Intellectual Property Office

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23 June 2023

PATENTS ACT 1977

APPLICANT	Medtrade Products Limited
ISSUE	Whether patent application GB 1802380.4 complies with Section 1(1)(b)
HEARING OFFICER	Peter Mason

DECISION

Introduction

1 This decision concerns patent application GB 1802380.4 entitled "Haemostatic material" in the name of Medtrade Products Limited, and whether the invention, as defined in the claims, comprises an inventive step as required by section 1(1)(b) of the Patents Act 1977 (herein after the "Act"). The application was filed on 14 February 2018 and was published on 21 August 2019 as GB 2571080.

2 In the examination report dated 02 February 2023 the examiner presented the view that the independent claims did not involve the inventive step required by section 1(1)(b) of the Act, in respect to cited prior art documents. In a letter accompanying this examination report the applicant was invited to request a hearing on the matter. The attorney accepted the examiner's invitation to refer the application to a hearing officer.

3 The hearing took place on 1 June 2022 where Mr. Christopher MacDonald of Wilson Gunn Patent and Trade Mark Attorneys, represented Medtrade Products Limited and was accompanied by Mr. Andrew Hoggarth and Mr. Matthew Grist, (both named inventors on the application).

Preliminary Matters

The only substantive matter before me is whether the invention involves an inventive step with respect to the cited prior art. At this time the search is up to date for both s.2(2) and s.2(3) art and therefore, if I find that the claimed invention comprises an inventive step with respect to the prior art, I will return the application to the examiner to conclude the processing.

The Invention

4 The application relates to a carrier material with a composition applied thereto wherein the composition comprises a haemostat agent, a bioadhesive agent and an antifibrinolytic agent wherein the bioadhesive agent is specified (see claim below) The material is intended, though not claimed as such, to be used as a wound dressing to prevent bleeding out.

5 The claims have been amended since filing and are now presented, as filed on 27 January 2023. There are three independent claims. Claim 1 reads:

> *A carrier material comprising a haemostatic composition applied thereto, wherein the haemostatic composition comprises a haemostat agent, a bioadhesive agent and an antifibrinolytic agent; wherein the bioadhesive agent comprises one or more selected from: a cross-linked polymer of acrylic acid, the polymer having a molecular weight of at least 50,000 g/mol to 300,000 g/mol; or a carbomer, 2-acrylamido-2-methylpropane sulfonic acid, or a high molecular weight acrylic acid polymer cross-linked with divinyl glycol or the salts of polyacrylic acid cross-linked with divinyl glycol.*

6 Claim 10 reads:

> *A method of manufacturing a carrier material according to any of claims 1-8, the method comprising the steps of combining a haemostat agent with a bioadhesive agent and an antifibrinolytic agent, wherein the bioadhesive agent comprises one or more selected from: a homopolymer comprising a polymer of acrylic acid cross-linked with allyl sucrose or allyl pentaerythritol; a copolymer comprising a polymer of acrylic acid and C_{10}-C_{30} alkyl acrylate cross-linked with allyl pentaerythritol; and/or a carbomer homopolymer or copolymer comprising a block copolymer of polyethylene glycol and a long chain alkyl acid ester, or a carbomer, 2-acrylamido-2-methylpropane sulfonic acid, or a high molecular weight acrylic acid polymer cross-linked with divinyl glycol or the salts of polyacrylic acid cross-linked with divinyl glycol.*

7 Claim 12 reads:

> *A carrier material according to any of claims 1-8 for the promotion of haemostasis.*

8 The applicant has also submitted an auxiliary claim set (29 March 2023) to be considered should the claims be deemed unallowable. The auxiliary request similarly contains three independent claims.

9 Auxiliary claim 1 reads:

> *A carrier material comprising a haemostatic composition applied thereto, wherein the haemostatic composition comprises a haemostat agent, a bioadhesive agent and an antifibrinolytic agent; wherein the haemostat agent comprises oxidised regenerated cellulose, kaolin, gelatin, calcium ions, collogen, chitin, chitosan or a chitosan salt, derivatives of chitosan, derivatives of chitin, and any combination thereof; and wherein the bioadhesive agent comprises one or more selected from: a cross-linked polymer of acrylic acid, the polymer having a molecular weight of at least 50,000 g/mol to 300,000*

g/mol; or a carbomer, 2-acrylamido-2-methylpropane sulfonic acid, or a high molecular weight acrylic acid polymer cross-linked with divinyl glycol or the salts of polyacrylic acid cross-linked with divinyl glycol.

10 Auxiliary claim 9 reads:

> *A method of manufacturing a carrier material according to any of claims 1-8, the method comprising the steps of combining a haemostat agent with a bioadhesive agent and an antifibrinolytic agent, wherein the haemostat agent comprises oxidised regenerated cellulose, kaolin, gelatin, calcium ions, zeolite, collogen, chitin, chitosan or a chitosan salt, derivatives of chitosan, derivatives of chitin, and any combination thereof; and wherein the bioadhesive agent comprises one or more selected from: a homopolymer comprising a polymer of acrylic acid cross-linked with allyl sucrose or allyl pentaerythritol; a copolymer comprising a polymer of acrylic acid and C_{10}-C_{30} alkyl acrylate cross-linked with allyl pentaerythritol; and/or a carbomer homopolymer or copolymer comprising a block copolymer of polyethylene glycol and a long chain alkyl acid ester, or a carbomer, 2-acrylamido-2-methylpropane sulfonic acid, or a high molecular weight acrylic acid polymer cross-linked with divinyl glycol or the salts of polyacrylic acid cross-linked with divinyl glycol.*

11 Auxiliary claim 11 reads:

> *A carrier material according to any of claims 1-7 for the promotion of haemostasis.*

12 It is noted, that although the attorney's covering letter accompanying the auxiliary request states that zeolite has been removed from the list of haemostatic agents, it is still present in auxiliary claim 5. Should I find in favour of the applicant on the basis of the auxiliary claims, this inconsistency should be removed.

13 The law – inventive step

14 Section 1(1) of the Act sets out the requirements which need to be met for a patent to be granted, my emphasis added:

> *A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –*
>
> *(a) the invention is new;*
>
> ***(b) it involves an inventive step;***
>
> *(c) is capable of industrial application;*
>
> *(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;*
>
> *and references in this Act to a patentable invention shall be construed accordingly.*

15 Section 3 of the Act sets out how inventive step is determined:

> *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).*

16 Matter which "forms part of the state of the art by virtue only of section 2(2)" is all matter which was made available to the public before the filing date of the application in question as no earlier priority date has been claimed. In this case all matter published before 14 February 2018.

17 The approach used to assess inventive step is set out in Windsurfing International v Tabur Marine[1] reformulated in light of Pozzoli SPA v BDMO SA[2]:

> *(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 I shall follow this approach below.

Arguments and analysis

19 The examiner's argument was set out in the pre-hearing report dated 10 February 2023.

20 The skilled person was stated to be "a scientist seeking to develop compositions to promote haemostasis and control bleeding in wounds which have reduced compression time for clotting"

21 The skilled person was considered to be aware of WO2012/123728 (hereinafter D8) which discloses a haemostat and a relevant bioadhesive on a wound dressing and Medical Hypotheses, vol. 81, no. 6, 2013, pages 1036-10389 (hereinafter D9) which is explicit in its title "Should chitosan and tranexamic acid be combined for improved hemostasis after sinus surgery?". Chitosan being a haemostatic agent and tranexamin acid (TXA) being an anti-fibrinolytic agent. I would just add that anti-fibrinolytic agents can be considered a subset of haemostat agents, anti-fibrinolytic referring to the mechanism, *i.e.* prevention of the blood clot from degrading. This is

[1] Windsurfing International v Tabur Marine (Great Britain) Ltd [1985] RPC 59
[2] Pozzoli SPA v BDMO SA: [2007] EWCA Civ 588

the case with D9 where TXA is referred to as a haemostat, but is stated to be used for anti-fibrinolytic purposes.

22 The examiner then identified the inventive concept as a composition suitable for promoting haemostasis comprising a combination of a haemostatic agent, an antifibrinolytic agent and a specified bioadhesive (as defined in the claims).

23 The difference between D8 and the inventive concept is therefore the inclusion of the anti-fibrinolytic agent.

24 Since D9 teaches that combining chitosan and TXA is a useful thing to do for improving blood clotting, the skilled person would therefore find it obvious to improve on D8 by using the better combination taught by D9. Any technical benefits deriving therefrom are merely lying in the road.

25 The attorney has argued three strands:

i) the inventive concept has been construed too broadly by the examiner

ii) there is a technical benefit from doing this (this isn't actually contrary to the examiner's comments who agrees but that it would still be obvious), and

iii) why hasn't it been done before?

26 I will consider each in turn.

27 i) The attorney argued that the inventive concept should also include the ability to control bleeding effectively in a defined period in both normal and coagulopathic blood. Having considered this, I agree with the examiner's assessment. Firstly, the law on inventive step does not concern itself with reasons for doing something, just whether it would be obvious to do something for any reason. Secondly, to consider the claim in light of the advantages disclosed in the application must involve a certain degree of knowledge of the application which is forbidden to the examiner when assessing inventive step. I find that the contribution is merely the combination of carrier, haemostatic agent, anti-fibrinolytic agent and said specified bioadhesive. Therefore, this does not undermine the examiner's argument.

28 ii) While patent law is framed with the policy of increasing the sum of useful human knowledge, the law regarding inventive step as framed in Windsurfing and Pozzoli does not have the question "is there a technical benefit?" Merely "is it obvious to do?" This can be for any purpose. If it is obvious to work any portion of the claim, then the claim is bad for want of inventive step. The unexpected technical effect is therefore merely a happy coincidence. The applicant has provided useful evidence supporting the presence of the improved clotting times for chitosan and TXA, and on subsequent request further evidence showing other haemostatic agents and plausible arguments that the precise identity of the anti-fibrinolytic agent is not relevant.

29 The skilled person would know that bioadhesives may interfere with actives in wound dressings, but would also know of options to avoid this. The specified bioadhesive in D8 is indeed one which does not interfere.

30 An unexpected technical effect may arise and be accounted for in the concept of a selection invention where a hitherto unknown technical contribution may suggest that the claims are inventive.

31 I should note here that to qualify for a selection invention, the invention has to be rendered plausible by the patent specification as filed. The later filed evidence is considered to be cited in support of that technical effect being plausible across a range of haemostatic agents.

32 During the hearing, the point was made that the evidence pointed only to a technical benefit arising from one specific combination of haemostat and antifibrinolytic agent, *viz* chitosan and TXA. An opportunity was given for the applicant to provide further submissions, the applicant has provided an auxiliary request claim set and also further evidence to show that the effects were plausible across a range other haemostats and anti-fibrinolytic agents. Having reviewed those extra submissions (dated 29 March 2023) I acknowledged that the arguments presented relating to the present claims are also relevant to the auxiliary request.

33 At first glance, the claims may suggest that in the context of selection inventions the claims may be inventive, this is not always so. If a step is obvious, it remains obvious however astonishing the result of taking it is. In the examiner's view, the claims are obvious regardless of the technical affects achieved. I also note that D9 already suggests the improved technical effect in blood clotting by combining chitosan and TXA, the TXA being explicitly added for its anti-fibrinolytic properties.

34 So far I agree with the examiner's view that modifying D8 in light of the improvements taught by D9 the skilled person would find it obvious to apply them to D8 and arrive at the subject matter of the claims.

35 iii) The attorney has argued that if it were obvious, why hadn't is been done before? The attorney seeks to ante-date the relevant disclosure to 1989 based on a reference in D9 which discusses the use of TXA alone. The skilled community of those working in the field of blood clotting failing to invent the claims over a period of almost 30 years. However, I am not persuaded of the date. The disclosure of combining chitosan and TXA in D9 is September 2013 and that is the relevant date here. Because that is the date when the skilled person would be aware of the advantages of combing a haemostatic agent and an anti-fibrinolytic agent (the two active components).

36 Why wasn't it done before is a relevant question to be asked, though the fact that no-one has followed a particular path before does not of course dispose of an obviousness objection. No further discussion has been provided by the attorney beyond the age of the document and suggesting the skilled person had not found it obvious. This could have pointed to an inventive step had there been a long gap between D9 teaching the advantages of combining chitosan and TXA. As noted above the relevant gap between the skilled person becoming aware D9's teaching and the applicant's filing is roughly 4 years and 5 months.

37 In considering this argument I have found help in some of the questions posed by Laddie J in Haberman v Jackel[3]. The most relevant of the questions are:

> *(a) What was the problem which the patented development addressed?*
>
> *(b) How long had that problem existed?*
>
> *(c) How significant was the problem seen to be?*
>
> *(d) How widely known was the problem and how many were likely to be seeking a solution?*
>
> *(g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?*

38 This is a field of technology where there are already good products and the problem lies in making them better. Often such products are improved incrementally and by considering the advances made by others. Hence a reasonably diligent literature survey would suffice to put D9 within the common general knowledge of the skilled person.

39 Question (g) then appears to be the most helpful when considering whether the advance not having been done before indicates invention. There are multiple pathways and although things may be obvious, for example budgets limit the scope of investigating all obvious pathways. Since the disclosure of D9 points towards a better blood clotting agent then it would be obvious to the skilled person to try that at some point. The reasons for not doing it yet are business reasons rather than technical ones. I would just add that one technical hitch could be in incompatibility with the bioadhesive, however, a wide range of these are known to the skilled person who would easily select a compatible bioadhesive such as those of D8 which lie within the scope of the applicant's claims.

40 None of the attorney's arguments are persuasive and therefore I find that claims 1, 9, and 11 are obvious.

41 All of the dependent claims limit by materials which are disclosed within D8 and D9 and are therefore also considered to be obvious.

42 Turning to the auxiliary request submitted on 28 March 2023. This proposes to restrict the claims by introducing the specific components of previous claim 3 (except for the zeolite). The attorney has argued that all antifibrinolytic agents are suitable. The explained pathway is plausible and the request is supported.

43 In the attorney's opinion the arguments put forward in relation to the latest claims on file are equally applicable to the auxiliary request. I agree with the attorney's opinion, the claims of the auxiliary request are a subset falling within the scope of the claims on file. In particular, they narrow the scope of the haemostat agent to specific compounds. The haemostat agent used in D8 and D9 still falls within the scope of

[3] Haberman v Jackel [1999] FSR 685

the auxiliary request, so the reasoning set out above is also equally applicable to the auxiliary claims. Therefore these claims are also refused.

Conclusion

44 It is my decision that the invention claimed in claim 1 is not patentable because it lacks an inventive step under s1(1)(b) and as such I refuse it under s.18(3).

Appeal

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

Peter Mason

Deputy Director, acting for the Comptroller