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**Datasheet for the decision  
of 26 April 2016**

**Case Number:** T 1810/10 - 3.4.01

**Application Number:** 05016123.1

**Publication Number:** 1621228

**IPC:** A61N5/10

**Language of the proceedings:** EN

**Title of invention:**

Particle beam therapy system and control system for particle beam therapy

**Patent Proprietor:**

Hitachi, Ltd.

**Opponent:**

ION BEAM APPLICATIONS S.A.

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2)

RPBA Art. 13(1)

**Keyword:**

added subject-matter (all requests)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 1810/10 - 3.4.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 26 April 2016**

**Appellant:** Hitachi, Ltd.  
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**Appellant:** ION BEAM APPLICATIONS S.A.  
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**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**  
**30 June 2010 concerning maintenance of the**  
**European Patent No. 1621228 in amended form.**

**Composition of the Board:**

**Chairman** G. Assi  
**Members:** H. Wolfrum  
C. Schmidt

## **Summary of Facts and Submissions**

- I. The appeals of the patent proprietor and the opponent lie from the interlocutory decision of the opposition division dispatched on 30 June 2010 maintaining European patent No. 1 621 228 in amended form on the basis of a third auxiliary request then on file. The opposition had been filed against the patent as a whole and based on the grounds of Articles 100(a), 100(b) and 100(c) EPC.

The notice of appeal of the patent proprietor/appellant I was received on 11 August 2010 and the prescribed fee was paid on 9 September 2010. On 9 November 2010 a statement of grounds of appeal was filed.

The notice of appeal of the opponent/appellant II was received on 9 September 2010 and the prescribed fee was paid on the same day. On 10 November 2010 a statement of grounds of appeal was filed.

- II. With the grounds of appeal appellant I requested that the patent be maintained in amended form on the basis of sets of claims according to a main request or an auxiliary request, claim 1 for both requests having been filed with the grounds of appeal.

In its grounds of appeal appellant II raised objections as to added subject-matter (Article 123(2) EPC), extension of protection conferred (Article 123(3) EPC), insufficiency of disclosure (Article 83 EPC) and lack of novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC) and requested that the patent be revoked in its entirety.

III. According to respective requests, the parties were summoned to oral proceedings by a notification dated 4 November 2015.

In an accompanying communication, the Board of Appeal indicated, *inter alia*, that it tended to share the objections concerning added subject-matter which had been raised by appellant II.

IV. By a letter of 23 March 2016, appellant I filed a revised main request and a new auxiliary request whilst maintaining the previous requests as further auxiliary requests.

V. Oral proceedings were held on 26 April 2016.

Appellant I requested that the patent be maintained in amended form on the basis of one of the sets of claims according to the main request or auxiliary requests 1 to 4, the main request and auxiliary request 1 having been filed with the letter of 23 March 2016, auxiliary requests 2 and 3 having been filed with the grounds of appeal as main request and auxiliary request, respectively, and auxiliary request 4 having been filed at the oral proceedings before the Board.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

As regards the main request and auxiliary requests 1 to 3 of appellant I, compliance with the requirements of Article 123(2) EPC was discussed, in particular with respect to the definitions of "*detectors*", "*one monitoring unit*" and a "*first control unit*".

As regards auxiliary request 4 of appellant I, its admission into the proceedings pursuant to Article 13(1) RPBA was discussed.

VI. Claim 1 of the main request of appellant I reads as follows :

*"1. A particle beam therapy system for irradiating a charged particle beam to an affected body part for treatment, the therapy system comprising:*

*a charged particle beam generator (1);*

*irradiation devices (3A, 3B; 4A, 4B) installed in a plurality of treatment rooms (7A, 7B; 8A, 8B);*

*a beam line (2) adapted to form a beam path for transporting the charged particle beam to the irradiation device (3A, 3B; 4A, 4B) in a selected one of said treatment rooms (7A, 7B; 8A, 8B); and*

*a plurality of detectors (25, 31; 33, 38) provided in each of said irradiation devices (3A, 3B; 4A, 4B) for detecting beam information of the charged particle beam,*

**characterized** *in that*

*said detectors include a profile monitor (25; 33) for measuring the centroid and width of the beam and a dose monitor (31; 38) for measuring dose;*

*one monitoring unit (66; 67) is shared by said irradiation devices (3A, 3B; 4A, 4B) for monitoring the state of the charged particle beam in one of said irradiation devices (3A, 3B; 4A, 4B) on the basis of the beam information detected by said monitors (25, 31; 33, 38);*

*a selector (70; 71) is provided for switchably selecting one of said irradiation devices (3A, 3B; 4A, 4B) which is to be monitored by said monitoring unit (66; 67); and*

*a first control unit (66; 67) is provided for*

*controlling said first [sic] selector (70; 71) such that said first [sic] selector (70; 71) establishes connection between the monitoring unit (66; 67) and the detectors (25, 31; 33, 38) of the irradiation device (3A, 3B; 4A, 4B) in the selected treatment room (7A, 7B; 8A, 8B) to which the charged particle beam is transported."*

Claims 2 to 15 are dependent claims.

The wording of claim 1 of auxiliary request 1 of appellant I differs from that of claim 1 of the main request in that the precharacterizing portion further specifies the feature *"the irradiation devices either being irradiation devices (3A, 3B) of the passive scattering irradiation type or irradiation devices (4A, 4B) of the scanning irradiation type"* and in that the characterizing portion reads :

*"1. ...*

*characterized in that  
said detectors include*

*a profile monitor (25; 33) for measuring  
the centroid and width of the beam,  
        a dose monitor (31; 38) for measuring dose,  
and*

*if the irradiation devices (3A, 3B) are of  
the passive scattering irradiation type, an energy  
monitor (29) for measuring an energy amount of the beam  
and a flatness monitor (30) for measuring uniformity of  
the beam in a direction perpendicular to the direction  
of travel of the beam, or*

*if the irradiation devices (4A, 4B) are of  
the scanning irradiation type, a spot position monitor  
(37) for measuring the centroid and width of the ion*

beam bent by scanning magnets (34, 35) provided in each of the irradiation devices (4A, 4B);

one monitoring unit (66; 67) is shared by said irradiation devices (3A, 3B; 4A, 4B) for monitoring the state of the charged particle beam in one of said irradiation devices (3A, 3B, 4A, 4B) on the basis of the beam information detected by said monitors (25, 29, 30, 31, 33, 37, 38);

a selector (70, 71) is provided for switchably selecting one of said irradiation devices (3A, 3B; 4A, 4B) which is to be monitored by said monitoring unit (66) and, if the irradiation devices are of the scanning irradiation type, the scanning magnets (34, 35) of which are to be controlled; and

a first control unit (66, 67) is provided for controlling said selector (70, 71) such that said first [sic] selector (70, 71) establishes connection between the monitoring unit (66, 67) and the detectors (25, 29, 30, 31, 33, 37, 38) of the irradiation device (3A, 3B; 4A, 4B) in the selected treatment room (7A, 7B; 8A, 8B) to which the charged particle beam is transported, and, if the irradiation devices (4A, 4B) are of the scanning irradiation type, establishes connection between a scan stroke control unit (67) and the scanning magnets (34, 35) in the selected treatment room (8A, 8B) such as to allow the scan stroke control unit (67) to control the scanning magnets (34, 35)."

Claims 2 to 6 are dependent claims.

The wording of claim 1 of auxiliary request 2 of appellant I corresponds essentially to that of claim 1 of the main request and differs therefrom in substance only in that it consistently refers to "a first selector" or "said first selector", respectively.



Claims 2 to 16 are dependent claims and correspond to claims 2 to 16 of the patent as granted.

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in substance only by the complement "*and either an energy monitor (29) and a flatness monitor (30) for measuring uniformity of the beam in a direction perpendicular to the direction of travel of the beam, or a spot position monitor (37)*", which is added to the first characterizing feature.

Claims 2 to 16 are dependent claims and correspond to claims 2 to 16 of the patent as granted.

Claim 1 of auxiliary request 4 is based on claim 1 of the main request and differs therefrom in that the terms "*monitoring unit*" and "*a first control unit*" are replaced by the term "*beam detection processing/control unit*" and in that the word "*first*" has been deleted in all references to "*a*" or "*said selector (70; 71)*".

Claim 2 to 15 are dependent claims.

### **Reasons for the Decision**

1. The appeals comply with the requirements of Articles 106 to 108 EPC and Rule 99 EPC and are, therefore, admissible.
2. Main request of appellant I - admission into the proceedings (Article 13(1) RPBA)

Appellant II did not object to the admission of the main request of appellant I into the proceedings.

Since the amendments made to the main request are, in comparison to the main request filed with the statement of grounds of appeal, essentially of editorial nature the Board did not see any reason not to admit the main request into the proceedings.

3. Main request of appellant I - added subject-matter (Article 123(2) EPC)

3.1 According to appellant II, the definitions of claim 1 of the main request infringed the requirements of Article 123(2) EPC in a number of aspects.

A first aspect concerned the fact that the claimed therapy system required only a "*profile monitor*" and a "*dose monitor*" to be provided in the irradiation devices, whereas, according to the application documents as originally filed, irradiation devices were equipped with further detectors, such as either an "*energy monitor*" and a "*flatness monitor*" or a "*spot position monitor*", which had to be monitored. The omission of these further detectors from claim 1 amounted to an arbitrary picking of features and thus constituted an inadmissible intermediate generalization.

A second aspect concerned the claimed feature that the "*one monitoring unit*" was the sole unit which was shared by the irradiation devices, contrary to what was disclosed by the description of the application as originally filed. What was in fact shared according to the description was a "*beam detection processing/control unit*" [in the following referred to as "*bdpc unit*"], which consisted of a "*monitoring unit*", a "*control unit*" and a "*determining unit*". Thus, by claiming a system with "*one monitoring unit*" and a

separate "*control unit*", the claim definitions encompassed embodiments which were not originally disclosed.

In this context, a third aspect which was not respected by the definition of "*one monitoring unit*" lay in the fact that claim 1 was unspecific as to the number and type of the irradiation devices which could be associated with the "*one monitoring unit*", whereas according to the original description irradiation devices of different types (*i.e.* of the "*passive scattering irradiation*" type and of the "*scanning irradiation*" type) were monitored and controlled by different "*bdpc units*".

Fourthly, due to the deletion of the word "*respectively*" from the original phrase "*a plurality of irradiation devices installed respectively in a plurality of treatment rooms*", present claim 1 encompassed systems with more than one irradiation device per treatment room. Such systems were not disclosed in the original application documents.

- 3.2 As regards the said first aspect, appellant I argued that the "*profile monitor*" and the "*dose monitor*" were exactly those two detectors which were common to all of the four embodiments that were presented in the description. Notably, the embodiment of Figure 14 and the corresponding description in paragraph [0094] of the published description referred to a shared monitoring of only these two kinds of detectors (by a "*monitoring unit 137*" shared by "*passive*" and "*scanning*" "*irradiation devices*"). Accordingly, original claim 14, which was directed to this embodiment, also specified only these common detectors. Therefore, a skilled reader of the original

application documents readily recognized that the shared monitoring of the "*profile monitor*" and the "*dose monitor*" played a prominent and adequate role for the present invention. The limitation of the claim definition to just the said two detectors was further justified by the facts that monitoring of the beam profile and the dose was not functionally linked to the type of irradiation device in which the respective detectors were employed and that the operation of these detectors was not functionally linked to that of possible further detectors.

Concerning the second aspect, appellant I took the view that it became abundantly clear from the original application documents that the gist of the invention concerned the sharing between a plurality of irradiation devices of a monitoring function of certain detectors by a single "*monitoring unit*". In this context, paragraphs [0026], [0028] and [0030] of the published application description clearly presented the "*monitoring unit*" as a separate and independently operating subunit of a "*bdpc unit*". Thus, it did not matter that the "*bdpc unit*" which was discussed in the description comprised other subunits or could perform additional functions. In distinction to the shared monitoring function by the "*monitoring unit*", there was no need to share between different irradiation devices for instance a determining function (which was only optional, as was evidenced by the fact that it was only the subject of a dependent claim (original claim 5)) or a control function, which was exercised by the "*first control unit*". In a certain sense, the "*first control unit*", which established a connection to a certain treatment room, operated at a higher level than the "*monitoring unit*". This control function could even not be shared. Moreover, according to the application

description, there was a plurality of other control components which did not form part of a "*bdpc unit 66*", such as a "*central controller 55*", a "*power supply controller 19*", or "*gantry controllers 58A, 58B*", "*bed controllers 60A, 60B*", "*irradiation nozzle controllers 62A, 62B*", and "*irradiation controllers 64A, 64B*", the majority of which was not shared between different irradiation devices. By the same token, it was not important whether in the case of "*scanning irradiation devices*" the monitoring of the "*scanning magnets*" was shared or not.

With regard to the third aspect, appellant I pointed to original claim 1, which defined the provision of "*a monitoring unit*" for "*a plurality of irradiation devices*" of unspecified types, as the basis of disclosure. In this context, the expression "*one monitoring unit*" had to be considered identical to the expression "*single monitoring unit*" used in claim 1 of the patent as granted.

As to the fourth aspect, appellant I was of the opinion that the former phrase given in original claim 1 "*a plurality of irradiation devices installed respectively in a plurality of treatment rooms*" did not make it unambiguously clear that there had always to be one irradiation device per treatment room. This fact became however clear from the reference to "*the irradiation device (3A, 3B; 4A, 4B) in the selected treatment room*" in the last feature of present claim 1, notwithstanding the omission of the term "*respectively*".

- 3.3 In particular as regards the aforementioned first to third aspects, the Board is not convinced by the arguments of appellant I.

3.3.1 First of all, it is to be noted that none of the originally-filed claims comprises the combination of features as it is included in claim 1 of the main request so that none of them serves as a proper basis of disclosure for the claimed subject-matter. This observation was as such not contested by appellant I.

This finding is insofar of relevance as there is a significant discrepancy between a particle beam therapy system as respectively claimed by the originally-filed claims and a therapy system as illustrated by the original drawings and discussed in the original description. According to original claims 12 and 13, which are dependent on original claim 1, there is "a *monitoring unit*" provided for all of the "*irradiation devices*" which may be present in the therapy system, regardless of whether these devices are of the same or of different irradiation types (*i.e.* of the "*passive scattering irradiation type*" and/or of the "*scanning irradiation type*"). In distinction thereto, according to the original description, whenever the therapy system comprises "*irradiation devices*" of different irradiation types with their respective sets of detectors, these are monitored and beam access to them is controlled by different "*bdpc units*" (see the embodiments illustrated by Figures 10 and 12 to 15).

Consequently, in the specific circumstances of the present case, it has to be determined whether the subject-matter of claim 1 of the main request of appellant I finds a basis of disclosure in the description and drawings of the application documents as originally filed.

3.3.2 As regards the aforementioned first aspect, the type of the irradiation device present in a treatment room determines the number and nature of the associated detectors. Throughout the application description, an "irradiation device" of the "passive scattering irradiation type" is always equipped with a "profile monitor", a "dose monitor", an "energy monitor" and a "flatness monitor", whereas an "irradiation device" of the "scanning irradiation type" is always equipped with a "profile monitor", a "dose monitor" and a "spot position monitor".

Contrary to the assertions of appellant I, this is also the case for the embodiments of Figures 14 and 15. The corresponding description refers expressly to a shared monitoring by a "bdpc unit 135" of "energy monitors 29" and "flatness monitors 30" for treatment rooms with a passive scattering irradiation device and to a shared monitoring by a "bdpc unit 136" of "spot position monitors 37" for treatment rooms with a scanning irradiation device (see in particular paragraph [0091] of the description as originally filed). The circumstance that the specific embodiments of Figures 14 and 15 foresee an additional "bdpc unit 137", which is shared on both the passive irradiation and the scanning irradiation sides and dedicated to a shared monitoring of the "profile monitors" and the "dose monitors", is immaterial in view of the fact that all of the detectors which are associated with an "irradiation device" are indispensable for a proper monitoring and control of the particle beam.

It follows from these observations that the subject-matter of claim 1 constitutes an unjustified generalization of the content of the original application documents as far as the provision of the

detectors in the respective treatment rooms is concerned.

- 3.3.3 As regards the aforementioned second aspect, the description refers consistently to a "*bdpc unit*" consisting of a "*monitoring unit*", a "*control unit*" and a "*determining unit*", as the unit which is in fact shared by the irradiation devices of a given irradiation type (see in particular paragraphs [0026] to [0032], [0079] and [0091]). This "*bdpc unit*" serves the combined functions of controlling a "*selector*" for establishing the connection between the "*bdpc unit*" and the detectors of a respective irradiation device in a selected treatment room, of monitoring the detectors so as to gain information about the state of the particle beam, as well as of determining on the basis of the gained information any deviation from allowable ranges. For "*irradiation devices*" of the scanning irradiation type the "*bdpc unit*" additionally monitors the scanning magnets (paragraphs [0070] and [0091]).

The argumentation of appellant I that the description proved that the "*monitoring unit*" was a separate and independently functional subunit of a "*bdpc unit*", that the object of the invention was already achieved if only this subunit was shared between a plurality of "*irradiation devices*", and that there was in particular no necessity to share any control unit between irradiation devices are without merit. First of all it is noted that claim 1 of the main request already fails to define the "*monitoring unit*" and the "*first control unit*" as subunits of a "*bdpc unit*". Even more importantly, the application description simply does not disclose a beam therapy system as claimed by present claim 1, in which a "*monitoring unit*" would be physically and functionally separated from a "*control*



*unit*" (and a *determining unit*"). On the contrary, it becomes abundantly clear from the application description (see in particular paragraphs [0031], [0032], [0079], [0080] and [0091]) that the function of monitoring the detectors of the *"irradiation device"* in a given treatment room requires the establishing of a connection to exactly these detectors and thus presupposes a shared control of the one common *"selector"*, which is foreseen for each plurality of *"irradiation devices"* of a given irradiation type. Sharing a common *"monitoring unit"* but not sharing a corresponding *"control unit"* is neither disclosed in the original application nor would it make technical sense. By the same token, sharing of the function of determining any abnormalities in the beam information obtained from the detectors is disclosed as an indispensable necessity (see for instance paragraphs [0028] and [0029]).

The reference made by appellant I to the presence in the therapy system of other controllers, some of which were common to all *"irradiation devices"* whereas others were not shared at all between the *"irradiation devices"*, is inconclusive because these other controllers concern elements of the therapy system which are not the subject of any of the claims on file, such as for instance a common power supply, the accelerator or a central supervisory computer, on the one hand, or controllers within the respective treatment rooms, such as a bed controller or gantry controllers, on the other hand. In fact, none of these other controllers is related to the operation of the *"bdpc unit"*, the *"control unit"* of which serves the claimed function of controlling the *"selector"* that establishes connection between the *"bdpc unit"* and the *"irradiation device"* of a selected treatment room.

Therefore, as regards the provision of a shared "*monitoring unit*" and a "*control unit*", claim 1 on file defines subject-matter which has no basis of disclosure in the originally-filed application documents.

- 3.3.4 As far as the third aspect is concerned, it has already been noted in point 3.3.1 above that, whenever the particle beam therapy system comprises "*irradiation devices*" of different irradiation types, the respective sets of detectors thereof are monitored and beam access to them is controlled by different "*bdpc units*" (see the embodiments illustrated by Figures 10 and 12 to 15).

Since this basic correlation is not respected by the definitions of claim 1 of the main request, the claimed subject-matter encompasses undisclosed therapy systems which possess a single "*monitoring unit*" even for "*irradiation devices*" of different irradiation types.

- 3.3.5 In view of the foregoing, the fourth aspect mentioned above can be left open.
- 3.3.6 For the reasons given above, claim 1 of the main request does not comply with the requirements of Article 123(2) EPC.

The main request is therefore not allowable.

4. Auxiliary request 1 of appellant I

- 4.1 Admission into the proceedings (Article 13(1) RPBA)

- 4.1.1 Appellant II objected to the admission of auxiliary request 1 of appellant I into the proceedings as being

late-filed and clearly defective in that some of the amendments made to claim 1 were unclear and introduced added subject-matter.

4.1.2 Appellant I defended the filing of auxiliary request 1 as constituting a reaction to observations given in the Board's communication. The proposed amendments were not excessive. Moreover, they aimed at simplifying the debate in the oral proceedings in that they removed at least some of the concerns as to added subject-matter which had been addressed in the Board's communication. Finally, having been filed one month before the date of the oral proceedings, appellant II and the Board had ample time to study the request.

4.1.3 Article 13(1) RPBA states that *"any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy."*

In the present case, the amendments do not introduce new problems of added subject-matter, but, instead, remove the problems associated with the aforementioned first aspect as discussed in point 3.3.2 above and thus do not impede procedural economy.

For these reasons, the Board admitted the auxiliary request 1 into the appeal proceedings.

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

As correctly pointed out by appellant II, the amendments made to auxiliary request 1 do not address

the second and third aspects of added subject-matter as argued in point 3.1 above.

Since appellant I did not add any further arguments in support of the claimed subject-matter, the deficiencies discussed in points 3.3.3 and 3.3.4 above apply with equal force to claim 1 of auxiliary request 1.

Auxiliary request 1 is therefore not allowable, either.

5. Auxiliary requests 2 and 3 of appellant I

5.1 These requests correspond to the main request and auxiliary request filed, respectively, with the grounds of appeal. They are in the appeal proceedings pursuant to Article 12(1)(a) RPBA.

5.2 Since appellant I did not advance any additional arguments in support of the subject-matter of auxiliary requests 2 and 3, the Board came to the conclusion that auxiliary request 2 suffers from the deficiencies given in points 3.3.2 to 3.3.4 above, whereas auxiliary request 3 suffers from the deficiencies given in points 3.3.3 and 3.3.4.

Auxiliary requests 2 and 3 are therefore also not allowable.

6. Auxiliary request 4 of appellant I - admission into the proceedings (Article 13(1) RPBA)

6.1 Appellant II objected to the admission of this request into the proceedings as being late-filed and not clearly allowable.

According to appellant I, the request was based on the main request and should be admitted into the proceedings because the amendments were not complicated in that they merely concerned the straightforward replacement of the terms "*monitoring unit*" and "*first control unit*" by the term "*bdpc unit*". Thus, the amendments removed a central objection under Article 123(2) EPC, as discussed in the oral proceedings, and therefore further simplified the issue.

- 6.2 In distinction to auxiliary request 1, auxiliary request 4 was filed at an advanced stage of the debate in the oral proceedings.

According to established case law, a decisive criterion for a board when exercising its discretion pursuant to Article 13(1) RPBA in favour of admitting a request filed at such a late stage of the proceedings is whether or not the new request would overcome all of the objections raised in the appeal proceedings and would be clearly allowable. If, when judged on a *prima facie* basis, a late-filed request does not comply with a requirement of the EPC, it should not be admitted into the proceedings.

In the present case, it is immaterial that the request addresses at least in part one of the problems under Article 123(2) EPC. What matters instead is the fact that it becomes immediately apparent that claim 1 of auxiliary request 4 does not overcome the deficiencies under Article 123(2) EPC as established for the main request in points 3.3.2 and 3.3.4 above.

Therefore, the Board did not admit auxiliary request 4 into the proceedings.

7. In conclusion, it has been found that there is no allowable request made by appellant I on file.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



R. Schumacher

G. Assi

Decision electronically authenticated