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**Datasheet for the decision
of 28 January 2019**

Case Number: T 1827/15 - 3.5.07

Application Number: 07253109.8

Publication Number: 1887581

IPC: G11C11/16, G11C11/22

Language of the proceedings: EN

Title of invention:

Use of gamma hardened RFID tags in pharmaceutical devices

Patent Proprietor:

Millipore Corporation

Opponents:

GE Healthcare Bio-Sciences AB
Newage Industries, Inc.

Headword:

Gamma-hardened RFID tags/MILLIPORE

Relevant legal provisions:

EPC Art. 56, 100(a)

Keyword:

Inventive step - all requests (no)



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1827/15 - 3.5.07

D E C I S I O N
of Technical Board of Appeal 3.5.07
of 28 January 2019

Appellant: Millipore Corporation
(Patent Proprietor) 290 Concord Road
Billerica
Massachusetts 01821 (US)

Representative: Uexküll & Stolberg
Partnerschaft von
Patent- und Rechtsanwälten mbB
Beselerstraße 4
22607 Hamburg (DE)

Respondent I: GE Healthcare Bio-Sciences AB
(Opponent I) Patent Department
Björkgatan 30
751 84 Uppsala (SE)

Representative: Bedford, Grant Richard
GPO Europe
GE International Inc.
The Ark
201 Talgarth Road
Hammersmith
London W6 8BJ (GB)

Respondent II: Newage Industries, Inc.
(Opponent II) 145 James Way
Southampton PA 18966 (US)

Representative: Lemcke, Brommer & Partner
Patentanwälte Partnerschaft mbB
Siegfried-Kühn-Straße 4
76135 Karlsruhe (DE)

Summary of Facts and Submissions

- I. The patent proprietor (appellant) appealed against the decision of the Opposition Division revoking European patent No. 1 887 581.
- II. The patent had been opposed as a whole on the basis of Article 100(a) EPC (lack of novelty and lack of inventive step) by opponent I (respondent I) and opponent II (respondent II).
- III. The decision cited, *inter alia*, the following documents:
- D1: "RF SAW, Inc. Announces Gamma Radiation Hard RFID Tags; Doses Up To 5 Mega Rads --500 Million Ergs/Gm-- With No Measurable Degradation", 10 December 2003;
- D3: S. Philpy et al.: "Reliability of Ferroelectric Memory for High-Rel and Space Applications", Celis Semiconductor Corporation, white paper, presented at the Jet Propulsion Laboratory MRQ conference, October 1999;
- D4: US 2003/0072676 A1, published on 17 April 2003;
- D5: "RFID tag with 256 bytes of FRAM", EE Times India, 12 August 2005;
- D11: US 2006/0016897 A1, published on 26 January 2006;
- D16: US 2006/0092013 A1, published on 4 May 2006;
- D17: D. Kamp et al.: "Adaptable Ferroelectric Memories for Space Applications", Proceedings of the 2004 IEEE Non-Volatile Memory Technology Symposium, November 2004, pp. 149-152;
- D19: US 2001/0007532 A1, published on 12 July 2001;
- A9: G. Derbenwick and A. Isaacson: "Ferroelectric Memory: On The Brink of Breaking Through", IEEE

Circuits and Devices Magazine, Vol. 17, No. 1,
January 2001, pp. 20-30;

B1: U. Schöffling: "Arzneiformenlehre", third
edition, ISBN 3-7692-2254-7, 1998, pp. 128, 129,
356 and 357.

The Opposition Division decided that the subject-matter
of claim 1 of the patent as granted (main request) was
not new in view of document D1, that the subject-matter
of claims 1 and 6 of auxiliary requests 1 to 5 did not
comply with Article 123(2) EPC, and that the subject-
matter of claims 1 and 6 of auxiliary request 6 and
claim 1 of auxiliary request 7 lacked inventive step
over document D1 in combination with document D19.

IV. With its statement of grounds of appeal, the appellant
filed claims of auxiliary requests I to X (labelled
"Auxiliary Request 1" to "Auxiliary Request 10"),
auxiliary requests I to V, IX and X being identical to
auxiliary requests 1 to 7 considered in the decision
under appeal. The appellant requested that the decision
under appeal be set aside and that the patent be
maintained as granted (main request) or, in the
alternative, that the patent be maintained on the basis
of the claims of one of auxiliary requests I to X.

