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D E C I S I O N
of 25 November 2005

Case Number: T 0284/02 - 3.4.01

Application Number: 95903585.8

Publication Number: 0793519

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Language of the proceedings: EN

Title of invention:
X-ray emitting interstitial implants

Applicant:
Theragenics Corporation

Opponent:
-

Headword:
-

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

Keyword:
-

Decisions cited:
T 0331/87, T 0240/91, T 0740/97

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0284/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 25 November 2005

Appellant: Theragenics Corporation
5203 Bristol Industrial Way
Buford
GA 30518 (US)

Representative: Denleavy, Kevin James
Knoble & Yoshida
p/o De Vries & Metman
Overschiestraat 180
NL-1062 XK Amsterdam (NL)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 8 October 2001 refusing European application No. 95903585.8 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
H. Wolfrum

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 10 December 2001, against the decision of the examining division, dispatched on 8 October 2001, refusing European patent application No. 95903585.8. The fee for the appeal was paid on 10 December 2001. The statement setting out the grounds of appeal was received on 15 February 2002.

II. In the contested decision, the examining division held that the application did not meet the requirements of Articles 123(2), 84 and 56 EPC.

III. During the appeal procedure, the following documents were considered:

(D1) US-A-4,702,228;

(D2) A.S. Meigooni *et al.*, "*Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants*", Endocurietherapy/Hyperthermia Oncology, Vol. 6, pages 107-117, April 1990;

(D3) P.V. Harper *et al.*, "*The Thick Target Yield and Excitation Function for the Reaction* $Rh^{103}(p,n)Pd^{103}$", Argonne Cancer Research Hospital Semiannual Report to the Atomic Energy Commission, 15, pages 124-128, 16 May 1961;

(D5) US-A-3,351,049;

(D6) P.V. Harper *et al.*, "*Palladium-103 as a therapeutic radiation source*", Argonne Cancer Research Hospital, Chicago, Illinois (USA), Vol. 2, 1965, pages 411-418.

IV. With the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of a main request and auxiliary requests 1 to 6. Moreover, the appellant requested oral proceedings, should the Board intend to reject the main request.

On 17 May 2005, the appellant was summoned to oral proceedings scheduled to take place on 13 October 2005. On 18 August 2005, the Board issued a communication intended to assist the appellant in preparing for oral proceedings.

With a letter dated 9 September 2005 the appellant withdrew its request for oral proceedings and requested a decision "*based on the written record*". The appellant also requested that the decision under appeal be set aside and that a patent be granted on the basis of new main and auxiliary requests 1 to 6.

With a notification of 27 September 2005 the appellant was informed that the oral proceedings were cancelled.

V. The wording of claim 1 of the main request reads as follows:

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto which includes X-ray emitting material bonded to a support (14) of a*

material that is substantially non-absorbing of x-rays encapsulated by a shell of biocompatible material (22) penetrable by x-rays in the 20-23 keV range, characterized in that the seed (10) contains, as the X-ray emitting material, carrier-free palladium-103 in an amount sufficient to provide an apparent activity measured from outside the seed of greater than $1.85x10^7$ Bq/seed and wherein the X-ray emitting material is bonded to the support in a manner that precludes release of the X-ray emitting material from the support when the X-ray emitting material is exposed to the body fluids or tissue of a patient."

The wording of independent claim 7 of the main request reads as follows:

"A method of making a seed (10) having a predetermined activity for implantation within a living body to emit X-ray radiation including the steps of preparing an X-ray emitting composition including palladium-103, electroplating the X-ray emitting composition onto an electroconductive support of a material that is substantially non-absorbing of x-rays, and encapsulating the X-ray emitting composition with a shell of biocompatible material penetrable by x-rays in the 20-23 keV range, characterized in that the step of preparing an X-ray emitting composition is carried out by irradiating a rhodium metal target in a charged particle accelerator under conditions that produce carrier-free Pd-103 from rhodium metal, recovering carrier-free palladium-103 from rhodium metal, forming an admixture of carrier-free palladium-103 and an amount of a palladium salt sufficient to promote

electroplating of an admixture of carrier-free palladium-103 and palladium metal onto the electroconductive support and adjust the activity to provide a predetermined apparent activity measured from outside the seed of greater than $1.85x10^7$ Bq/seed, and measuring the activity of the admixture."

