America
Exclusive Licensee	
Requester	Dr Walther Wolff & Co, on 6 March 2008
Observer(s)	
Date Opinion issued	12 May 2008

The request

- 1 The comptroller has been requested to issue an opinion as to whether claims 1-35 of EP (UK) 0 854 911 (“the patent”) are inventive over the following documents:

US 3, 3326, 401 (De Long) (US’401)

DE 3, 817, 906 (Boehringer Mannheim GmbH) (DE’906)

- 2 In particular, Dr Walther Wolff & Co (“the requester”) seeks an opinion as to whether claims 1-35 are inventive with regards to US’401, and whether claims 1-20 are inventive with regards to DE’906.
- 3 The requester also cited two further documents, US 5, 398, 837 (US’837), and EP 0 337 677 (EP’677), which were considered pre grant in the European Patent Office. In line with decisions BL O/370/07, BL O/298/07 and BL O/289/07, no opinion will be given in respect of questions already considered pre grant in either the EPO or the UK Intellectual Property Office.
- 4 It should be noted that the US equivalent of DE’906, US 5, 309,649 (US ‘649), was considered during the course of the examination at the EPO. However, the requester has argued that the German document differs significantly from its US counterpart.

Observations

- 5 Observations in response to the request were received from the patent

holder's attorney, FJ Cleveland ("the proprietor") on 11 April 2008. These maintain that the invention involves an inventive step. The proprietor also challenged the requester's argument that DE'906 differs from the US equivalent cited in the international search report. The proprietor argued that there is no substantive difference between the two documents, and therefore the arguments presented by the requester do not raise any new arguments over those considered by the EPO pre-grant.

Observations in reply

- 6 Observations in reply were received from the requester on 28 April 2008 that countered the challenges of the proprietor. The requester also argued that the wording of claim 9 of DE'906 differs to its US equivalent.
- 7 In his response, the requester considers that the EPO has not considered the novelty or inventive step of independent claims 2, 21 and 22 in light of US'837, and EP'677. However, I disagree with this as it is clear to me that the EPO has considered these documents against all of the claims (see EPO Examination report issued 5 November 2002, para 5, which reads "*All other claims relating to processes and containers particularly configured for use in high speed centrifugation, are deemed to meet the requirements according to Art. 54, 56 and 57 EPC, since the prior art does not disclose or suggest said particular configuration for resistance to high speed centrifugational forces*"). Therefore, I will not be issuing an opinion based upon these documents.

The patent

- 8 International patent application number PCT/US1996/015371 was filed on 20 September 1996, and was granted by the EPO on 24 November 2004, with the title "Container for drying biological samples, method of making such container, and method of using same".
- 9 The patent is based upon a method for drying a sample containing a vaporizable material, wherein the drying method takes place within a tube that can withstand a centrifugal force and that has an opening in the top which is covered by a filter element. The filter element allows the vaporizable material to permeate from the tube but prevents microbes from permeating into the tube and contaminating the dried sample. It consists of 34 claims, including independent claims 1, 2, 21 and 22.

The claims

- 10 Independent claims 1, 2, 21 and 22 read as follows:
1. *A method of drying a solid or liquid sample including a vaporizable material in a container, comprising the steps of:*

providing said container containing said sample, said container defining an opening, which opening is sealed substantially with a filter means, which filter means permits permeation of said vaporizable material therethrough and substantially prevents permeation of microbes therethrough; and permitting at least a portion of said vaporizable material to permeate said filter means including subjecting said sample to centrifugation, thereby affording at least a partial drying of said sample without substantial microbial contamination thereof.

