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19 December 2012

PATENTS ACT 1977

APPLICANT Alaa Al-Darraji

ISSUE Whether patent application GB0907571.4 complies with sections 14(3) and 14(5)(c)

HEARING OFFICER Mrs S E Chalmers

DECISION

Introduction

1 Patent application GB0907571.4, entitled "The reason of all cancer types", was filed on 5 May 2009, and published on 10 November 2010 as GB2470001A.

2 During substantive examination of the application, the examiner has repeatedly objected that the disclosure of the invention is insufficient, and that the claims are not clear and are not supported by the description. Despite amendment, and extensive correspondence, the applicant has been unable to persuade the examiner otherwise. In view of the fundamental nature of these matters, the examiner has not yet fully addressed the novelty and inventiveness of the invention, and so these issues are not being considered as part of this decision.

3 The applicant, Mr Al-Darraji, was offered a hearing in a letter from the examiner dated 31 May 2012, but instead requested a decision based on the papers on file. This decision is based on the set of claims filed on 14 March 2011.

4 Mr Al-Darraji is an unrepresented applicant, and although I appreciate that he has attempted to address the examiner's objections fully, there is, nevertheless, a significant communication gap, which has hampered the examination of his application considerably. I have taken these factors into account in my decision.

The application

5 The description discusses a purported method for determining the "reason of all cancer types". Page 1 of the description includes the following explanation of the invention:

"...the reason of all cancer types may be a mistake in the human brain system. Therefore, for confirming these results, and to know which part of the brain that this mistake occurs and why? Depending on the brain anatomy science, this may finally lead to find a successful treatment for all cancer types. For this purpose, it can be

used different procedure types but all of them should follow some basics and principles. These principles are; to prepare three or more different compounds; gamma Linolenic acid, organic and inorganic carcinogenic and cancer treatment compounds also They should be prepared from specific Radioisotopes metals or they should contain specific Radioisotopes metals in them chemical structure. After that, these compounds will inject, inhalant or orally taken into experimental animal or human body make it possible to follow them inside this body depending on nuclear medicine imaging systems (i.e. gamma camera). This process will give us the information about the pathways of these compounds through the body tissues (them work inside the body). to confirm our study about the relation between these compounds and the brain. Our thought is when know the reason of all cancer types, them successful treatment will be possible to prepare."

6 There are five amended claims that form the basis of this decision, of which I think it is only necessary to set out claim 1:

"1. There are certain compounds classified as carcinogenic compounds and as cancer's drugs and they have two structure formula either organic or inorganic. In addition, according to the references, there is a good anticancer agent called gamma linolenic acid. However, all these compounds (the three types) must do something in specific organ of human's body. This action if it is carcinogenic or treatment actions can be detected by using nuclear medicine images techniques as it is illustrated in the description. Depending on nuclear medicine images techniques, action of above compounds inside human's body or inside animal's body can be detected or diagnosed for finding the reason of all cancer types."

The law

7 Section 14(3) of the Patents Act requires that the specification of an application must disclose the invention in a manner which is clear enough and complete enough for it to be performed by a person skilled in the art.

8 Section 14(5)(c) requires that the claims of an application must be supported by the description.

Arguments and analysis

9 Before considering the specific arguments, I first need to consider what a person skilled in the art would understand the language of the claim to mean. In this instance I think that a reasonable suggestion for the skilled person is a nuclear imaging scientist with an interest in investigating the causes of cancer.

10 As I think is quite apparent from the passages I have quoted above, the specification presents the reader with significant problems in ascertaining the true scope of the invention. The language used throughout is not at all clear, and this makes understanding the invention, and the principles behind it, very difficult indeed. However, I think that the relevant skilled person would understand that claim 1 relates to the use of certain compounds in nuclear imaging for discovering the cause ("reason") of all cancer types. In particular, claim 1 requires the use of three types of compound: carcinogenic compounds (organic and inorganic); cancer drugs (organic and inorganic); and gamma linolenic acid. In view of the applicant's submissions,

and for the sake of argument, I shall proceed on the basis that claim 1 effectively requires the use of five different compounds, even though this is not really very clear from the claim. Furthermore, although claim 1 contains no explicit reference to it, I believe that it is implicit that it requires the use of these compounds modified in some way so as to be suitable for use in nuclear imaging.