V. With its reply, respondent II filed the following
document:

D20: J. Collins: "Company Seeks to Add MRAM to Tags",
RFID Journal, 24 March 2005.

In its reply, respondent II relied on the disclosures
of documents D1, D3, D4, D5, D11, D17, D19 and D20.

VI. No reply was received from respondent I.

- VII. In a communication accompanying the summons to oral proceedings, the Board summarised the points to be discussed.
- VIII. In a letter dated 1 November 2018, respondent I commented on the Board's communication.
- IX. In a letter dated 7 November 2018, the appellant maintained its requests and commented on the Board's communication.
- X. Oral proceedings were held on 28 January 2019 and were attended by the parties. At the end of the oral proceedings, the chairman pronounced the Board's decision.
- XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, alternatively, in amended form on the basis of one of auxiliary requests I to X submitted with the statement of grounds of appeal.

Respondents I and II requested that the appeal be dismissed.

- XII. Claim 1 of the patent as granted reads as follows:

"A method of sterilizing a pharmaceutical device, wherein said device comprises a remotely readable memory device, whereby the contents of said memory device are not corrupted by said sterilization, comprising:
affixing said memory device employing a non-charge based storage mechanism to said device; and
characterised by

subjecting said device to radiation based sterilization."

- XIII. Claim 1 of auxiliary request I differs from claim 1 as granted in that "rewritable and" has been inserted before "remotely readable memory device".
- XIV. Claim 1 of auxiliary request II differs from claim 1 of auxiliary request I in that "comprising gamma radiation" has been added at the end of the claim.
- XV. Claim 1 of auxiliary request III differs from claim 1 of auxiliary request I in that "which comprises a 25 kGray dosage of gamma radiation" has been added at the end of the claim.
- XVI. Claim 1 of auxiliary request IV differs from claim 1 of auxiliary request I in that "comprising a magnetoresistive memory device" has been inserted after "a rewritable and remotely readable memory device".
- XVII. Claim 1 of auxiliary request V differs from claim 1 of auxiliary request IV in that "comprising gamma radiation" has been added at the end of the claim.
- XVIII. Claim 1 of auxiliary request VI reads as follows:
- "A pharmaceutical device, comprising a rewritable memory element, which when subjected to radiation-based sterilization, retains the contents of said memory element, comprising a memory element utilizing a non-charge based storage mechanism."
- XIX. Claim 1 of auxiliary request VII differs from claim 1 of auxiliary request III in that "rewritable and" has been deleted.

- XX. Claim 1 of auxiliary request VIII differs from claim 1 of auxiliary request VI in that "comprising a 25 kGray dosage of gamma radiation" has been inserted after "radiation-based sterilization".
- XXI. Claim 1 of auxiliary request IX differs from claim 1 of auxiliary request IV in that "rewritable and" has been deleted.
- XXII. Claim 1 of auxiliary request X differs from claim 1 of auxiliary request VI in that "and comprising a magnetoresistive memory" has been added at the end of the claim.
- XXIII. The parties' arguments, where relevant to the decision, are discussed in detail below.

Reasons for the Decision

1. The appeal complies with the provisions referred to in Rule 101 EPC and is therefore admissible.
2. *The invention*

The patent relates to radio-frequency identification (RFID) tags that can be affixed to devices such as pharmaceutical components that are exposed to radiation. To overcome the problem of conventional charge-based memory elements being susceptible to corruption caused by radiation, the patent proposes the use of non-charge-based memory elements (paragraphs [0007] and [0008] of the patent).

3. *Admission of auxiliary requests VI, VII and VIII into the proceedings*
- 3.1 Auxiliary requests VI, VII and VIII were filed with the statement of grounds of appeal. They are closely related to the requests on which the contested decision was based, with the method claims being omitted in auxiliary requests VI and VIII, and the words "rewritable as" being omitted in auxiliary request VII. The appellant submitted that they constituted an immediate reaction to the oral proceedings before the Opposition Division, during which opponent I had argued for the first time that the application as filed did not disclose a tag which was both rewritable and remotely readable.
- 3.2 In its reply, respondent II argued that the appellant had had the opportunity during the oral proceedings before the Opposition Division to address the objection of added subject-matter but had chosen to file only auxiliary requests 6 and 7. Since the appellant had voluntarily refrained from filing auxiliary requests VI, VII and VIII earlier, they should not now be admitted under Article 12(4) RPBA.
- 3.3 Auxiliary requests VI, VII and VIII do indeed address the objection that the application as filed does not disclose a "rewritable and remotely readable memory device", which was the ground for refusing auxiliary requests 1 to 5. Although the objection had already been raised by opponent I one month before the oral proceedings before the Opposition Division, the Board considers that the requests raise no new issues. It therefore exercises its discretion under Article 12(4) RPBA to admit them into the appeal proceedings.