VI. The wording of claim 1 of the first auxiliary request reads as follows:

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto which includes X-ray emitting material bonded to a support (14) of a material that is substantially non-absorbing of x-rays, encapsulated by a shell of biocompatible material (22) penetrable by x-rays in the 20-23 keV range, characterized in that the seed (10) contains, as the X-ray emitting material, carrier-free palladium-103 in an amount sufficient to provide an apparent activity measured from outside the seed of greater than $1.85x10^7$ Bq/seed, and wherein the X-ray emitting material bonded to the support is obtainable by electroplating the X-ray emitting material onto an electroconductive support.*"

Independent claim 7 of the first auxiliary request corresponds to claim 7 of the main request.

VII. The wording of claim 1 of the second auxiliary request reads as follows:

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto obtainable by the steps of preparing an X-ray emitting composition including*

palladium-103, electroplating the X-ray emitting composition onto an electroconductive support of a material that is substantially non-absorbing of x-rays, and encapsulating the X-ray emitting composition with a shell of biocompatible material penetrable by x-rays in the 20-23 keV range, characterized in that the step of preparing an X-ray emitting composition is carried out by irradiating a rhodium metal target in a charged particle accelerator under conditions that produce carrier-free palladium-103 from rhodium metal, recovering carrier-free palladium-103 from rhodium metal,
forming an admixture of carrier-free palladium-103 and an amount of a palladium salt sufficient to promote electroplating of an admixture of carrier-free palladium-103 and palladium metal onto the electroconductive support and adjust the activity to provide a predetermined apparent activity measured from outside the seed of greater than $1.85x10^7$ Bq/seed, and measuring the activity of the admixture."

Independent claim 7 of the second auxiliary request corresponds to claim 7 of the main request.

VIII. The wording of claim 1 of the third auxiliary request reads as follows:

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto which includes X-ray emitting material bonded to a support (14) of a material that is substantially non-absorbing of x-rays encapsulated by a shell of biocompatible material (22) penetrable by x-rays in the 20-23 keV range, characterized in that the seed (10) contains, as the X-*

ray emitting material, carrier-free palladium-103 in an amount sufficient to provide an apparent activity measured from outside the seed of greater than 1.85x10^7 Bq/seed and wherein the X-ray emitting material is bonded to the support by electroplating the X-ray emitting material onto an electroconductive support."

Independent claim 8 of the third auxiliary request corresponds to claim 7 of the main request.

IX. The wording of claim 1 of the fourth auxiliary request reads as follows (see the "*Marked-Up*" version which deviates from the non-marked version of this claim as enclosed with the letter dated 9 September 2005 in which the passages within square brackets were omitted):

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto which includes X-ray emitting material bonded to a support (14) of a material that is substantially non-absorbing of x-rays encapsulated by a shell of biocompatible material (22) penetrable by x-rays in the 20-23 keV range, characterized in that the seed (10) contains, as the X-ray emitting material, carrier-free palladium-103 in an amount sufficient to provide an apparent activity measured from outside the seed of greater than 1.85x10^7 Bq/seed, the seed (10) further contains palladium metal in an amount sufficient to promote electroplating of a composition including palladium metal and carrier-free palladium-103 onto the support, and wherein the X-ray emitting material [and palladium metal are] bonded to the support by electroplating the X-ray emitting material [and palladium metal] onto an electroconductive support.*"

Independent claim 8 of the fourth auxiliary request corresponds to claim 7 of the main request.

X. The wording of claim 1 of the fifth auxiliary request reads as follows:

"*A seed (10) for implantation into a living body to emit X-ray radiation thereto which includes X-ray emitting material bonded to a support (14) of a material that is substantially non-absorbing of x-rays, and encapsulated by a shell of biocompatible material (22) penetrable by x-rays in the 20-23 keV range, characterized in that the support is electroconductive and has electroplated thereon a palladium composition consisting of:*
(1) carrier-free palladium-103 as the x-ray emitting material in an in an amount sufficient to provide an apparent activity measured from outside the seed of greater than 1.85×10^7 *Bq/seed, and*
(2) palladium metal in an amount sufficient to promote said electroplating."

Independent claim 5 of the fifth auxiliary request corresponds to claim 7 of the main request.

XI. Claim 1 of the sixth auxiliary request corresponds to claim 7 of the main request.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural considerations*

2.1 During the appeal procedure, in preparation for the oral proceedings requested by the appellant, the Board sent a communication pursuant to Article 11(1) RPBA listing the issues which were considered to have a bearing on the decision (see point IV, supra). In this way, the Board gave the appellant notice of certain deficiencies of the present application. The appellant presented its comments in writing in the form of the reply dated 9 September 2005. With this letter, new sets of amended claims were filed, the request for oral proceedings was explicitly withdrawn, and a decision "*based on the written record*" was requested.

2.2 The present decision is based on the same grounds and evidence referred to in the Board's communication. Thus, in the particular circumstances of the case, the provisions of Article 113(1) EPC are met even if the decision is based on the claims filed with the letter of 9 September 2005.

3. *Claim 1 according to the main request - admissibility of the amendments*

3.1 The seed according to claim 1 of the application as originally filed comprises, *inter alia*, at least one pellet of an electroconductive support having electroplated thereon a layer of a palladium composition consisting of carrier-free Pd^{103} having added thereto palladium metal in an amount sufficient to promote the electroplating.

In distinction thereto, the seed according to claim 1 of the main request is characterized in that it contains, as X-ray emitting material, carrier-free Pd^{103} in an amount sufficient to provide a given activity. Moreover, the X-ray emitting material is bonded to the support in a manner that precludes release of the X-ray emitting material from the support when the X-ray emitting material is exposed to the body fluids or tissue of a patient.

Thus, the subject-matter of claim 1 according to the main request has been amended in such a way that "*carrier-free Pd^{103}*", and not a "*palladium composition*" consisting of carrier-free Pd^{103} and palladium metal, is somehow bonded to the support.

The question arises whether this amendment introduces technical information which extends beyond the content of the application as filed (Article 123(2) EPC).

3.2 In the appellant's view, a literal support for the amendment was provided by the paragraph from page 6, line 32 to page 7, line 7, of the application as filed relating to a statement of an object of the invention concerning the seed. According to it, the addition of palladium metal was not necessary. The appellant thus considered that it was entitled to claim the full scope of its invention as literally described.

3.3 The statement in question mentions "*an object of the invention*", which consists in providing a seed of Pd^{103} of high isotopic purity, i.e. carrier-free (see page 1, lines 36-38), and desired therapeutic activity. The seed should also be safe for use as an interstitial

implant, whereby the term "*safe*" means that the seed should not be toxic and have carrier-free Pd^{103} bonded to the support carrying the same in a manner that precludes release therefrom. In this way, the chances of the radioactive isotope leaking into the circulatory system of the patient are reduced.

The statement referred to by the appellant follows an introduction (see page 1, line 12 to page 6, line 31) describing the isotopes commonly used for therapeutic seed manufacture and the drawbacks of carrier Pd^{103} produced in a nuclear reactor as compared to carrier-free Pd^{103} obtained in a particle accelerator. In this context, it is noted that the object mentioned on page 6, line 32 to page 7, line 7, simply repeats in other words the desire already expressed on page 6, lines 25-31, to provide a safe seed containing Pd^{103} of sufficient purity as the X-ray emitting material.

With its approach, the appellant has derived a teaching defining the invention for which protection is sought from a single statement formulating, in general terms, the desire to achieve a safe seed of carrier-free Pd^{103}. The Board, however, disagrees with this approach leading, in particular, to the definition of a teaching that is not consistent with the whole of the disclosure, as the following summary of the application as filed reveals.

On page 7, lines 8-15, "*another object of the invention*" is mentioned, which also concerns the provision of the seed. Here, the seed is defined, *inter alia*, as being composed of carrier-free Pd^{103} having added to it small amounts of palladium metal. Further

objects concern the process for the production of the seed (see page 7, line 16 to page 8, line 3).

