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Datasheet for the decision of 20 March 2019

Case Number: T 2329/13 - 3.4.01

Application Number: 03799042.1

Publication Number: 1545704

IPC: A61N1/40

Language of the proceedings: EN

Title of invention:
APPARATUS FOR TREATING A TUMOR BY AN ELECTRIC FIELD

Applicant:
Novocure Limited

Headword:
Selective destruction / NOVOCURE

Relevant legal provisions:
EPC Art. 56, 83, 84, 123(2)

Keyword:
Claims - clarity after amendment (yes)

Decisions cited:
T 0190/99, T 0939/92

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Case Number: T 2329/13 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 20 March 2019

Appellant: (Applicant)	Novocure Limited Le Masurier House La Rue Le Masurier St. Helier, Jersey (Channel Islands) JE2 4YE (GB)
Representative:	Boden, Keith McMurray Fry Heath & Spence LLP Unit A, Faraday Court Faraday Road Crawley, West Sussex RH10 9PU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 26 June 2013 refusing European patent application No. 03799042.1**

Composition of the Board:

Chairman	P. Scriven
Members:	P. Fontenay
	D. Rogers

Summary of Facts and Submissions

I. This is the Board's decision on the applicant's appeal filed against the Examining Division's decision to refuse European patent application 03 799 042.

II. The application was refused because the subject-matter of claim 1 of the (sole) request on file did not involve an inventive step in the sense of Article 56 EPC in view of a combination of document:

D1: WO-A-01/60994,

considered to illustrate the closest prior art, with document:

D3: US-A-6 413 255.

III. The appellant requested that the impugned decision be set aside and that a patent be granted based on the application documents on file.

IV. In the statement of grounds, the appellant provided arguments as to why the claimed subject-matter involved an inventive step.

V. In a communication under Article 15(1) RPBA, the appellant was informed of the Board's preliminary view.

The Board considered the definition of the claimed subject-matter to be ambiguous, contrary to Article 84

EPC. Specifically, it appeared unclear whether the feature regarding the voltage waveform being selected so that an electric field intensity in the living tissue to be treated is between 0,1 V/cm and 10,0 V/cm defined a use of the claimed apparatus or whether it reflected a functionality of the claimed apparatus.

If the latter interpretation was intended, then it appeared questionable whether the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person, as required by Article 83 EPC. It was observed, in this respect, that the application as a whole appeared to be devoid of any indication as to the way the apparatus was controlled in order to produce the intended electric field intensity. This control was not straightforward, since the intended intensity in the tissue to be treated depended, for a given frequency, on various parameters such as the thickness of the tissue to be treated, the thickness of the dielectric coatings, and their respective dielectric constants.

With regard to inventive step, the Board concurred, in essence, with the arguments put forward by the appellant.

VI. Under cover of a letter dated 20 February 2019, the appellant filed new first and second auxiliary requests. Claim 1 of both requests had been amended so as to define the generation of the electric field intensity expressly in terms of a feature of the apparatus. Claim 1 of auxiliary request 2 included an additional limitation regarding the dielectric constant of the insulating coatings covering the electrodes.

VII. Oral proceedings before the Board took place on 20 March 2019 in presence of the appellant's representative.

VIII. In the course of oral proceedings, the appellant filed a new main request, consisting of claims 1 to 16. It replaced all previous requests on file and was the sole request on which the Board had to adjudicate.

IX. Claim 1 of the appellant's main request reads:

An apparatus (200) for selectively destroying dividing cells in tissue to be treated beneath the skin, the dividing cells having polarizable or polar intracellular members, the apparatus comprising:

a first insulated electrode (230) having a first conductor, wherein the first electrode (230) includes a first dielectric member (310) that is in contact with the first conductor, the first dielectric member (310) being for placement against the skin to form a capacitor;

a second insulated electrode (230) having a second conductor, wherein the second electrode (230) includes a second dielectric member (310) that is in contact with the second conductor, the second dielectric member (310) being for placement against the skin to form a capacitor; and

an electric field source for applying an alternating electric potential across the first and second conductors, wherein passage of the electric field through the dividing cells in late anaphase or telophase transforms the electric field into a non-homogenous electric field that produces an increased density electric field in a region of a cleavage furrow of the dividing cells, wherein the electric field source comprises a generator (210) that generates an alternating voltage waveform at frequencies between 50KHz to 500KHz, whereby the non-homogeneous electric field produced within the dividing cells is of sufficient intensity to move the polarizable intracellular members toward the cleavage;

characterised in that:

each of the first and second dielectric members (310) comprises a dielectric coating having a thickness between 1 micron to 50 microns; and

the voltage waveform generated by the generator (210) is adapted to provide an electric field intensity in the tissue to be treated of between 0.1 V/cm to 10.0 V/cm.

Reasons for the Decision

1. All references to the original application are to the application as published under the PCT (WO-A-2004/030760).

Added subject-matter (Article 123(2) EPC)

2. Claim 1 derives primarily from original claim 6.

3. While original claim 6 referred to dielectric members having a dielectric coating having a thickness about 5 to about 50 microns, current claim 1 refers to a thickness between 1 micron to 50 microns. Basis for this enlarged range can be found in the passage of the application on page 43, lines 17-19.

4. The passages of the original application as filed on page 32, lines 9-14 or on page 38, lines 14-17 provide sufficient basis for the feature regarding the range of frequencies of the alternative waveform produced by the generator.

5. As to the electric field intensity in the tissue to be treated, reference is made e.g. to the passage of the original application as published on page 37, lines 17-19.

6. In effect, the skilled person would recognise that the key aspect of the present invention resides in the field intensity to be obtained in the tissue to be treated (see section "Inventive step"). This is to be achieved by appropriately selecting the various parameters of the apparatus. This further implies that

each range of values defining, for example, the frequency of the generated waveforms, the thickness of the dielectric coating, or the dielectric constant of said dielectric coating, is not essential on its own. It further justifies that said parameters be treated in isolation or in association. In particular, the absence of reference in claim 1 to the range of dielectric constants is unproblematic.

7. With regard to the first and second insulated electrodes being for placement against the skin and for the tissue to be treated being positioned beneath the skin, reference is made to Figures 7 and 11 and to the embodiments of the description regarding the presence of a tumour below the skin (cf. e.g. page 40, line 8 - page 41, line 41; Page 46, lines 1-8).

8. Dependent claim 2 reflects the content of original claim 6 (the narrower range of of dielectric thicknesses).

9. Support for the range of dielectric constants recited in dependent claims 3 and 4 may be found in the passages of the original description on page 41, lines 17 - 18, in combination with the suggestion on page 42, lines 1-4, to use insulating materials with very high relative dielectric constants which could reach values of about 200.

A basis for the list in claim 5 of various materials to be used as dielectric members, either alone or in combination, may be found on page 42, lines 1-17 of the application as filed.

Original claims 7 to 9, respectively, appear to provide a basis for dependent claims 6 to 8, respectively.

Explicit reference for the range of thicknesses recited in dependent claim 9 together with the use of gold as conductive coating may be found on page 44, lines 14 and 15, of the original application.

Claim 10 derives from original claim 10.

Claim 11 reflects the content of original claim 13.

Explicit reference for the range of thicknesses recited in dependent claim 12 together with the use of an intervening filer may be found on page 43, lines 4 to 16 of the original application.

A basis for claim 13 may be found i.a. in original claim 35.

Dependent claim 14 reflects the content of original claim 15.

Figure 7 and the passage on page 40, lines 11-13 of the original application appear to constitute a sufficient basis for claim 15.

The passage of the original description on page 43, lines 7-9, is considered to provide a sufficient basis for claim 16.