4. *Admission of document D20 into the proceedings*

4.1 Respondent II filed document D20 with its reply to the statement of grounds of appeal. It submitted that the document was *prima facie* highly relevant to the requests relating to MRAM technology, which had been filed late in the oral proceedings before the Opposition Division.

4.2 At the oral proceedings, the appellant argued that document D20 had been filed late and should have been filed during the opposition period. The document was not *prima facie* relevant because it related to a prototype rather than commercially available products and did not mention gamma radiation but only X-rays, a much lower-energy radiation.

4.3 In the Board's view, document D20, which consists of a single page and is easy to understand, is indeed *prima facie* relevant to the question of whether radiation-tolerant MRAM-based RFID tags were known. Although limitations to "a magnetoresistive memory device" were already present in claim 2 as granted and in the independent claims of auxiliary requests 4 and 5, which had been filed one month before the oral proceedings before the Opposition Division, the Board notes that paragraph [0015] of the patent suggests that MRAM technology was a known non-charge-based memory technology and that paragraph [0005] of document D19 - introduced by the Opposition Division during the oral proceedings - likewise mentions that MRAM shows high radiation resistance. Since document D20 therefore has the potential to simplify the discussion, the Board exercises its discretion under Article 12(4) RPBA to admit it into the appeal proceedings. Whether the document, in view of the appellant's criticisms of its

content, lives up to this expectation will be discussed below in relation to auxiliary requests IV and X.

Main request - patent as granted

5. *Interpretation of claim 1*

5.1 Claim 1 of the main request relates to a method of sterilising a pharmaceutical device. The pharmaceutical device is defined as comprising a remotely readable memory device.

The method includes a step of affixing the memory device, which employs a non-charge-based storage mechanism, to the pharmaceutical device and a step of subjecting the pharmaceutical device to radiation-based sterilisation.

The claim further specifies that the contents of the memory device are not corrupted by the sterilisation.

5.2 The step of affixing the memory device to the pharmaceutical device implies that the memory device is initially not part of the pharmaceutical device, notwithstanding the feature "wherein said device comprises a remotely readable memory device".

5.3 Although claim 1 does not explicitly state that the sterilisation step is performed after the affixing step, this temporal restriction can be inferred from the feature specifying that the contents of the memory device are not corrupted by the sterilisation.

5.4 Hence, claim 1 defines a method comprising a step of affixing a remotely readable memory device employing a non-charge-based storage mechanism to a pharmaceutical

device and a step of subjecting the pharmaceutical device and the affixed memory device to radiation-based sterilisation, whereby the contents of the memory device are not corrupted by the sterilisation.

6. *Inventive step*

6.1 In its reply to the statement of grounds of appeal, respondent II argued that it had been known that RFID tags were used on medical devices to store product information, that such devices required sterilisation by gamma radiation, and that radiation could pose a problem to chip-based tags. The skilled person would therefore have looked for RFID devices with a higher resistance to gamma radiation. He would have found that radiation-hard memory devices such as FRAM or MRAM, which were memory devices employing non-charge-based storage mechanisms, were available and could be used in RFID tags.

6.2 The Board agrees with respondent II that, at the patent's priority date, it was common practice, both in general and in medical environments, to affix RFID tags to products to keep track of information about the product. Indeed, paragraph [0001] of the patent explains that the use of RFID tags has become prevalent in the area of inventory management and permits the monitoring of the production line and the movement of assets or components through the supply chain. And paragraph [0003] states that the use of RFID tags for labelling and monitoring drugs has been advocated within the drug and pharmaceutical industries, in particular in a report issued in February 2004 by the United States Food and Drug Administration.

One example of such use of RFID tags is given by document D4, which relates to blood containers to which a read/write RFID chip is affixed (paragraphs [0008] and [0032]). Information such as manufacturing or post-manufacturing inventory data can be (re)written to the chip during different phases of manufacturing, sterilisation, shipping, storage and use in blood processing (paragraph [0009]).

Another example is given by document D16, which relates to a closure for a medical container (paragraph [0002]). The closure comprises a cap seal having a removable overcap attached by means of a mechanism that prevents it from being replaced after removal (paragraphs [0024] and [0025]). The overcap contains information related to the container or its contents (paragraph [0002]). The overcap incorporates a decorated film 16 (paragraph [0026]) to which a memory device 28 is attached, which may be an RFID tag (paragraphs [0028] and [0030]).

- 6.3 The Board also agrees that it was common practice to sterilise appropriate pharmaceutical devices with gamma radiation. This is confirmed by paragraph [0010] of the patent, which states that pharmaceutical components are often subjected to gamma radiation. It is also confirmed by document B1, an extract from a textbook in the field of pharmaceuticals that discloses that medical products such as disposable syringes, cannulas, instruments, bandaging materials or primary packaging and implants are sterilised with ionising radiation such as gamma radiation (see page 128, lines 32 to 36, and page 357, Table 5-21, item 3).
- 6.4 The Board further considers that the skilled person was aware that exposing regular RFID tags to gamma

radiation could result in the loss of data stored in the RFID tag's memory. Indeed, if no precautions were taken, data loss would inevitably have occurred and would not have gone unnoticed.

- 6.5 The appellant did not dispute that the use of RFID tags for tracking pharmaceutical devices was known or that it was common to sterilise appropriate pharmaceutical devices with gamma radiation. But it argued that, without the benefit of hindsight, the skilled person would not have sought to sterilise pharmaceutical devices having an attached RFID tag with gamma radiation without incurring data loss.

In particular, although document D4, in paragraph [0006], stated that an RFID chip assembly "can and preferably does withstand gamma radiation, so the complete assembly (the chip device/assembly and the object on which the chip assembly is mounted) can be gamma sterilized", this did not mean that the tags had to survive gamma radiation without any data loss. There was nothing in document D4 that ruled out that the RFID tag was written to only after the pharmaceutical device had been sterilised or that the data it contained was rewritten to the tag after the sterilisation. And the RFID tag attached to the blood processing tubing set shown in Figure 6 could easily be shielded from the radiation.

Likewise, although document D16, in paragraph [0037], disclosed that "[c]ontainers which have been closed with the closure 10 may be exposed to sterilizing by autoclaving, e-beam radiation, gamma radiation, and ethylene oxide gas and to long term storage at freezing temperatures", the skilled person reading the document would not have assumed that the contents of the memory

device were not corrupted by gamma radiation. In this respect, it was of significance that document D16 did disclose, in claim 22, that images on the overcap remained readable following exposure to gamma radiation but was silent on the absence of data corruption in the memory device.

- 6.6 The Board agrees with the appellant that neither document D4 nor document D16 unambiguously discloses that an RFID tag attached to a pharmaceutical device is exposed to gamma radiation without suffering data corruption. It also accepts that the skilled person would normally have been able to work around the problem of data corruption in RFID tags due to exposure to gamma radiation, for example by ensuring that gamma radiation is applied to a pharmaceutical device before any data is written to the tag or by rewriting the data to the tag after sterilisation by gamma radiation.

However, the very need for such measures shows that a skilled person, working with pharmaceutical devices to which RFID tags are attached, would indeed have wanted the RFID tags to withstand exposure to gamma radiation without data loss.

- 6.7 The skilled person looking for such RFID tags at the patent's priority date would have consulted the relevant literature and learned that RFID tags comprising a ferroelectric memory are resistant to radiation. Indeed, document A9 discloses that ferroelectric memories are well suited for read/write RFID tag applications (see page 26, right-hand column, lines 1 to 9, below the text box, and page 27, Figure 13) and are tolerant to high doses of ionising radiation (see page 29, section "Space - the Ferroelectric Frontier"). It is well known that gamma

radiation is a form of ionising radiation (see document B1, page 357, Table 5-21, item 3).

6.8 Since, as confirmed in paragraph [0014] of the patent, ferroelectric memories are non-charge based, the skilled person would therefore have arrived at a method comprising a step of affixing an RFID tag comprising a non-charge-based storage mechanism to a pharmaceutical device and a step of subjecting the device and the tag to gamma radiation, whereby the contents of the RFID tag would not have been corrupted. As RFID tags are remotely readable memory devices, the skilled person would therefore have arrived at the subject-matter of claim 1 without the exercise of inventive skill.

6.9 Hence, the subject-matter of claim 1 as granted lacks inventive step (Article 56 EPC).

Auxiliary requests

7. None of auxiliary requests I to X overcomes the objection of lack of inventive step. These requests are dealt with below in the order seen fit by the Board.