11 In her most recent examination report of 26 January 2012, the examiner raises a number of objections with regard to support and the completeness of disclosure[1], which I have summarized below:

i. The invention purports to lie in the discovery that cancer is a result of "a mistake in the human brain system" (page 1 of the description, lines 6 to 7), but the specification does not demonstrate this is the case, and therefore there is no evidence to suggest that any of the methods described in the application actually work;

ii. There is no evidence to support a second medical use claim, as set out in the judgment in *Prendergast's Applications* [2000] RPC 446 ('Prendergast');

iii. The skilled person would not be able to perform the claimed invention without the undue burden of carrying out a research programme, and so it is not sufficiently disclosed.

12 With regard to point (i), although Mr Al-Darraji's response, in his letter dated 23 March 2012[2] does not seem to clearly address this issue, I think that whether or not the description contains enough evidence to establish a link between the brain and causes of cancer is not directly related to the question of whether the disclosure of the claimed invention is complete enough. Claim 1 itself is apparently silent as to the link between cancer and a 'mistake' of the brain, as are the other claims, and so any lack of evidence on this issue does not, on its own, demonstrate insufficiency.

13 With regard to point (ii), having construed claim 1 as relating to the use of a group of three compounds in the investigation as to the cause of cancer, I do not think that it can be considered a medical use type claim, and therefore the requirement to file supporting experimental evidence (as was held in Prendergast) is not relevant in this case. However, on the issue of support, I do not think that claim 1 can be considered to be supported across its entire breadth since it clearly encompasses a vast number of potential compounds (including for instance all organic and inorganic carcinogenic compounds). While page 3 of the description lists four example compounds that can be used along with gamma linolenic acid[3], this cannot be considered enough to fully support such a broad claim.

14 Turning now to point (iii), I do not think that Mr Al-Darraji's response in his letter of 23 March 2012, clearly addresses the examiner's particular objection. However, he does make the following comments, which I think have a bearing on it[4]:

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[1] At paragraphs (8) to (10).
[2] At paragraph (10).
[3] Cisplatin, altretamine, "arsenic compounds" and 1,3-butadiene.
[4] At paragraph (16).

"....Edison put his ideas and many others scientists developed it step by step until we get this power now. Einstein find nuclear ideas with other scientists nuclear weapon is a powerful weapon in this earth. All science fields began with ideas and developed step by step until become what we know now. Therefore, my idea is a new idea in cancer it is a new way for finding the reason of cancer. Also it is depending on a lot of experimental tests."

To me, this is an acknowledgement that the invention is really no more than the idea that certain compounds can be used in nuclear imaging, in order to determine the cause of all cancers. Having read the specification carefully, I can find no clear disclosure of anything that goes beyond this. Mr Al-Darraji clearly envisages that the invention requires much (yet to be completed) experimental work. I agree with the examiner that such an invention cannot be considered to be sufficiently disclosed, as it represents, in effect, no more than the starting point for a potentially huge research programme.

15 As I have noted above, claim 1 encompasses the use of a vast number of potential compounds, and other than the use of gamma linolenic acid, there are no directions anywhere in the application as to the criteria upon which the other four compounds are to be selected. Even if claim 1 were limited to the use of gamma linolenic acid and the four example compounds listed at page 3 of the description, and even if it was also accepted that the skilled person would be able to prepare such compounds for use in nuclear imaging without difficulty, it is entirely unclear from the description as to whether those compounds should be used individually, or in combination. More importantly, there is nothing in the application that so much as points the skilled reader in the right direction as to exactly what to do with them, let alone offers a credible method by which the invention can be worked. I think it is completely unrealistic of the applicant to suggest that once equipped with these particular compounds, the skilled person would be able to go away and simply use standard methods of nuclear imaging to find the cause of all types of cancer.

16 The specification therefore leaves the skilled reader with no more than a vague notion of what to do (determine the cause of all cancers), and an unclear direction as to how to go about doing it (prepare gamma linolenic acid for nuclear imaging, along with four other compounds selected from a near infinite list of possible choices, and use standard imaging techniques). The disclosure of the invention in the specification is therefore completely unclear, and is insufficient.

Conclusion

17 I conclude that the claimed invention is not disclosed in a manner that is clear and complete enough for it to be performed by a skilled person, and is not fully supported by the description. Since I can find nothing in the specification that could overcome these issues, I therefore refuse the application under section 18(3) for failing to comply with sections 14(3) and 14(5)(c).

Appeal

18 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

MRS S E CHALMERS

Deputy Director, acting for the Comptroller