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**Datasheet for the decision
of 13 July 2017**

Case Number: T 0797/14 - 3.3.07

Application Number: 07733302.9

Publication Number: 2029178

IPC: A61K51/00, A61K51/12, G21F5/10

Language of the proceedings: EN

Title of invention:
RADIOPHARMACEUTICAL PRODUCTS

Patent Proprietor:
GE Healthcare Limited

Opponents:
Bergenstrahle & Lindvall AB
Lantheus Medical Imaging, Inc.

Headword:
RADIOPHARMACEUTICAL PRODUCTS/GE Healthcare Limited

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 100(b)

Keyword:

Sufficiency of disclosure - All requests (no)
Composition of commercial product not public

Decisions cited:

Catchword:



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Boards of Appeal
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Case Number: T 0797/14 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 July 2017

Appellant: GE Healthcare Limited
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 11 February
2014 revoking European patent No. 2029178
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

| | |
|-----------------|--------------|
| Chairman | J. Riolo |
| Members: | D. Boulois |
| | I. Beckedorf |

Summary of Facts and Submissions

- I. European patent No. 2 029 178 based on application No. 07 733 302.9 was granted on the basis of a set of 15 claims.

Independent claim 1 as granted read as follows:

"1. An imaging agent product which comprises a radiopharmaceutical composition supplied within a sealed container, wherein:

(i) said radiopharmaceutical composition comprises a radioisotope suitable for medical imaging provided in a biocompatible carrier, in a form suitable for mammalian administration;

(ii) said sealed container is provided with a closure suitable for puncturing with a hypodermic needle whilst maintaining seal integrity, and said closure is coated on those of its surface(s) which are in contact with the container contents with a coating comprising ethylene-tetrafluoroethylene copolymer (ETFE)."

Dependent claim 4 read as follows:

"4. The imaging agent product of any one of Claims 1 to 3, where the coating is the modified ETFE coating Flurotec™."

Independent claim 9 as granted read as follows:

"9. A kit for the preparation of the imaging agent product of any one of Claims 1 to 8, which comprises the sealed container with closure as defined in Claims 1 to 5, having provided therein a non-radioactive precursor suitable for the preparation of the radiopharmaceutical composition as defined in Claims 1

and 6 to 8, wherein said precursor comprises a reactive substituent (X^R) capable of reaction with a supply of the radioisotope of Claims 1, 6 or 7 to give said radiopharmaceutical composition."

- II. Two oppositions were filed against the granted patent under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.
- III. The appeal by the patent proprietor (hereinafter called appellant) lies from the decision of the opposition division to revoke the patent. The decision was based on 4 sets of claims filed during the oral proceedings on 11 December 2013 as main request and auxiliary requests 1-3.
- IV. The documents cited during the opposition proceedings included the following:
- D1: The West Company brochure for Daikyo Flurotec® Closures, dated 15 August 1992, publicly available at least as of December of 1992.
 - D3: US 6,162,648
 - D4: : Myoview™ prescribing information, Amersham Health/Medi-Physics, Inc., March 2005
 - D5: US 7,011,816
 - D9: Adelphi Healthcare Packaging, brochure titled "Adding our personal touch"
 - D10: US 2002/0119200
 - D13: The Source article from West Pharmaceutical Services
 - D15: West Pharmaceutical Services – Barrier Film web page
 - D16: Daikyo Seiko – Flurotec web page

D19: Extract from Ullmann's Encyclopedia of Industrial Chemistry, fifth edition

D26: WO 2006/044908

- V. According to the decision under appeal, all requests filed with the letter of 11 November 2013 were withdrawn during the oral proceedings and replaced by a new main request and auxiliary requests 1-3.

The main request as filed during oral proceedings was considered as admissible under Rule 116 EPC and met also the requirements of Article 123(2) EPC.

The opposition division could not follow the opponents as regard an insufficient disclosure regarding the subject-matter of dependent claim 4, relating to "the modified ETFE coating FlurotecTM", since the term was not seen as a modification of the ETFE coating, but referring simply to a known commercial product. Example 3 of D26 was relevant to the novelty of claim 9 of the main request, which did not meet the requirements of Article 54 EC for this reason.

As regards auxiliary request 1, D4 was selected as closest prior art. The technical difference between the claimed subject-matter and the teaching of D4 was the ETFE coating of the stopper. The problem was defined as the provision of an alternative closure sealed radiopharmaceutical composition. The solution was obvious in view of documents D1, D13, D15 or D16, all of which disclosing the properties of ETFE coated stoppers. The claimed subject-matter was not inventive over D4 for this reason.

The second auxiliary request was not admitted under Rule 116 RPC into the proceedings since its object was not converging with the subject-matter of the main or

first auxiliary request, and that some features were prima facie not supported by the application as originally filed.

The third auxiliary did not comply with the requirements of inventive step for the same reasons that the first auxiliary request.

VI. With the statement of grounds of appeal dated 17 June 2014, the appellant filed a main request and 9 auxiliary requests.

The subject-matter of independent claim 1 and dependent claim 4 of the main request and auxiliary requests 1-3 was identical to that of claims 1 and 4 as granted. The claims of these requests differed from the claims as granted in the modification or suppression of the independent kit claim corresponding to claim 9 as granted.

The subject-matter of claim 1 of auxiliary requests 4-6 was modified by the specification of the a coating comprising ethylene-tetrafluoroethylene copolymer (ETFE), namely "**where said coating is the modified coating FlurotecTM**", corresponding to the subject-matter of the dependent claim 4 as granted.

The subject-matter of claim 1 of auxiliary request 8 was restricted by the specification of the radiopharmaceutical, namely "**the ^{99m}Tc complex of tetrofosmin**". The subject-matter of dependent claim 4 was identical to that of dependent claim 4 as granted.

The subject-matter of claim 1 of auxiliary request 9 was restricted by the specification of the radiopharmaceutical, namely "**the ^{99m}Tc complex of**

tetrofosmin" and by the specification of the coating comprising ethylene-tetrafluoroethylene copolymer (ETFE), namely "**where said coating is the modified coating FlurotecTM**", corresponding to the subject-matter of the dependent claim 4 as granted.

- VII. A communication from the Board, dated 9 June 2017, was sent to the parties. In this it was stated in particular that the use of the specific commercial product defined by the trade mark FlurotecTM in the claims led to an insufficient disclosure since the composition of this product was kept secret by the producing firm and was not known at the filing date of the contested patent.
- VIII. With a letter dated 14 June 2017, the appellant stated that it will not be represented at the oral proceedings.
- IX. Oral proceedings took place on 13 July 2017, in the absence of the appellant in accordance with Rule 115(2) EPC and Article 15(3) RPBA.
- X. The arguments of the appellant, as far as relevant to the present decision may be summarised as follows:

The appellant did not provide any argument as regards sufficiency of disclosure in its statement of grounds of appeal, and did not respond to the objections raised by the respondents in their reply to the statement of grounds and appeal and submission of the main and auxiliary requests.

Certain arguments of the appellant as regards inventive step were however possibly relevant to the question of disclosure. Appellant indeed contended that the present

claims were supported by the examples of the contested patent. It mentioned D19 which stated that "Unmodified TFE-ethylene copolymers have poor thermal stress-crack resistance, which severely limits their utility. This problem has been overcome by incorporating 0.1-10 mol% of termonomers, such as perfluoro-(alkyl vinyl ethers) and perfluoroalkylethylenes, in the polymer backbone [54]-[56]. Commercial ETFE-resins are all modified in this way." Thus, D19 taught clearly that all commercial ETFE resins have such modification. D19 mentions five specific commercial suppliers of such modified ETFE resins.

Furthermore, the appellant stressed that the contested patent was enabled by the fact that suitable closures having a coating which comprised ETFE were commercially available. That fact had not been contested by the opponents.

XI. The arguments of the respondents (opponents 01 and 02), as far as relevant to the present decision, may be summarised as follows:

According to responding 01, each filed request included the feature that the coating of the closure was the modified ETFE coating Flurotec™. In the main request, and in the auxiliary requests 2 and 8, this feature appeared in claim 4, However, in auxiliary requests 5, 6, 7 and 9, this was a feature of claim 1.

Respondent 01 maintained that the alleged invention was insufficiently disclosed. The reliance on a trademark in the claims not only reduced the clarity of the claims, it introduces a profound insufficiency. Respondent 01 could not follow the opinion of the opposition division in its decision which noted that

the Flurotec™ stoppers appeared to be available at least since 1992 as shown by D1 until 2010 as shown by D10 (*sic, although D10 has been published in 2002*), and thus that the stoppers were available at the effective date of the present patent and consequently, the subject-matter of claim 4 was regarded to be sufficiently disclosed.

First, the requirement of sufficiency of a claim applied to the entire life of a patent. The fact that stoppers with a coating referred to with the trademark Flurotec™ have been marketed in the interval of 1992 to 2010 did not guarantee that the coating had the same composition during this time. Second, even a long term availability of a commercial product was no guarantee that the product would be in the same form, or even available for the remaining life of the patent. The arguments that Flurotec™ was well known and widely available to a skilled person did not legitimize its use in the claims.

Further any embodiment of the invention, as defined in the broadest claim, had to be capable of being realised on the basis of the disclosure.

According to respondent 02, at least claim 1 of the main request was not sufficiently disclosed across its full scope, offending Article 83 EPC. The main request required "a coating comprising ethylene-tetrafluoroethylene copolymer (ETFE)". This phrase encompassed modifications to the ETFE; aside from the example of Flurotec™, other possible modifications were undisclosed. Therefore, the skilled person was unable to work these all undisclosed modifications that fell within the scope of at least claim 1 of the main request.

Moreover, Flurotec™ was a trade mark. Its precise formulation and the method of producing were were not

public knowledge. The appellant did not produce Flurotec™ nor appeared to know the details of its composition, and certainly none were disclosed in the patent. The fact that said Flurotec™ stoppers were available before the effective date of the patent and continued to be available made the sufficiency of the term wholly reliant on a third party continuing to market a closure with a coating of a particular composition called Flurotec™. This was contrary to the principle of sufficiency of disclosure: what would have happened if the third party were to change the composition of Flurotec™ or were to cease manufacturing?

Therefore, the presence of the term Flurotec™ in the claims led also to a lack of sufficiency.

XII. Requests

Appellant requests that the decision under appeal be set aside and the patent be maintained according to the sets of claims filed as main request or auxiliary requests 1-9 with letter of 17 June 2014.

Respondents 01 and 02 request that the appeal be dismissed and the patent be revoked.

Respondents 01 and 02 also request that the main request and auxiliary requests 1, 4-7 and 9 not be admitted into the proceedings.

Reasons for the Decision

1. Admission of the main request and auxiliary requests 1, 4-7 and 9 into the proceedings (Article 12(4) RPBA)

The admission of these requests into the proceedings has been contested by the respondents.

In view of the serious deficiencies regarding the sufficiency of disclosure of all requests submitted by the appellant that were already pointed out in the Board's communication, the Board sees no need to discuss extensively the admission of these requests into the proceedings.

Hence, the Board exerts its discretionary power and admit the main request and auxiliary requests 1, 4-7 and 9 into the proceedings.

2. Main request - Article 100(b) EPC
 - 2.1 Claim 1 is directed to a radiopharmaceutical composition supplied with a container sealed with a closure coated with a coating comprising an ethylene-tetrafluoroethylene copolymer (ETFE). Dependent claim 4 is directed to a specific closure coating made from the modified ETFE coating FlurotecTM. Said coated closure is the key element of the claimed invention, the selection of the claimed closures having an ETFE coating having indeed been shown to be particularly suitable for radiopharmaceuticals, since their purity and integrity composition is maintained during manufacture, transport and clinical use (see par. [0008], [0009], [0040] of the specification).
 - 2.2 More precisely, the coating of the closures is made from a coating composition comprising an ethylene-tetrafluoroethylene copolymer, preferably a modified

ETFE commercialised by Daikyo Seiko as FlurotecTM, as disclosed in the application as originally filed on page 13 (see also the specification in par. [0042]-[0044], [0050]). Said commercial product FlurotecTM is the only coating composition disclosed in the description of the contested patent and all examples of the contested patent disclose closures coated exclusively with said FlurotecTM coating.

- 2.3 It appears however that the preferred and unique coating composition disclosed by the contested patent, namely the product FlurotecTM, has a composition and method of production which is not of public knowledge and is kept secret by the manufacturer, Daikyo Seiko Ltd or its licensee Westpharma (see description of the contested patent par. [0050]).

The appellant did not provide any information as regards said composition during the opposition or during the appeal proceedings, though this point has been raised repeatedly by the respondents, as well as by the Board in its communication to which the appellant chose not to react on the substance . The description of the contested patent does also not provide more information as regards the structure and composition of the FlurotecTM coating.

- 2.4 Said FlurotecTM coating is a known commercial product and is mentioned in several cited documents, such as the commercial brochures or Internet commercials D1, D10, D13, D15 or D16 but none of said documents brings further details as regards the structure and composition of the coating composition FlurotecTM.

D19 is the only cited document giving an vague indication as to a modification possibly undergone by

the ETFE polymer, namely by "incorporating 0.1-10 mol% of termonomers, such as perfluoro(alkylvinylethers) and perfluoroalkylethylenes, in the polymer backbone. Commercial reins are all modified in this way.". There is however no certainty that FlurotecTM has been modified in this way.

2.5 There is also neither any certainty as to the availability as such or in a constant composition of the product FlurotecTM, nor as to the possibility that the FlurotecTM can be analysed and reproduced by the skilled person.

2.5.1 As to the availability and accessibility of the product to the public, it is only apparent from the technical brochure D1 showing all Daikyo Flurotec[®] Closures, that stoppers coated with FlurotecTM were available at least since 1992, and that said product FlurotecTM was still available at the filing date of the contested patent, as shown by D16; according to the respondents, the product was still available in 2010.

This does however not mean that the product FlurotecTM had a stable and constant composition before the filling date of the contested patent or will keep its composition stable and constant over time after the filing date, since there might be or have been continuous further developments leading to improved compositions from 1992 on.

This does also not mean that said FlurotecTM product will remain available or accessible to the public after 2010, since this is dependent on the manufacturer and on the demand for said commercial product.

2.5.2 Given the complexity of a polymeric structure, there is also no certainty beyond a reasonable doubt that an accurate analysis of the product FlurotecTM is feasible. The process of preparation of the product being also unknown, the reproducibility of the product is also very questionable.

2.6 The Board comes therefore to the conclusion that the essential element of the claimed invention, namely the coating composition FlurotecTM, is not of public knowledge and that there is also not enough information available to the skilled person for him to reliably determine the composition or structure of the product. The counterpart of a monopoly by a patent is however the disclosure of the invention, in particular of its essential elements, and not the provision or use of a commercial product which structure and composition are not public.

For these reasons the Board concludes that the requirements of sufficiency of disclosure are not met (Article 100(b) EPC).

3. Auxiliary requests 1-3 - Article 100(b) EPC

The subject-matter of claim 1 and claim 4 of these request is identical to those of the main requests, and the conclusions reached for the main request apply thus *mutatis mutandis* for auxiliary requests 1-3, for which the requirements of sufficiency of disclosure are also not met (Article 100(b) EPC).

4. Auxiliary requests 4-7 - Article 100(b) EPC

The subject-matter of claim 1 of all auxiliary requests 4-7 is identical. In comparison to claim 1 of the main

request, it has been restricted by the specification of the ETFE copolymer, namely by the feature "where said coating is the modified ETFE coating FlurotecTM". The key feature of the invention for which a lack of disclosure was stated for the main request, is now present in independent claim 1 of all these requests and the conclusions reached for the main request apply thus *a fortiori* also for auxiliary requests 4-7.

The invention claimed by these requests is therefore not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art for the same reason than the main request (Article 100(b) EPC).

5. Auxiliary request 8 - Article 100(b) EPC

The subject-matter of claim 1 of this request has been restricted to a specific radiopharmaceutical complex. The subject-matter of dependent claim 4 remains however the same as for the main request, and the points raised for the main request apply *mutatis-mutandis* for this request, which does not meet the requirements of Article 100(b) EPC.

6. Auxiliary request 9 - Article 100(b) EPC

In comparison to the main request, the subject-matter of claim 1 of this request has been restricted to a specific radiopharmaceutical complex and by the incorporation of the subject-matter of dependent claim 4, namely by the feature "where said coating is the modified ETFE coating FlurotecTM". Since the subject-matter of this request includes the subject-matter of the main request for which negative conclusions were reached as regard sufficiency of

disclosure, the reasoning and conclusions apply *mutatis mutandis* to auxiliary request 9, which does not meet the requirements of Article 100(b) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated