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Datasheet for the decision of 18 June 2015

Case Number: T 0218/12 - 3.2.02

Application Number: 07253438.1

Publication Number: 1897500

IPC: A61B17/04, A61B17/06

Language of the proceedings: EN

Title of invention:
Barbed sutures

Patent Proprietor:
Covidien LP

Opponent:
Angiotech Pharmaceuticals, Inc.

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Keyword:
Grounds for opposition - added subject-matter (yes)

Decisions cited:
G 0001/93

Catchword:

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Case Number: T 0218/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 June 2015

Appellant: (Patent Proprietor)	Covidien LP 15 Hampshire Street Mansfield, MA 02048 (US)
Representative:	Alcock, David D Young & Co LLP Briton House Briton Street Southampton SO14 3EB (GB)
Respondent: (Opponent)	Angiotech Pharmaceuticals, Inc. 1618 Station Street Vancouver, British Columbia V6A 1B6 (CA)
Representative:	Gowshall, Jonathan Vallance Forresters Skygarden Erika-Mann-Strasse 11 80636 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 December 2011 revoking European patent No. 1897500 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	P. L. P. Weber

Summary of Facts and Submissions

I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 2 December 2011, to revoke European patent No. 1 897 500.

II. The Opposition Division held that the subject-matter of claim 1 of the main request, corresponding to the patent as granted, extended beyond the content of the application as originally filed. The auxiliary requests were considered not to comply with Article 123(2) or (3) EPC.

III. The notice of appeal was received on 26 January 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 27 March 2012.

IV. The respondent's reply to the statement of grounds was received on 5 October 2012.

V. The Board summoned the parties to oral proceedings and set out its provisional opinion by a communication dated 11 March 2015.

VI. Oral proceedings were held on 18 June 2015.

VII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in the alternative, of one of the first to third auxiliary requests, all filed with letter dated 27 March 2012.

A request related to the opponent status was withdrawn.

VIII. The respondent requested that the appeal be dismissed.

IX. Claim 1 of the main request, which corresponds to claim 1 of the patent as granted, reads as follows:

"A surgical suture (10, 110) comprising:
an elongated body (14, 114) comprising at least one filament having a proximal end and a distal end;
the elongated body (14, 114) having barbs (12, 12a, 12b) projecting from the elongated body (14, 114) towards at least one end of said suture thereby forming an angle between the barbs (12, 12a, 12b) and the suture body (14, 114);
and an effective amount of a bioactive agent disposed solely within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114)."

Claim 1 of the first auxiliary request reads as follows (additions compared to claim 1 of the main request are underlined):

"A surgical suture (10, 110) comprising:
an elongated body (14, 114) comprising at least one filament having a proximal end and a distal end;
the elongated body (14, 114) having barbs (12, 12a, 12b) projecting from the elongated body (14, 114) towards at least one end of said suture thereby forming an angle between the barbs (12, 12a, 12b) and the suture body (14, 114);
and an effective amount of a bioactive agent disposed solely within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114) so as to place the bioactive agent at precisely defined locations within a tissue wound closure."

Claim 1 of the second auxiliary request reads as follows (additions compared to claim 1 of the main request are underlined):

"A surgical suture (10, 110) comprising:
an elongated body (14, 114) comprising at least one filament having a proximal end and a distal end;
the elongated body (14, 114) having barbs (12, 12a, 12b) projecting from the elongated body (14, 114) towards at least one end of said suture thereby forming an angle between the barbs (12, 12a, 12b) and the suture body (14, 114);
and an effective amount of a bioactive agent disposed solely within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114), wherein the bioactive agent is disposed within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114) by spraying."

Claim 1 of the third auxiliary request reads as follows (additions compared to claim 1 of the main request are underlined):

"A surgical suture (10, 110) comprising:
an elongated body (14, 114) comprising at least one filament having a proximal end and a distal end;
the elongated body (14, 114) having barbs (12, 12a, 12b) projecting from the elongated body (14, 114) towards at least one end of said suture thereby forming an angle between the barbs (12, 12a, 12b) and the suture body (14, 114);
and an effective amount of a bioactive agent disposed solely within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114) so as to place the bioactive agent at precisely defined locations within a tissue wound closure, wherein the bioactive agent is

disposed within the angle between the barbs (12, 12a, 12b) and the suture body (14, 114) by spraying."