8. *Auxiliary request I*

8.1 Claim 1 of auxiliary request I adds to claim 1 as granted that the remotely readable memory device is rewritable.

8.2 Since rewritable RFID tags are well known in the art and ferroelectric memory are suitable for read/write RFID tag applications (see document A9, page 26, right-hand column, lines 1 to 9), the subject-matter of claim 1 of auxiliary request I also lacks inventive step (Article 56 EPC).

9. *Auxiliary request VI*

9.1 Claim 1 of auxiliary request VI is directed to a pharmaceutical device comprising a rewritable memory element utilising a non-charge-based storage mechanism, which retains its contents when subjected to radiation-based sterilisation.

9.2 The subject-matter of claim 1 encompasses the pharmaceutical device obtained by the "affixing" step of claim 1 of auxiliary request I, which means that it lacks inventive step (Article 56 EPC).

10. *Auxiliary requests IV and X*

10.1 Claim 1 of auxiliary requests IV and X adds to claim 1 of auxiliary requests I and VI that the memory device is a magnetoresistive memory device.

10.2 Document D20 announces the commercialisation of a version of magnetoresistive random access memory (MRAM) for RFID tags (page 1, first paragraph). Whereas EEPROM and flash memory can be vulnerable to the effects of X-rays and other forms of radiation, the MRAM being developed "can stand up to extreme exposures of radiation without breaking down and without the device malfunctioning" (page 1, sixth paragraph). At the time of the document's publication (24 March 2005), a "1-bit prototype" had been developed (page 1, last paragraph).

10.3 According to paragraph [0015] of the patent, MRAM, also known as magnetoresistive RAM, is a non-charge-based storage mechanism utilising magnetic fields, which is why MRAM-based memory devices are much less susceptible to gamma radiation than charge-based memory devices. Document D20 shows that it was known at the priority

date to employ MRAM in RFID tags and that the resulting RFID tags were resistant to ionising radiation.

- 10.4 The appellant pointed out that document D20 did not mention gamma radiation but only X-rays, radiation of a much lower energy.

However, document D20 in fact refers to "X-rays and other forms of radiations" and to MRAM's potential tolerance to "extreme exposures of radiation". The skilled person reading document D20 would have understood that the MRAM chips being discussed would be tolerant to high-energy ionising radiation such as gamma radiation.

- 10.5 The appellant further drew attention to the fact that document D20, in its last paragraph, stated that so far a "1-bit prototype" had been developed.

It is true that the particular MRAM-based RFID tags discussed in document D20 had not yet been commercialised. But this does not take away from the fact that document D20 would have taught the skilled person that MRAM-based RFID tags were a suitable choice for RFID tags resistant to ionising radiation such as gamma radiation. The appellant specifically did not argue that MRAM-based RFID tags would not have been available to the skilled person at the patent's priority date - which would have been tantamount to arguing that the invention according to claim 1 of auxiliary requests IV and X was insufficiently disclosed.

- 10.6 In sum, the subject-matter of claim 1 of auxiliary requests IV and X lacks inventive step (Article 56 EPC).

11. *Auxiliary requests II, III, V and VIII*

11.1 Claim 1 of auxiliary requests II and V adds to claim 1 of auxiliary requests I and IV that the radiation is gamma-based radiation. Claim 1 of auxiliary requests III and VIII adds to claim 1 of auxiliary requests I and VI that the radiation comprises a 25 kGray dosage of gamma radiation.

11.2 At the patent's priority date, it was well known to sterilise pharmaceutical devices with ionising radiation, in particular with a 25 kGray dosage of gamma radiation (see document B1, page 357, Table 5-21, item 3). Document A9 confirms that ferroelectric memories are tolerant to such radiation dosages (see page 29, section "Space - the Ferroelectric Frontier", mentioning a dosage of 10 Mrad, which is 100 kGray). The amendments therefore do not overcome the objection of lack of inventive step.

11.3 Hence, the subject-matter of claim 1 of auxiliary requests II, III, V and VIII lacks inventive step (Article 56 EPC).

12. *Auxiliary requests VII and IX*

Since claim 1 of auxiliary requests VII and IX is broader than claim 1 of auxiliary requests III and IV, their subject-matter also lacks inventive step (Article 56 EPC).

Conclusion

13. Since none of the appellant's substantive requests is allowable, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



I. Aperribay

R. Moufang

Decision electronically authenticated