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**Datasheet for the decision
of 6 December 2012**

Case Number: T 1961/08 - 3.4.01

Application Number: 03764687.4

Publication Number: 1539298

IPC: A61N 5/02

Language of the proceedings: EN

Title of invention:

Method for improved safety in externally focused microwave
thermotherapy for treating breast cancer

Applicant:

Celsion (Canada) Limited

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Added subject-matter (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1961/08 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 6 December 2012

Appellant: Celsion (Canada) Limited
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 9 May 2008
refusing European patent application
No. 03764687.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: F. Neumann
Members: H. Wolfrum
A. Pignatelli

Summary of Facts and Submissions

I. European patent application 03 764 687.4 (publication No. EP 1 539 298) was refused by a decision of the examining division dispatched on 9 May 2008 refusing the application for the reason of lack of novelty (Article 52(1) and 54(3) EPC 1973) of the subject-matter of a main request then on file and for the reason of added subject-matter (Article 123(2) EPC) for an auxiliary request then on file.

II. The applicant lodged an appeal against the decision on 18 July 2008. The prescribed appeal fee was paid on the same day. A statement of grounds of appeal was filed on 18 September 2008.

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of a single claim (claim 1) annexed thereto as attachment A. The claim corresponds to that of the auxiliary request on which the contested decision is based.

Moreover, an auxiliary request for oral proceedings was made.

III. On 18 June 2012 the appellant was summoned to oral proceedings.

In an annex accompanying the summons pursuant to Article 15(1) RPBA the Board addressed in particular the issue of added subject-matter (Article 123(2) EPC). In this context, the Board doubted that the application documents as originally filed provided a clear and unambiguous disclosure of a thermotherapy system with two

separate groups of fans or tubes for cooling different regions of the breast.

- IV. In the oral proceedings, which took place on 6 December 2012, the appellant reiterated its request made in writing. A printout of the internet site of Lockwood Products, Inc. (www.loc-line.com) concerning contact information and excerpts of information about Loc-Line - Quarter Inch products was filed.
- V. Independent claim 1 of the appellant's request reads as follows :

"1. Thermotherapy system, comprising

two or more coherent waveguide applicators (100) controlled by an adaptive phased array algorithm, wherein each waveguide applicator (100) comprises an air-cooled rectangular waveguide applicator aperture (600),

a two-channel adaptive phased array to heat deep tissues,

two compression plates (200) made from a dielectric, a metallic shielding strip (605) having a width of 1 to 2 cm covering the top section of the waveguide aperture (600), and

a microwave absorbing pad (610) attached to the top surface of at least one of the waveguide applicators (100) and covering the entire top surface of the at least one waveguide applicator (100)

a microwave absorbing pad (620) on the top surface of each compression plate (200);

a metallic shield (615) covering the top portion of each compression plate (200) on the surface facing the waveguide applicator (100);

fans or tubes configured to direct air or cooled air into an air gap (635) region near the top of the compression plates (200) to avoid overheating the breast skin and chest wall region;

characterized by

fans or tubes configured to direct air or cooled air towards the sides of the breast skin and nipple to avoid overheating the sides of the breast skin and nipple."

VI. The appellant's arguments may be summarized as follows:

A basis of disclosure for a thermotherapy system having two distinct groups of fans or tubes was to be seen in originally-filed method claim 1 which comprises two distinct steps of cooling breast tissue, ie a step of directing air by means of fans or tubes into an air gap region near the top of the compression plates to avoid overheating the breast skin and chest wall region (step e)) and a step of directing air by means of fans or tubes toward the sides of the breast skin and nipple to avoid overheating the sides of the breast skin and nipple (step f)).

Moreover, although there was admittedly no disclosure *expressis verbis* of separate groups of cooling fans or tubes to be used for the cooling of different breast regions, such an arrangement would be apparent to the skilled reader of the original application as a whole. On page 25, lines 26 to 28, of the originally-filed description the reader found the information "*To provide additional protection against skin damage from the microwave fields, air flow 180 is provided by one or more cool-air fans (not shown).*" Due to the indication that no further details are shown, the skilled person was forced to contemplate where exactly cooling was needed. On

page 39, line 27 to page 40, line 1, the original description referred to the provision of tubes or fans pointing into a gap region provided between the applicator and breast tissue (*ie* gap region 635 as it was depicted *inter alia* in Figure 15) "*to cool the region in proximity to the base of each side of the breast and chest wall region*". It was indicated that airflow could be guided into the said gap by means of "*plastic air tubes with flared or conical shaped nozzles, such as those manufactured by Lockwood Products, Inc., Lake Oswego, OR*". A datasheet obtained from the internet homepage of Lockwood Products, Inc, revealed that since 1984 (*ie* well before the priority date of the present application) such nozzles had orifices of the size of an inch and fractions thereof. The skilled reader of the application documents as filed was thus immediately aware of the fact that the cooling fans referred to on page 39 of the description were unsuitable for the task of cooling the side of the breast and the nipple, *ie* those parts of the breast which were referred to in step f) of originally-filed claim 1, and that in consequence a second, different set of fans had to be provided for their cooling.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 99 EPC and is, therefore, admissible.
2. Added subject-matter (Article 123(2) EPC)
 - 2.1 The single claim on file is directed to a thermotherapy system which is specified to comprise, *inter alia*, "*fans or tubes configured to direct air or cooled air into an*

air gap (635) region near the top of the compression plates (200) to avoid overheating the breast skin and chest wall region" and is characterized by "fans or tubes configured to direct air or cooled air towards the sides of the breast skin and nipple to avoid overheating the sides of the breast skin and nipple".

The repeated definition in the preamble and the characterizing portion of the claim of fans or tubes for directing air or cooled air to different regions of the breast implies the provision of two distinct groups of fans or tubes serving different purposes.

- 2.2 The application as originally filed does not contain any device claim but claims only methods which were found in the examination proceedings to constitute methods of therapeutic treatment of the human body which, as such, were excluded from patentability.

In order to overcome this deficiency, original method claim 1 was transposed into the device claim now on file. In this context, the step of directing air by means of fans or tubes into an air gap region near the top of the compression plates to avoid overheating the breast skin and chest wall region (original claim 1 : step e)) and the step of directing air by means of fans or tubes toward the sides of the breast skin and nipple to avoid overheating the sides of the breast skin and nipple (original claim 1 : step f)) were converted into the two apparatus features of present claim 1 which define respective fans or tubes for cooling these two distinct regions.

2.3 As a matter of fact, step f) of originally-filed claim 1 is the only piece of information in the original application documents which specifically concerns the cooling of the sides of the breast skin and nipple.

However, the mere fact that original claim 1 defines separate steps of directing air by means of fans or tubes to avoid overheating of the breast skin and chest wall region, on the one hand, and to avoid overheating the sides of the breast skin and nipple, on the other hand, does not constitute in itself a direct and unambiguous disclosure for the provision of separate means for directing air, ie for the provision of separate groups of fans or tubes. This is all the more true as one could readily envisage the originally-claimed tasks to be performed by the operation of a single moveable fan.

2.4 Moreover, searching the originally-filed description for relevant pieces of disclosure in this respect does not reveal any basis for the provision of distinct groups of fans or tubes, either.

The statement referred to by the appellant "*To provide additional protection against skin damage from the microwave fields, air flow 180 is provided by one or more cool-air fans (not shown).*" on original page 25, lines 26 to 28 forms part of the description of Figure 6 of the application. The figure depicts a female patient lying face down on a treatment table and includes a graphical depiction of an "AIR FLOW FROM FANS OR TUBES" towards one of the breasts that is compressed between two parallel plates. The air flow is shown to be at one of the sides of the breast which is left open by the plates and is directed at an oblique angle from below the nipple upwards to the breast in the direction of the chest.

There is nothing in this illustration which would even remotely incite a skilled viewer to contemplate the use of two different cooling means for cooling specific breast regions.

The only further reference to an airflow from tubes or fans for the purpose of cooling the breast is given on page 39, line 27 to page 40, line 1, of the originally filed description. This passage, which was also referred to by the appellant, reads: "*Applicators 100 are designed so that a gap region 635 is provided between the applicator and the breast tissue. Gap region 635 allows airflow from external air tubes or fans that are pointed into the gap to cool the region in proximity to the base of each side of the breast and chest wall region. In a preferred embodiment, plastic air tubes with flared or conical shaped nozzles, such as those manufactured by Lockwood Products, Inc., Lake Oswego, OR may be used to guide airflow into gap region 635 to cool the breast region.*" The gap region 635 is shown in Figures 15 and 16, neither of which, however, comprises any indication as to the location of any air tubes or fans or the direction of any associated air flow.

As a matter of fact, gap region 635 as depicted in Figures 15 and 16 opens to the same side from which the air flow indicated in Figure 6 originates. For this reason alone and in the absence of any concrete indication to the contrary, the skilled reader of the application documents as filed has no reason to assume that different groups of fans or tubes should be provided for supplying the air flow referred to in the aforementioned references.

2.5 Based on selected excerpts from the internet site of Lockwood Products, Inc., regarding nozzles for a modular hose system, the appellant has composed a scenario, according to which the skilled reader would understand the reference in the cited passage of page 39 of the description to the "*external air tubes or fans that are pointed into the gap*" (emphasis added) which is "*provided between the applicator and the breast tissue*" as a disclosure of tubes and fans with associated nozzles that were so small that they were suited exclusively for the cooling of the breast skin close to the chest wall region. Consequently, it was immediately clear to the reader of the application documents as originally filed that another, separate set of tubes or fans had to be employed for the cooling of the side of the breast skin and nipple.

2.6 This line of argumentation is not convincing.

It ignores the fact that the application documents as originally filed fail to provide any concrete information as to the structure and arrangement of the tubes or fans for providing the cooling air flow. In particular, the mere reference to a manufacturer of tubes and nozzles included in the cited passage on page 39 of the application, though it may be regarded as a cross-reference to a potential source of information, falls short of identifying any concrete technical features of the specific tubes and nozzles used in the claimed thermotherapy system or their particular function within this system. In particular, there is not indication in the reference on page 39 of the application that the "plastic air tubes with flared or conically shaped nozzles" have the specific dimensions cited by the appellant to support his assertion that the air flow was provided as a fine jet. The decisive criterion is not

which potential embodiments a skilled reader could have possibly imagined but which technical information he would directly and unambiguously gather when reading the application.

The excerpt from an internet site produced by the appellant cannot, as a matter of principle, serve to complete technical information that is missing from the application as originally filed. For this reason, the Board saw no need for discussing the admissibility into the proceedings of the purported evidence with which it was confronted for the first time in the oral proceedings and of which it had no opportunity to establish validity and completeness.

In summary, the appellant's argumentation does not prove that two separate sets of tubes or fans for the cooling of different portions of the breast, as is currently claimed, has a basis of disclosure in the application as filed. An unequivocal disclosure - the standard consistently employed in the case law of the boards of appeal - has not been demonstrated.

- 2.7 The Board has thus come to the conclusion that the claim of the appellant's sole request comprises subject-matter which has not been disclosed in the originally-filed application documents and thus does not comply with the requirement of Article 123(2) EPC.

The appellant's request is therefore not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chair

R. Schumacher

F. Neumann