10. The claims of the appellant's request appear to derive directly and unambiguously from the original application documents. Claims 1 to 16 thus meet the requirements of Article 123(2) EPC.

Clarity and Support - Article 84 EPC

11. The last feature in claim 1 has been amended following the issuance by the Board of its preliminary opinion. It now reads: "the voltage waveform generated by the generator is adapted to provide an electric field intensity in the tissue to be treated of between 0.1 V/cm to 10.0 V/cm". The claim is now drafted in terms of functional features. The objection that the claimed subject-matter incorporated features regarding its use no longer applies.

12. A first distinction is made in the claim between the "skin" and the "tissue to be treated". This distinction contributes to a further clarification of the last feature in the claim regarding the electric field intensity in the latter.

13. As expounded with regard to Figure 6, on page 41, line 5 to line 18, of the original application, the electrical properties of the skin are substantially different from those of the tissue beneath it, where the tissue to be treated (the tumor) is located. When a potential difference is applied between two electrodes placed against respective surfaces of skin, higher voltage drops occur in the skin as compared to the voltage drop in the tissue beneath. This leads to higher electric field intensities in the skin as compared to the tissue beneath.

14. The explicit reference, in the last feature of the claim, to the tissue to be treated is thus unambiguously associated with tissue that does not include the skin, that is, to a volume of tissue where a rather uniform field intensity is to be expected.

15. The claim further distinguishes between "tissue" and "dividing cells". The latter relates, in the context of claim 1, to entities of substantially smaller dimensions compared to those of skin or tissue. The reference, in the claim, to the anaphase, telophase and the cleavage furrow of the dividing cells, makes it clear that the term "cell" should be given its generally recognised meaning, thus excluding all the other entities referred to on page 14, lines 4-13, of the description, which do not fall under this generally accepted definition.

16. The feature in claim 1 according to which "passage of the electric field through the dividing cells in late anaphase or telophase transforms the electric field into a non-homogeneous electric field that produces an increased density electric field in a region of a cleavage furrow of the dividing cells" is thus to be construed as referring to the effects taking place at the cellular level, that is, at a microscopic scale.

17. By contrast, because of the reference to the "tissue to be treated", the feature in claim 1 according to which "the voltage waveform generated by the generator is adapted to provide an electric field intensity in the tissue to be treated of between 0.1 V/cm to 10.0 V/cm" is to be construed, in the claim's context, as referring to volumes of much larger dimensions. The reference to the electric field intensity is hence to be understood, as referring to the rather uniform electric field created in said volume without consideration of the inhomogeneity existing at the cellular level.

18. The use of the singular in the terms "an electric field intensity in the tissue to be treated" supports this

interpretation. It underlines that at a macroscopic scale the electric field is generally uniform within the volume of tissue to be treated, i.e. within the tumor present in the volume of tissue encompassed by the two insulated electrodes.

19. In the present circumstances, the claimed intensity range is selected in order to provoke the destruction of the dividing cells present within the tissue to be treated. It follows that an interpretation of the claim such that the conditions regarding the field intensity should apply only to a limited volume within the tissue to be treated should be ruled out.

20. In consequence, the subject-matter of claim 1 satisfies the requirements of Article 84 EPC.

Sufficiency of disclosure - Article 83 EPC

21. Some of the parameters directly influencing the intensity of the electric field to be generated by the claimed apparatus in tissue to be treated relate to components of the apparatus itself.

22. This is the case for the thickness of the insulating material covering the first and second electrodes and for its dielectric constant. These are factors that the skilled person would have to consider when carrying out the claimed invention. This is straightforward and only requires the skilled person to apply his/her common general knowledge.

23. The intensity of the electric field in the tissue to be treated depends, however, on other parameters which depend on the tissues present between the first and

second electrodes. These are *a priori* unknown. Concretely, this is the case for the dielectric constants and thickness of the skin layers, and for the tissue beneath.

24. The Board has, however, no doubts that the electric properties of biological materials can be estimated with sufficient precision. In this respect, reference is made to page 41, lines 5-16, for example, of the published application. It is also noted that reasonable assumptions can be made as to the thickness of the tissues which might be present between the two electrodes.

It follows that the skilled person would be in a position, on the basis of the electrical properties of the components of the claimed apparatus itself, common general knowledge regarding properties of biological media for which the apparatus is to be used, and reasonable assumptions as to the geometry of the body parts to be treated, to design the claimed apparatus accordingly.

25. The invention is thus disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person (Article 83 EPC).

Inventive step - Articles 52, 56 EPC

26. Document D3 discloses a treatment device which delivers thermal energy to the skin and underlying tissue to cause a contraction of collagen. Such devices may be used for skin remodelling/resurfacing, wrinkle removal, spider veins etc. Document D3 serves purposes that are unrelated to the purpose of the claimed invention since

it focuses on problems related to the presence of hot spots on the edges of coated electrodes.

27. In effect, the present invention constitutes a further development of the apparatus disclosed in document D1. The principle underlying the destruction of the dividing cells according to the claimed invention is the same as the one underlying the teaching of D1.

The apparatus of D1 comprises all structural features of the claimed apparatus. It thus qualifies as closest prior art.

28. The apparatus according to claim 1 is distinguished from the apparatus known from document D1 in that:

a) each of the first and second dielectric members, which are part of the first and second insulated electrodes, have a thickness between 1 µm and 50 µm, and in that
b) the voltage waveform generated by the generator provides an electric field intensity in the living tissue to be treated beneath the skin of between 0.1 V/cm to 10.0 V/cm.

29. Concerning distinguishing feature (a) as to the thickness of the dielectric members, the Board considers, in the absence of any indication regarding the dielectric constant of the coating material, that it does not provide any effect that could contribute to solving a problem regarding the treatment, as such(cf. T 939/92, Triazoles/AGREVO, OJ 1996, 309, Headnote II, points 2.4 to 2.6)). Feature (b) does provide such an effect (see below).

30. In view of the fact that D1 also proposes the treatment of tissues with electric fields generated by insulated electrodes (cf. page 10, lines 12, 13), the partial problem solved by distinguishing feature (a) may thus be considered, under the circumstances, to be the minimal one of selecting a range of thicknesses sufficient to guarantee isolation of the electrode from the skin.

31. The claimed range of thickness, extending from 1 to 50 µm, appears to be an arbitrary selection for which no contribution to inventive step can be recognised.

32. With regard to the voltage waveform, feature (b), the Board does not see any motivation for the skilled person to modify the teaching of D1 so as to arrive at a range for the electric field intensity corresponding to the recited definition.

33. Document D1 discloses a field intensity of 78 V/cm for cells grown in a tissue culture medium. D1 does not make any suggestions as to the field intensities that may be required for in-vivo applications. It is certainly true, as observed by the Examining Division, that the values to be considered for tissue cultures cannot be simply extrapolated to in-vivo therapy. They constitute, however, a reasonable basis considering that the intended effect regarding the field concentration in the dividing cells to be destroyed is the same whether the cells are in a culture or present in living tissues. In this respect, the skilled person would have *a priori* expected the field intensities required in living tissue to be of a similar order. He would thus have experimented around said known value. The selection of a range extending from 0,1 V/cm to 10 V/cm compared with the much larger value 78 V/cm

known from D1 suggests that the claimed invention is based on new insight on the part of the appellant, from which the existence of an inventive step can be inferred.

34. None of the other available documents suggests to use field intensities corresponding to the claimed range in order to destroy dividing cells.

35. The claimed subject matter of the main request thus involves an inventive step under Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent with the following claims and a description to be adapted:

- Claims 1 to 16 of the main request submitted at the oral proceedings before the Board on 20 March 2019.

The Registrar: The Chairman:

R. Schumacher P. Scriven

Decision electronically authenticated