X. The appellant's arguments may be summarised as follows:

In the impugned decision the Opposition Division considered that the term "solely" in claim 1 of the main request could not be directly and unambiguously derived from the application as filed.

It was undisputed that the application as filed did not provide any literal basis for the term "solely". However, the Opposition Division had taken an overly literal approach, whereas the requirements of Article 123(2) EPC should be assessed focusing on what is really disclosed to a technical audience. The Opposition Division's conclusion was incorrect for the main reasons that the Opposition Division had not placed sufficient weight on the technical teaching in the application concerning the positioning of the bioactive agent.

From the description of the background art it could be seen that the application as filed was related to barbed sutures. However, it was immediately apparent to the skilled reader that the invention could not just be directed to barbed sutures in general, since the discussion of the state of the art made clear that barbed sutures as such were already known. The invention was therefore directed to something else. That was the content of the summary of the invention which was not acknowledged to be present in the background art, i.e. barbed sutures including a bioactive agent deposited with the angle formed between the barb and the suture surface. The presence of the bioactive agent at that location was the essence of the

invention.

The application described the invention in detail, in particular the technical effect and advantages of including the bioactive agent on the barbed suture. In paragraph [0005] it was explained that a use of lower amounts of antimicrobial agents to achieve the desired antimicrobial effect in vivo was permitted. Paragraph [0013] explicitly taught that the presence of the bioactive agent within the angle between the barb and the suture body resulted in the placement of the bioactive agent at precisely defined locations within a tissue wound closure which thereby provided a unique controlled and sustained release dosage form. The meaning of the term "precisely", employed in that paragraph, was critical. It had to be given sufficient weight when considering the content of the application as filed. A definition by the Collins English Dictionary, 21st Century Edition, is:

"designating a certain thing and no other: this precise location".

It would be a significant violation of the term "precisely" to say that the bioactive agent had to be placed at that location, but it could also be at other undefined locations as well. As soon as one started spreading around the bioactive agent, the precision would be lost. Moreover, the entire application only mentioned one particular location of the bioactive agent on the suture. Accordingly, the only logical and technically sensible interpretation that could be taken from the description of the background art, the summary of the invention, paragraph [0013] and the rest of the detailed description, was that the bioactive agent had to be placed within the angle between the barb and the

suture body, and no other location.

Many of the methods of preparing the sutures disclosed in the application as filed were quite suitable for placing the bioactive agent solely in the angle between the barb and the suture body. With some it might be difficult, but not impossible. In any case, one should conclude that there was no original disclosure of the placement of the bioactive agent solely in the angle only if all disclosed methods were not suitable for that placement.

The Opposition Division's conclusion that it was possible to provide a unique controlled and sustained dosage form as required by paragraph [0013] by placing the bioactive agent "predominantly" within the angle as well as in other places on the suture was in conflict with the use of the term "precisely" in that paragraph. The term "predominantly" employed in the impugned decision could not be found in the application as filed.

With regard to the auxiliary requests, the added features had an explicit basis in the application as filed.

The presence of the term "so as to place the bioactive agent at precisely defined locations within a tissue wound closure" in claim 1 of the first and the third auxiliary requests specified the technical meaning of having the bioactive agent at those locations. The precision had to come from the active agent being within the angle. As a result, the term "solely" added nothing technical and was permitted according to decision G 1/93.

The definition of the method for disposing the bioactive agent in the angle as in claim 1 of the second and third auxiliary requests was intended to address any issues regarding possible methods of preparation of the suture which could be considered not suitable for disposing the bioactive agent solely in the angle. By spraying that was clearly possible.

XI. The most relevant of the respondent's arguments, which led to the dismissal of the appeal, are elaborated in the reasons for the decision.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention relates to a surgical suture, of the kind used for stitching up wounds with the aid of a surgical needle.

More particularly, the invention proposes a barbed suture comprising an elongated body having barbs projecting at an angle from the suture body. Such barbs prevent the slippage of the suture in the wound, thereby enabling the placement of the desired tension in the tissue in order to effectively keep the wound closed. A bioactive agent, e.g. a drug, is disposed in the barb angles, formed between each barb and the suture body. This allows placing the bioactive agent "at precisely defined locations within a tissue wound closure, which thereby provides a unique controlled and

sustained release dosage form" (paragraph [0013] of the application as filed).

3. Main request

It has to be established whether the definition that the bioactive agent is disposed solely within the angle, i.e. the addition of the term "solely", extends the subject-matter of claim 1 of the patent as granted beyond the content of the application as filed.

As the respondent pointed out in the reply to the statement of grounds and the appellant did not dispute, in the application as filed the word "solely" or any of its derivatives does not appear anywhere.

It is also clear that, on the basis of claim 1, the description of the background art and the detailed description of the technical effects of the application as originally filed (in particular paragraphs [0005], [0006] and [0013]), a central point of the invention as originally disclosed - or the "essence of the invention", as argued by the appellant in the statement of grounds - in contrast with the background art, is the provision of a bioactive agent within the angle between the barbs and the suture body.

However, this fact by itself does not amount to a disclosure that the bioactive agent is not meant to be present anywhere else on the suture.

The fact that the original application mentions several times that the bioactive agent should be placed in that angle but does not specify any other location can only confirm the importance of its placement in that angle. However it cannot amount to a direct and unambiguous

disclosure that it is present only there.

The appellant's submissions based on paragraph [0013] of the application as filed, which states that the presence of the bioactive agent in that angle "places the bioactive agent at precisely defined locations within a tissue wound closure, which thereby provides a unique controlled and sustained release dosage form" are not convincing.

In the Board's opinion, the technical meaning of that paragraph, in context, is that the presence of the bioactive agent in the angles will ensure its release "precisely" at the points of the suture which need it most, because they apply the most tension on the tissue. It is the local release at these precise points that permits the use of a lower amount of antimicrobial agents to achieve the desired antimicrobial effect in vivo, in accordance with the objective of the application as filed (paragraph [0005]) as pointed out by the appellant.

However, as the respondent submitted, while the term "precisely" qualifies the locations which must be provided with the bioactive agent, it does not provide exclusivity. The original application does not hint at any disadvantage or problem connected with the presence of the active agent elsewhere on the suture as well. Hence, other locations may well be provided with the bioactive agent too, even if that is possibly less important for therapeutic purposes.

The appellant's interpretation of the sentence in paragraph [0013] including the wording "precisely defined locations" is not confirmed by any other part of the description either.

On the contrary, paragraph [0060] reads "Suture 10 may include a bioactive agent (not shown) disposed within the angle between the barb 12 and suture body 14" (emphasis added). Paragraph [0062], lines 42 to 44 reads "An antimicrobial agent may be disposed within the angle formed between the barbs 112a and 112b and suture body 114" (emphasis added).

It follows that the appellant's interpretation that "precisely defined locations" should mean those locations and no others cannot be accepted.

Furthermore, the Board shares the respondent's view that the methods of manufacture of the barbed suture as described in the original application (paragraphs [0019], [0032], [0034], [0036] and [0037]) imply, as a general principle, the presence of the bioactive agent on the whole suture. Whether some of these methods could also be employed, taking certain steps, to deposit the bioactive agent solely in the angle is not disclosed and not self-evident. Hence, there is no direct and unambiguous disclosure of such steps.

Consequently, the Board is of the opinion that the application as filed discloses the provision of the bioactive agent **also in the angle** between the barbs, but there is no direct and unambiguous disclosure that the bioactive agent is **only there**.

As a result, the addition of the term "solely" extends the subject-matter of claim 1 of the patent as granted beyond the content of the application as filed.

Hence, the main request is not allowable under

Article 100(c) EPC.

4. *Auxiliary requests*

Claim 1 of all the auxiliary requests still comprises the problematic term "solely".

In contrast to the appellant's view, the Board is of the opinion that the additional functional features concerning the placement, in use, at "precisely defined locations" and the method for disposing the bioactive agent on the suture by spraying do not have an impact on the interpretation of the term "solely" so as to deprive it of any technical meaning or limiting effect. Hence, the ruling of decision G 1/93 does not apply.

As the respondent submitted, for the same reasons as those explained above with regard to the disclosure of paragraph [0013] of the application as filed, the fact that the locations of placement are "precisely defined" in the claim does not provide the exclusivity of those locations, which still derives from the disputed term "solely".

The definition of the method of deposition of the bioactive agent by spraying does not change the situation. Such a method alone does not imply the presence of the bioactive agent "solely" in the angle either. Hence, the term "solely" still provides the limitation of excluding the presence of the bioactive agent elsewhere on the suture, which, originally, was not directly and unambiguously disclosed.

It follows that the subject-matter of claim 1 of each auxiliary request extends beyond the content of the application as filed too.

Hence, the auxiliary requests are not allowable under Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated