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28th April 2010

PATENTS ACT 1977

APPLICANT Maxluck Biotechnology Corp

ISSUE Whether patent application Nº GB 2428007 should be refused for lack of inventive step

HEARING OFFICER Stephen Probert

Ms Lucy Trueman (of Barker Brettell) for the applicant

Hearing date: 28th April 2010

TRANSCRIPT OF ORAL DECISION

1 The invention as now claimed in this application concerns a composition for use in the prevention or treatment of myocardial infarction, which in layman's terms is a heart attack.

2 In the latest examination report, dated 5th March 2010, the examiner maintains her previous objection that the claimed invention is obvious in the light of six earlier published documents, when combined with the common general knowledge. A pre-hearing report was issued by the Office shortly before the hearing, and by a different examiner. It is dated with yesterday's date (Tuesday 27th), although I understand that it was sent by email to one of Ms Trueman's colleagues at Barker Brettell on Monday.

3 There are two independent claims (1 & 7), and they read as follows:

> 1. A composition comprising:
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> a lactoferrin; and
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> a trivalent chromium compound;
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> wherein the trivalent chromium compound is selected from the group consisting of chromium (III) chloride hexahydrate, chromium (III) choride, chromium (III) acetate, chromium (III) sulfate, chromium picolinate, chromium nicotinate, chromium (amino acid chelate), GTF chromium, chromium yeast extract, chromium yeast and combinations thereof, for use in the prevention or treatment of myocardial infarction.
>
> 7. Use of a lactoferrin and a trivalent chromium compound, wherein the the trivalent chromium compound is selected from the group consisting of chromium (III) chloride hexahydrate, chromium (III) choride, chromium (III) acetate, chromium (III) sulfate, chromium picolinate, chromium nicotinate, chromium (amino acid chelate), GTF chromium, chromium yeast extract, chromium yeast and combinations thereof

in the manufacture of a medicament for the treatment or prevention of myocardial infarction.

4 The six documents relied upon by the examiner are said to all disclose "compositions comprising trivalent chromium and lactoferrin, which are useful in the control of diabetes, in particular by reducing blood glucose levels." Ms Trueman, for the applicant, agrees that these documents do teach the use of compositions comprising trivalent chromium and lactoferrin to treat diabetes, and there is therefore no need for me to review them in detail.

5 The examiner then says that since it is well known that diabetes promotes myocardial infarction, it would be obvious to a skilled person to consider using a diabetes treatment (eg. a composition comprising trivalent chromium and lactoferrin) to treat myocardial infarction. The examiner further states that it was known from medical journals pre-dating the application[1] that at least some hypoglycaemic drugs (eg. Metformin®) were known to reduce the risk of cardiovascular diseases, including myocardial infarction.

6 The applicant argues that there is also clear evidence that some hypoglycaemic drugs actually ***increase*** the risk of cardiovascular disease, such as myocardial infarction, and others give rise to side effects that increase the risk of cardiovascular disease. Therefore, Ms Trueman submitted to me that it cannot be said to be obvious to the skilled person to consider investigating hypoglycaemic drugs for use in treating myocardial infarction. In the specific case of Metformin®, Ms Trueman argued that it had only been shown to reduce the risk of cardiovascular disease in a restricted group of people who are obese and have type 2 diabetes.

The Law

7 Section 1(1)(b) says that a patent may granted only for an invention if, among other things, it involves an inventive step. Section 3 then defines what is meant by "inventive step" as follows:

> **Inventive Step**
>
> 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).

8 Ms Trueman agreed that the correct test for determining inventive step is the structured approach found in *Windsurfing* [2] as restructured by the Court of Appeal in *Pozzoli* [3]:

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;

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[1] References reviewed in the European Journal of Endocrinology

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

[3] Pozzoli SPA v BDMO SA [2007] EWCA Civ 588

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?

Applying the Windsurfing/Pozzoli steps

Step 1(a) The notional "person skilled in the art"

9 There was no difficulty here. The notional person skilled in the art is likely to be a chemist or pharmaceutical scientist involved in the research and/or development of drugs. He or she is likely to be qualified to at least degree level in chemistry or a related subject. The notional person may also be a team of such people.

Step 1(b) The common general knowledge

10 The common general knowledge is a bit harder to establish, not least because this is a technical field in which I have no relevant experience. The examiner reports that it is well known that diabetes is a condition that promotes myocardial infarction. She also reports that "hypoglycaemic drugs are known to be useful in treating myocardial infarction."

11 However, when deciding what is common general knowledge, one cannot just take those parts of it that support (or rebut) the objection that is being made. To do so opens oneself up to an accusation of ex post facto selection. The notional skilled person comes armed with **all** the common general knowledge[4], and cannot pick and choose selectively with the benefit of hindsight. Some aspects of the common general knowledge may lead the skilled person from the prior art ***towards*** the inventive concept; but equally other aspects of common general knowledge may lead him ***away*** from the inventive concept. That appears to be the case here, because Ms Trueman maintained that the skilled person would also know that some hypoglycaemic drugs actually increase the risk of cardiovascular disease, such as myocardial infarction, and others give rise to side effects that increase the risk of cardiovascular disease.

12 So the common general knowledge includes both of these apparently conflicting 'pointers', in addition to eg. degree-level chemistry and/or pharmacology.

Step 2 Identify the inventive concept

13 The inventive concept, in both claim 1 and claim 7, is found in the recognition that a specific composition (previously used in the treatment of diabetes) may be used to prevent or treat myocardial infarction. The specific composition being the combination of a lactoferrin and a trivalent chromium compound.

[4] Ratiopharm GmbH v Napp Pharmaceutical Holdings [2009] RPC 11 at 155-159

Step 3 Identify the difference(s)

14 There are six documents cited as forming part of the state of the art. Ms Trueman agreed that, for present purposes, there is no need for me to regard them separately. The difference in each case is, to all intents and purposes, the same. That is to say, they do not teach that the composition may be used to prevent or treat myocardial infarction. That is the difference.

Step 4 Is the difference obvious to the person skilled in the art?

15 I have to say that the answer to this question is far from clear to me. I can see the force of the examiner's objection, but it is tempered in my mind by the possibility that it is based on a limited view of the common general knowledge. I think it is possible to work backwards from a knowledge of the invention, and find support in the common general knowledge for an objection of lack of inventive step. But as I have indicated above, it is likely that the common general knowledge of the skilled person would not be as clear and untainted as the examiner has presented it.

16 Since, as Ms Trueman submitted, the common general knowledge also shows that some of the treatments for diabetes increase the risk of cardiovascular diseases, then this must ***reduce*** the likelihood that the skilled person would consider using a particular composition from the range of diabetic medicines to prevent or treat myocardial infarction. I was also impressed by Ms Trueman's argument that just because there is a clinical link between diabetes and heart disease, it does not follow that treatments for diabetes would be effective in treating or preventing heart attacks.

17 So where does that leave me? There is clearly doubt in my mind as to whether the invention claimed in this application involves an inventive step, and in such circumstances the applicant is entitled to the benefit of that doubt. The Manual of Patent Practice (MoPP) sets out Office practice in this situation at paragraphs 3.67 to 3.69. On the balance of probabilities, I think that the arguments (for and against inventive step) favour the applicant. I should also add that I thought paragraph 3.69 of MoPP was particularly relevant in this case.

Hyperlipidaemia

18 In the pre-hearing report that was issued shortly before the hearing, the new examiner set out an alternative objection of lack of inventive step based on a subset of the six documents already mentioned. Three of the six documents disclose the use of trivalent chromium and lactoferrin to treat hyperlipidaemia (ie. high cholesterol). Like Ms Trueman, I was slightly taken by surprise by this alternative objection as it was not mentioned in the final examination report.

19 Although the connection with hyperlipidaemia had been mentioned in a previous examination report, Ms Trueman said that she had assumed that this particular line of attack against the application had been abandoned as it had not been mentioned in the last two examination reports. Ms Trueman added that the hyperlipidaemia alternative had always seemed to her to be the weaker objection, not least because the non-patent literature found by the examiner (to show what was common general knowledge) had only suggested a link with diabetes and not with hyperlipidaemia.

20 It appeared to me that if I had doubts about the obviousness of the claims with regard to use of the composition (comprising lactoferrin and a trivalent chromium compound) in treating diabetes, those doubts would only be greater in relation to the use of that same composition in treating hyperlipidaemia — particularly as I have no basis for supposing that the common general knowledge of the skilled person would include a link between hyperlipidaemia and myocardial infarction. Consequently, for the same reasons as given above, I would give the applicant the benefit of the doubt here also.

Next steps

21 I have found that the objection(s) against this application cannot be sustained, and I am therefore sending the case back to the examiner to conclude the examination process. I note that the extended compliance period ends on 5 May 2010, and that the Office has indicated that it is unlikely to be extended further; which is why I have given this decision orally.

S PROBERT
Deputy Director acting for the Comptroller