2. *A method of venting a sample contained in a container, comprising the steps of:
providing said container containing said sample, said container having an opening sealed substantially with a filter means, said filter means permitting permeation therethrough of said least one gas and substantially preventing permeation therethrough of microbes, said container being configured to withstand a high speed centrifugation of 50 or more times the force of gravity; and permitting said gas to enter or exit said container by permeating through said filter means, thereby affording venting of said sample without substantially contaminating said sample with microbes.*
21. *A container assembly to be placed in a centrifuge, comprising: a container having a closed end and an open end and defining an interior volume therein, said container capable of withstanding centrifugation at about 50 or more times the force of gravity; and a cap having an open position and a closed position for sealing said open end, said cap including a microbe-impermeable filter means for allowing gas flow into said interior volume from external the container and for allowing gas flow out from said interior volume.*
22. *A container assembly to be placed in a centrifuge, comprising: a container having a closed end and an open end and defining an interior volume therein, said container shaped to conform to the shape of a centrifuge rotor or bucket; and a cap having an open position and a closed position for sealing said open end, said cap including a microbe-impermeable filter means for allowing gas flow into said interior volume from external the container and for allowing gas flow out from said interior volume.*

11 In my assessment of the inventive step of the claims I will make a purposive construction of the claims, following the judgment of Lord Hoffman in *Kirin Amgen*¹. I will therefore interpret the claims in the way that I consider a

¹ *Kirin Amgen v Hoechst Marion Roussel Ltd* [2005] RPC 9

person skilled in the art would have understood the patentee to mean by the language of the claim.

Document DE'906

- 12 Before assessing the inventive step of the claims I will compare the content of De'906 to the content of its US equivalent that was cited during pre-grant proceedings at the EPO, as this will have a bearing on whether or not I issue an opinion in relation to DE'906.
- 13 The requester has argued that the disclosure of DE'906 differs from that of US'649. In particular the requester argues that claim 9 of DE'906 "*when correctly translated*" discloses a bottle rather than a flask, and as such would have a more robust construction and be more likely to withstand the force of a centrifuge. The word in claim 9 of DE'906 is "flasche", which can be translated from German to English as either bottle or flask. This claim is the equivalent of claim 11 of US'649, which specifies a flask. Moreover, this claim in the numerous other members of this patent family also specifies a flask. Given the nature of the invention in DE'906, in my opinion a person skilled in the art would also translate "flasche" as flask, as flask is the common technical term used for a growth container in this field. Consequently, I disagree with the requester and consider claim 9 of DE'906 does not differ from claim 11 of US'649.
- 14 The requester also argues that the description of US'649 is necessarily restricted to the drawings that show specific forms and shapes of the containers. Whilst there are no drawings in DE'906, the contents of the description are substantially the same as the content of US'649. The description of both documents considers a preferred embodiment to be "*the use of a bag or tube, which preferably consists of two walls tightly and pressure-resistantly connected with one another at their edges, one wall of which consists of a liquid-tight material and the other wall of which is formed by the membrane*". The drawings of US'649 simply clarify this preferred embodiment, and therefore I do not consider that this provides a substantive difference between the documents.
- 15 Consequently, as US'649 was considered pre-grant by the EPO, and as DE'906 does not differ from this document, in line with decisions BL O/370/07, BL O/298/07 and BL O/89/07 I will not provide an opinion in respect of DE'906.
- 16 Therefore my assessment of inventive step will be based upon the disclosure of US'401 alone.
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Discussion

- 17 Neither the requester nor the proprietor have considered the *Windsurfing*² test in their assessment of inventive step. I will use this test as recently reformulated in *Pozzoli*³. The assessment of inventive step using the *Windsurfing/ Pozzoli* approach is as follows:
- (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?
- 18 In my opinion the person skilled in the art in this case would be a molecular biologist/ microbiologist, who would have a good knowledge of DNA purification techniques and of the culture and isolation of microorganisms. They would be aware of methods of drying samples, such as using the SpeedVac^{RTM}, where samples are dried under vacuum using centrifugation. They would also appreciate that such a method requires the tube to be open in order to allow the vaporizable material to escape. The skilled workers would also be aware of the problems of contamination with other microorganisms, and of mechanisms in place to limit this risk.
- 19 This forms the basis of the common general knowledge in the area at the filing date of the patent.
- 20 Even though there are four independent claims, there is a common inventive concept between each of these claims, which is the attachment of a semi-permeable membrane (or filter) to the top of a tube to allow drying of a sample without contamination by microbes. The tube must be capable of withstanding the forces exerted upon it during centrifugation. Both the requester and the proprietor agree that this forms the basis of the inventive concept of the claims.
- 21 The next step in the *Windsurfer/Pozzoli* approach is to identify the differences between the prior art and the invention. The only prior art for me to consider is

² *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59

³ *Pozzoli SPA v BDMA SA* [2007] EWCA Civ 588

US'401, which discloses a closure for a container for aerobic microorganisms. The closure itself has an opening into which a disposable plug may be inserted. The plug can be sterilized by autoclaving and allows the transfer of gases to and from the container but prevents contamination by external microorganisms. The plug is preferably made from a porous foam plastic, such as polyethylene or Teflon^{RTM}. Its intended use is during the growth of microorganisms, for the closure of the flask in which the microorganisms are grown. However, I appreciate that this closure may be suitable for other uses outside of this area.

- 22 I will now consider whether the differences between the invention as claimed and the prior art would be obvious to the person skilled in the art. In my opinion, the question of inventive step lies in whether or not a person skilled in the art would consider using the filter means of the culture flask of US'401 to seal a centrifuge tube used for drying a biological sample. The requester claims that the proprietor has *"taken a conventional container, such as a centrifuge tube... and attached to the opening a commercial filter membrane... which has the required microfiltration capability to let through gas but not microbes."* The proprietor on the other hand has acknowledged that there is a problem of contamination in the area of lyophilization of biological samples, and that the addition of the filter top prevents permeation of microorganisms into the container. In the requester's opinion *"this subtle insight allows lyophilization to be carried out with centrifugation in the absence of bacterial contamination of the sample container"*.
- 23 I agree with the proprietor that there was a need for a mechanism to reduce contamination risk during the lyophilization of samples. However, I also agree with the requester in that the proprietor has taken a conventional container, and simply attached to it a commercial membrane. The question is therefore would it have been obvious to attach the closure means of US'401 to the top of a tube that was to be used in a centrifuge? This question forms the basis of the inventive step analysis of each of the independent claims, and therefore I will consider this before I assess each of independent claims 1, 2, 21 and 22 individually.
- 24 The closure of US'401 is designed for use on a container for the growth of microorganisms. Such containers are not generally used in a centrifuge and therefore may not withstand the pressure of the centrifugal force, particularly when combined with a vacuum. Moreover, the attachment of the filter means to the closure in US'401 is also not designed to withstand any force; in fact the filter means is removable, and under vacuum and gravitational pressure would most likely become dislodged. Therefore, in my opinion the closure of US'401 would not be suitable for use in a centrifuge or under a vacuum, and this is of importance when considering the inventive step of the claims.
- 25 Claim 1 defines a method of drying a sample in a container with an opening

sealed by a filter means, and whereby the sample is subjected to centrifugation. US '401 discloses culture methods and not methods of drying of samples, and therefore in my opinion it would not be obvious to use a container comprising the closure of US'401 for the drying of a sample.

- 26 Claim 2 defines a method of venting a sample in a container with an opening sealed by a filter means, and wherein the container must be able to withstand a high speed centrifugation of 50 or more times the force of gravity. It could be argued that US'401 does disclose a method of venting a sample, as it allows passage of air into and out of a container. However, it is a requirement of claim 2 that the container can withstand centrifugation, and for the reasons given in paragraph 24 above, I do not consider that the container of US'401 would be able to withstand this. Therefore, there is nothing in US'401 that would direct a skilled person to use such a container in a centrifuge. I can apply the same reasoning to claim 21, which merely discloses a container to be placed in a centrifuge with the same characteristics as the container of claim 2.
- 27 There is nothing in claim 22 that specifies that the container must withstand centrifugation of 50 or more times the force of gravity. However, claim 22 does define "a container assembly to be placed in a centrifuge", and also that the container is "shaped to conform to the shape of a centrifuge rotor or bucket". In my mind a skilled person would consider that this container would necessarily need to withstand centrifugation, and although the force of the centrifuge is not specified, I still do not think that the closure means of US'401 would withstand any degree of gravitational force imposed upon it, particularly as it is designed to be removable.
- 28 Therefore, in my opinion, claims 1, 2, 21 and 22 are inventive over the disclosure of US'401.

Opinion

- 29 I conclude that independent claims 1, 2, 21 and 22 involve an inventive step in light of US'401 submitted by the requester. Consequently, appendant claims 3-20 and 23-35 are also inventive in light of this document

Rowena Dinham
Examiner