According to the "*Summary of the invention*" on pages 8 to 10 of the application as filed, the objects of the invention are obtained by a process for preparing a safe seed (see page 8, lines 5-29). This process comprises, *inter alia*, the steps of adding palladium metal to carrier-free Pd^{103} and of electroplating a layer of the Pd^{103}/palladium admixture onto an electroconductive material, the palladium metal being added to promote electroplating and to obtain the desired level of self-shielding. Similar steps are also mentioned in the paragraph from page 8, line 30 to page 9, line 18, concerning the seed defined in terms of its manufacturing process. According to page 9, line 19 to page 10, line 2, the obtained seed includes, *inter alia*, a layer of carrier-free Pd^{103} having palladium added thereto, the layer being electroplated onto an electroconductive support and the amount of said palladium being sufficient to promote the electroplating and to obtain the desired level of self-shielding.

With regard to the "*Description of the preferred embodiments*" (see pages 10-16), the X-rays are emitted from a pair of pellets of electroconductive material having electroplated thereon the carrier-free Pd^{103}/palladium admixture "*of the present invention*" (see page 10, lines 31-35). According to page 12, line 7 to page 13, line 3, the palladium is added to a solution containing rhodium salts. The addition of palladium in accordance with the present invention is reported to be essential and advantageous in several

respects. An advantage consists in that "*the added palladium promotes the subsequent electroplating and ensures strong adhesive of the Pd^{103}/palladium admixture to the support therefor*". Further advantages are related to the ability to adjust the activity of the admixture and to the reduction of loss of Pd^{103} occurring during purification of Pd^{103}. The amount of palladium to be added is mentioned in page 13, lines 4-11.

Figure 1 shows a seed with pellets having a layer of the Pd^{103}/palladium admixture (see page 14, lines 7-20). The same applies for the seed shown in Figure 2 (see page 16, lines 17-19).

According to the "*Example*" of the invention (see pages 16-21), at least 5 mg of palladium carrier is added to a filtrate having Pd^{103} activity (see page 18, lines 24-28). Graphite seed pellets are electroplated with a solution of palladium amine complex (see page 19, lines 31-34).

Finally, as regards the originally filed independent claims, which normally reflect the teaching of the invention in its most general form, the seed according to claim 1 comprises, *inter alia*, at least one pellet of an electroconductive support having electroplated thereon a layer of a palladium composition consisting of carrier-free Pd^{103} having added thereto palladium metal in an amount sufficient to promote electroplating. The method according to claim 8 includes, *inter alia*, the step of forming a carrier-free Pd^{103}/palladium admixture by adding palladium metal to the carrier-free Pd^{103} in a small amount sufficient to promote

electroplating of the admixture and to adjust its specific activity followed by the step of electroplating a layer of the Pd^{103}/palladium admixture having a known specific activity and self absorption onto at least one pellet of an electroconductive material.

In summary, the disclosure of the application as filed consistently presents the provision of an admixture of carrier-free Pd^{103} and palladium metal as being an essential and advantageous element of the invention. In distinction thereto, the citation from pages 6 and 7 of the application relied on by the appellant merely states the general desire for a seed having pure Pd^{103} bonded to the support in a non-releasable manner. Such an indication of a problem to be solved should not, however, be confused with the corresponding technical solution disclosed by the application.

3.4 The appellant did not dispute the fact that the addition of palladium is disclosed as an advantageous feature. In its view, however, an advantage of adding palladium was to "*promote*" the subsequent electroplating (see page 12, lines 14-22), whereby a skilled person would understand this disclosure in the sense that the palladium metal simply "*improved or enhanced*" the electroplating step. Thus, the appellant denied that the addition of palladium metal was explained as essential for the invention. In particular, the alleged essentiality could not be inferred solely from the fact that it was consistently presented in combination with other features of the invention. Rather, the application of the essentiality test according to decision T 331/87 (OJ EPO 1991, 022)

confirmed that the application as filed did not provide a sufficient basis to conclude that the seed according to the invention necessarily comprised both Pd^{103} and palladium metal.

According to point 6 of the reasons in decision T 331/87, "*the replacement or removal of a feature from a claim may not violate Article 123(2) EPC provided the skilled person would directly and unambiguously recognise that (1) the feature was not explained as essential in the disclosure, (2) it is not, as such, indispensable for the function of the invention in the light of the technical problem it serves to solve, and (3) the replacement or removal requires no real modification of other features to compensate for the change*". If these conditions are met, a feature may indeed be inessential "*even if it was incidentally but consistently presented in combination with other features of the invention*". However, in the Board's view, conditions (1) and (2) are not met in the present case. As disclosed in page 12, lines 9-14, palladium has a high atomic number and would normally be considered an undesirable additive to a low energy X-ray emitting seed. Nevertheless, its addition was *expressis verbis* found to be essential in several respects. Foremost, as already stated, the added palladium promotes the subsequent electroplating and ensures strong adhesion of the Pd^{103}/palladium admixture to the support. This advantage is clearly related to the object of providing a "*safe*" seed according to the statement in the paragraph bridging pages 6 and 7. Considering that safety represents an essential issue in the field of radiation-emitting seeds for therapeutic purposes, the skilled person would

understand the verb "*promote*" in line 15 of page 12 as indicating a teaching to add palladium rather than an optional measure. The skilled person would thus recognise that the addition of palladium is essential for the invention in the light of the whole disclosure and, in particular, of the technical object to provide a safe seed.

3.5 In support of its argumentation, the appellant cited further decisions of the boards of appeal, among which T 240/91 (not published) and T 740/97 (not published) deserve particular attention.

3.5.1 In the appellant's view, a situation similar to the present one arose in T 240/91.

In T 240/91 (see point 4 of the reasons), the examining division considered that a statement of an object of the invention was a promise of what the person skilled in the art could expect to achieve by carrying out the invention, but that such a statement was not a definition of technical subject-matter for which protection was, or might subsequently be, sought. The Board, however, held the following: "*At the basis of this opinion lies apparently the interpretation of the word "object" as meaning the purpose or the aim of the invention or the problem to be solved by the invention, without any indication of the technical features necessary for achieving that aim or solving that problem, i.e. the invention itself. The Board acknowledges that, on the basis of such an interpretation, there may be circumstances in which a statement of an object of an invention may not be considered as a disclosure of the invention itself. The*

Board is, however, of the opinion that this is not necessarily the case under all circumstances." The Board then noted that the statement of object in the parent application comprised not only a number of technical features, but also their interrelationships and all this in such a way that it might be considered as a broad statement of the invention itself. The conclusion was that the wording "*Another object of the present invention is to provide ...*" could and should equivalently be read as "*The present invention also relates to ...*" or "*The present invention also provides ...*".

In the present case, according to the appellant, the paragraph bridging pages 6 and 7 of the application as filed included a first statement defining an object of the invention, i.e. to provide a safe seed of Pd^{103} of sufficient purity and desired activity, and a second statement describing the technical means for achieving the stated object, i.e. bonding carrier-free Pd^{103} to the support. Thus, in the light of T 240/91, the statement of an object of the invention in question, which comprised technical features (carrier-free Pd^{103} and the support) and their relationship (bonding), could be properly relied upon to support claim 1 as amended.

The Board is not convinced that the circumstances and the conclusions of T 240/91 can readily be applied to the present case. The "technical means" which the appellant considered to be disclosed in the statement of the object of the invention in the paragraph bridging pages 6 and 7 of the application is in fact a definition of the term "*safe*" "*as used ... in appended*

claims". The definition refers to the indispensable and as such trivial prerequisite that the palladium is bonded to the support and further specifies the required quality of the bonding, namely that it precludes release of the palladium from the support. However, the given definition does not indicate any aspect of the solution, i.e. how the desired property of the bonding would be achieved, as it is disclosed in the application document as a whole, an issue which did not arise in T 240/91.

3.5.2 The applicant also considered T 740/97 to be applicable to the present case.

In T 740/97 (see point II of the summary of facts and submissions; points 2.4 and 2.5 of the reasons), the reason for the refusal of a divisional application by the first instance was that an applicator for effecting thermal cauterization of the tissue lining of a human body cavity could not be isolated from the apparatus as a whole, since there was no basis for this in the earlier application as filed. To solve the problem addressed in the application in suit, it was necessary that the applicator be used only in connection with the whole cauterization apparatus, i.e. comprising also means external to the applicator, so that a claim directed to an applicator taken in isolation was not justified nor founded. In the appeal proceedings, the Board relied on the fact that in the application different objects were stated for a method and an apparatus underlying the invention. In its broadest definition, the main object of the invention was to provide a method for cauterizing the tissue lining of a body cavity. However, having regard to the apparatus

for performing the method, the main object of the invention was to provide an applicator as such, "*heated by non-toxic fluid ... and controlled by means external to the applicator*". It resulted therefrom that the term "*applicator*" was to be understood in a narrower sense, according to which the heating applicator alone was regarded as the object for which protection was sought, beyond any specific application or additional control means. The Board held that all essential features for effecting cauterization were present in claim 1. While external control means might be suitable for optimising the efficiency of the treatment, such means were not necessary for achieving a result, whatsoever. Therefore, there was no reason to limit the scope of the main claim to the entire tubing system as long as the applicator itself has not been seriously questioned during the subsequent substantive examination. As a consequence, in the Board's judgment, the subject-matter of claim 1 was clear, complete and fairly supported by the divisional application as filed.

In the present case, the appellant took the view that, as in T 740/97, different objects of the invention were mentioned with regard to the seed (see page 6, line 32 to page 7, line 7) and the method for the production of the seed (see page 7, line 16 to page 8, line 3). In the light of the conclusion in T 740/97 that there was a basis in the application as filed to claim the applicator without including two elements deleted from the original claim, it was clear from the objects of the invention in the present case that protection was sought for a seed containing carrier-free Pd^{103} bonded to the support without the addition of palladium metal.

As for T 240/91, the Board is not convinced that the circumstances and the conclusions of T 740/97 can be applied to the present case. In particular, a substantial difference consists in that, in T 740/97, the external control means were not regarded as being "*necessary for achieving a result, whatsoever*". In the present case, however, the addition of palladium metal is presented as an essential feature for obtaining a safe seed. The problem of the essentiality of features deleted from the original independent claims did not arise in T 740/97.

3.6 In conclusion, claim 1 of the main request has been amended in such a way that its subject-matter extends beyond the content of the application as filed read as a whole. The provisions of Article 123(2) EPC are not met and, therefore, the main request is not allowable.

4. *Claim 1 according to the first and third auxiliary requests - admissibility of the amendments*

The provisions of Article 123(2) EPC are not met for the same reasons mentioned in relation to claim 1 of the main request. Therefore, the first and third auxiliary requests are not allowable too.

5. *Independent method claim according to the second and fourth to sixth auxiliary requests - inventive step*

5.1 The wording of the independent method claim is the same for the second and fourth to sixth auxiliary requests.

5.2 Document D2 discloses a seed for implantation into a living body to emit X-ray radiation thereto. The "*model*

200 source" shown in Figure 1 includes two palladium-plated graphite pellets and a lead X-ray marker, which are arranged in a titanium - i.e. a biocompatible material - shell. In particular, the radioactive pellets comprise an electroconductive graphite support, which has electroplated thereon, as the X-ray emitting material, Pd^{103} obtained by neutron activation of Pd^{102} in a nuclear reactor and purified by a chemical separation procedure (see page 108, right-hand column, second paragraph). The X-ray emitting material is available in an amount sufficient to provide an apparent activity measured from outside the seed of up to $7.4 \cdot 10^7$ Bq/seed (see page 110, right-hand column third paragraph). This activity range clearly overlaps with that recited in the independent method claim.

It results from the disclosure according to D2 that the known model 200 Pd-seed is made by the following steps:

(1) preparing an X-ray emitting composition including carrier Pd^{103} by neutron activation of Pd^{102},

(2) electroplating the X-ray emitting composition onto an electroconductive support of a material that is substantially non-absorbing X-rays, and

(3) encapsulating the X-ray emitting composition with a shell of a biocompatible material penetrable by X-rays in the 20-23 keV range, this range representing the energy of the characteristic X-rays emitted by Pd^{103} (see D2, page 108, left-hand column, second paragraph; page 116, left-hand column, "*Discussion*", second paragraph).

5.3 Therefore, the subject-matter of the independent method claim essentially differs from the method derivable from the disclosure of D2 by the following steps:

(4) preparing the X-ray emitting composition by irradiating a rhodium metal target in a charged particle accelerator under conditions that produce carrier-free Pd^{103} from rhodium metal, carrier-free Pd^{103} being recovered from the rhodium metal,

(5) forming an admixture of carrier-free Pd^{103} and an amount of a palladium salt sufficient to promote electroplating of an admixture of carrier-free Pd^{103} and palladium metal onto the electroconductive support and adjust the activity to provide the desired activity, and

(6) measuring the activity of the admixture.

5.4 In the grounds of appeal (see point C on pages 9 and 10), the appellant submitted that the problem addressed by the present invention was to provide a therapeutic radioactive seed that was safe for use as an interstitial implant and wherein the undesirable self-shielding properties characterising a seed with neutron-activated palladium had been substantially reduced. In its view, the aspect of safety was related to the elimination of unwanted active impurities (such as Pd^{109}) and to the need of bonding the radioactive material to the support in a manner that precluded release therefrom into the circulatory system of the patient. This aspect was solved by the use of carrier-free Pd^{103} (see step (4)) and by electroplating a

composition of carrier-free Pd^{103} and palladium metal onto the support (see step (5)). The other aspect concerning self-shielding was related to the requirement of a predictable dosage distribution and was solved by the fact that a smaller amount of palladium material was required to provide a seed of desired activity when employing a carrier-free Pd^{103}/palladium combination sufficient to promote electroplating (see step (5)) than would be required if neutron-activated Pd^{103} were used.

5.5 It is known from the disclosure according to D3 or D6 that Pd^{103} obtained by neutron bombardment of a palladium target in a nuclear reactor is not carrier-free. This results from the fact that the target comprises various naturally occurring palladium isotopes so that, by the neutron bombardment, Pd^{103}, other palladium isotopes and also non-palladium isotopes are formed (D3, page 124, first paragraph; D6, page 411). Irradiation originating from active isotopes other than Pd^{103} should then be avoided, as much as possible, by suitable measures, for example waiting for the decay of Pd^{109} and purification to remove Ag^{111}, both these elements being contained in neutron-activated Pd^{103} (D6, page 411, last paragraph). Moreover, it is known that the carrier-palladium and other impurities that may be present lead to a low activity of the end seed due to self-shielding (D3, page 124, first paragraph).

According to the cited documents D3 and D6, the mentioned difficulties can be avoided by the use of carrier-free Pd^{103} prepared by irradiating a rhodium metal target with protons in a charged particle

accelerator. Therefore, the skilled person, faced with the problem of providing a therapeutic seed without undesired active impurities and with low self-shielding, would consider employing cyclotron-irradiated carrier-free Pd^{103} instead of neutron-activated Pd^{103} for the manufacture of the model 200 Pd-seed according to D2. In this respect, the appellant itself acknowledged in the grounds of appeal (see paragraph bridging pages 11 and 12) that the skilled person would derive from document D3 that the use of carrier-free Pd^{103} for interstitial implants - like those of D2 - was indeed desirable.

5.6 Now, the skilled person, with regard to the model 200 Pd-seed according to D2 but including carrier-free Pd^{103} instead of the disclosed neutron-activated carrier Pd^{103}, knows that the high purity of carrier-free Pd^{103} reduces the self-shielding effect. Therefore, a smaller amount of carrier-free Pd^{103} would be sufficient to provide the required therapeutic activity. The question then arises whether and how the smaller amount of carrier-free Pd^{103} can be electroplated on the graphite support, as D2 teaches with regard to neutron-activated Pd^{103}. This question is related to the issue of safety, in particular to the need of obtaining a safe bond of the radioactive material to the support precluding release therefrom.

On page 12 of the grounds of appeal (see second paragraph), the appellant stated that "*it is not trivial to attempt to electroplate carrier-free Pd^{103} onto a support since the amount of carrier-free Pd^{103} required to obtain the desired activity of a seed is so small that it is nearly impossible to electroplate the*

material onto the support since there is simply insufficient mass of the Pd^{103} to accomplish reasonable electroplating". An obvious implication of this technical knowledge would, however, be the provision of a suitable carrier material for carrying out the electroplating process of carrier-free Pd^{103} on the support. An obviously suitable carrier material would then be palladium metal because it is known to have substantially the same chemical properties and, moreover, if added to the desired isotope Pd^{103}, would compensate for possible losses if further purification thereof is necessary. Once this choice has been made, the amount of palladium to be added to the carrier-free Pd^{103} for carrying out the bonding process can be determined on the basis of a trade-off between the interest of having a mass sufficient for electroplating and the disadvantage due to the well-known palladium self-shielding effect (see document D1, column 4, lines 50-63; document D5, column 8, line 9).

The appellant, in its letter of 9 September 2005 (see page 11), submitted that the problem of having too little mass of carrier-free Pd^{103} to make a suitable electroplating solution was not known at the filing date of the present application. Thus, it was important to consider whether the skilled person, faced with the problem of bonding a mass of about $6.6 \cdot 10^{-9}$ grams of carrier-free Pd^{103} - the amount required to provide an activity of $1.85 \cdot 10^{7}$ Bq/seed - to a support, would even envisage electroplating to be an option in the first place. In its view, it would have been extremely problematic for the skilled person to even attempt to make a suitable electroplating solution using such a small mass of material to be plated. Moreover, in the

file there was no evidence that the skilled person would rely on an electroplating process when confronted with application of such a minute quantity of material.

This argumentation is not convincing. As already stated, document D2 teaches to electroplate neutron-activated carrier Pd^{103} onto a graphite support. Due to its knowledge about the advantages achieved, the skilled person would consider to replace carrier Pd^{103} with carrier-free Pd^{103}. The replacement leads to a smaller mass to be bonded. Nevertheless, there would be no reason to depart, at least in a first attempt, from the teaching of D2 concerning electroplating provided that a bonding mass is added, a measure that represents an obvious consequence of the decision to use carrier-free Pd^{103}. In this respect, the Board disagrees with the appellant's view that, once the skilled person has determined that electroplating was possible, it had to go against a prejudice in the art and add an amount of self-shielding palladium metal to the carrier-free Pd^{103} to accomplish electroplating. Indeed, there is no evidence in the file for the existence of such a prejudice in the art. Rather than with a prejudice, the skilled person is faced with a trade-off, as stated above.

5.7 In summary, the skilled person, starting from the model 200 Pd-seed according to D2 and faced with the problem addressed above, would consider, in view of the disclosure of D3 or D6, to replace the neutron-activated carrier Pd^{103} with carrier-free Pd^{103} obtained by irradiation of a rhodium target in a charged particle accelerator. It is well-known that carrier-free Pd^{103} causes a lower self-shielding than carrier

Pd^{103}. Thus, a smaller mass of carrier-free Pd^{103} is needed to achieve the desired therapeutic activity. Its normal technical competence would lead the skilled person to recognize that the electroplating process, as taught by D2, can still be carried out in spite of the small mass of carrier-free Pd^{103}, by adding a palladium bonding mass to the carrier-free Pd^{103}. In order to envisage this measure, an inventive activity is not necessary and no prejudice has to be overcome. Rather, the amount of carrier-free Pd^{103} will depend on the desired activity of the seed and the amount of the palladium to be added will result from a trade-off between the interest of reliably electroplating carrier-free Pd^{103} on the support and the disadvantage deriving from the known self-shielding effect of palladium metal. Finally, once the end seed is obtained, it would be obvious to measure its activity.

The provisions of Article 56 EPC are thus not met because the claimed method results in an obvious way from the combination of documents D2 and D3 or D6. Therefore, the second and fourth to sixth auxiliary requests are not allowable either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann