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Datasheet for the decision of 15 October 2014

Case Number: T 0821/10 - 3.5.05

Application Number: 02743236.8

Publication Number: 1402453

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Language of the proceedings: EN

Title of invention:
MONITORING DRUG PACKAGING IN CLINICAL TRIAL PROCESS

Applicant:
Glaxo Group Limited
SmithKline Beecham Limited

Headword:
MONITORING DRUG PACKIGING IN CLINICAL TRIAL PROCESS/Glaxo Group Limited et al.

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)
Inventive step - auxiliary request (no)

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Catchword:

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Case Number: T 0821/10 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 15 October 2014

Appellant: (Applicant 1)	Glaxo Group Limited 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Appellant: (Applicant 2)	SmithKline Beecham Limited 980 Great West Road Brentford Middlesex TW8 9GS (GB)
Representative:	Walker, Ralph Francis GlaxoSmithKline Global Patents (CN925.1) 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 1 December 2009 refusing European patent application No. 02743236.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	D. Prietzel-Funk
	P. Corcoran

Summary of Facts and Submissions

I. This is an appeal against the decision of the examining division to refuse European patent application No. 02 743 236.8, originally filed as international application PCT/EP02/06895 and published as WO 03/001429 A2.

II. The decision under appeal was based on the examining division's finding that the subject-matter of claim 1 of the main request and of the auxiliary request, both submitted with the letter dated 6 October 2009, did not comply with the requirements of Article 84 EPC and did not involve an inventive step in the light of the prior art document D1 (GB-A-2 342 203).

III. Notice of appeal was received at the EPO on 21 December 2009 with the appropriate fee being paid on 11 January 2010. A statement setting out the grounds of appeal was received at the EPO on 30 March 2010. The appellant filed the identical main request and auxiliary request (now first auxiliary request) underlying the decision under appeal and further a second and a third auxiliary request with said statement.

IV. In a communication accompanying a summons to oral proceedings to be held on 14 October 2014 the board gave its preliminary opinion that the applicant's requests were not allowable. The following documents were introduced by the board:

D2: WO 98/09598 A;

D3: N. Raza, V. Bradshaw, M. Hague, "Applications of RFID technology", IEE Colloquium on RFID Technology (Ref. No.1999/123), pp. 1/1 to 1/5, 25 Oct. 1999,

London, UK;

D4: "Pharmaceuticals picks-up on radio tags", Control Systems, July/August 1993, Vol. 10, No. 7, pp. 15-16, ISSN 0266-2493.

V. Regarding the main request and the first auxiliary request the board raised objections under Articles 84 and 123(2) EPC. Further, the board expressed doubts as to whether the subject-matter of claim 1 of these two respective requests complied with the inventive step requirement of Article 52(1) EPC. The board gave detailed reasons for its preliminary opinion, taking also into consideration the newly introduced documents D2 to D4. Regarding the second and third auxiliary requests, the board pointed out that these were apparently amended versions of the main request and first auxiliary request, respectively, but that they did not suffice to overcome the board's reservations concerning compliance with the requirements of Article 84 EPC with respect to the main and first auxiliary requests.

VI. With a letter of reply dated 2 September 2014, the appellant withdrew the main request and the first auxiliary request on file. It submitted amended versions of the former second and third auxiliary requests as a new main and new auxiliary request, respectively, together with a retyped description adapted to the amended claims and a new set of drawings, respectively. It also informed the board that it would not be attending the scheduled oral proceedings.

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or of the auxiliary

request both submitted with the letter dated 2 September 2014.

VIII. Claim 1 of the main request reads as follows:

"A method for automatically validating that an operation comprising part of a clinical trials process involving one or more operations involving one or more container (20,320,420,422) used in said operation has been completed to meet a compliance standard, the method comprising providing a container (20,320,420,422) having an identifier (10,310,410) connected to the container (20,320,420,422), the identifier (10,310,410) comprising a radio frequency identifier (10,310,410) comprising an antenna for transmitting or receiving radiofrequency energy, and an integrated circuit chip connecting with said antenna, said chip comprising a memory, the memory having a unique signature data item thereon,
characterised by
automatically writing (322) the unique signature data item to a relational database;
automatically performing an operation comprising applying a label (480) bearing information to the container (20,320,420,422);
automatically checking the performance of said operation comprising applying a label (480) against a compliance standard comprising checking that the correct label (480) has been applied to the container (20,320,420,422);
following the successful completion of said operation comprising applying a label (480) as indicated by the compliance standard associated with the operation having been successfully complied with, automatically writing an associated compliance data item to the relational database and to the memory of the identifier (10,310,410)."

Claim 1 of the first auxiliary request adds to claim 1 of the main request the following steps relating to a "further operation"/"second operation":

"then performing a second operation (233) relating to the container (20,320,420,422),
following the completion of the further operation (233) as indicated by a compliance standard associated with the second operation having been successfully complied with, automatically writing a compliance data item associated with the second operation on the relational database and the memory of the identifier (10,310,410), automatically reading the data compliance item associated with the second operation in the memory of the identifier (10,310,410) and checking this data compliance item against a defined criterion stored on the relational database and following the successful completion of the second operation (233) as indicated by a compliance standard associated with the second operation having successfully complied with, automatically performing a third operation (233) relating to the container (20,320,420,422), or in the event of non-compliance with the compliance criterion abandoning the clinical trial process for the container (20,320,420,422) and rejecting the container (20,320,420,422)."

IX. The appellant indicated that the amendments to the claims had been made to bring these claims into compliance with Article 84 EPC. With respect to the new requests it put forward arguments on the requirements of Articles 84, 123(2) and 52(1), 56 EPC and submitted comments on the preliminary views given in the board's communication. It agreed in essence with the statements

made in points 18.1 to 18.15 of the communication. However, it differed from the board's view as set out in points 18.16 onwards.

In particular, it disagreed with the board's preliminary opinion that D1 directly disclosed, or non-inventively suggested, the claimed writing to the identifier memory of the present specified "compliance data item". D1, in its view, only disclosed the generalised possibility to record details and status of materials, assembly and storage as required for planning and scheduling, material transfer from a warehouse, filling and labelling and package assembly. Moreover D1 appeared to disclose or suggest no more than recording the fact that the label was applied to a specific container, this on the explicit assumption that "there is no risk of mis-labelling". This implied that D1 saw no need for the compliance check of present claim 1 consisting of the two steps of checking the label against the compliance criterion and writing compliance with this compliance criterion to the tag. Faced with the problem of improving D1, the skilled reader would consider ways of improving the label generation process itself rather than considering the present procedure of recording the compliance data item on the tag.

Further, the appellant indicated that D3 and D4 appeared to be very general disclosures teaching the possibility of applying RFID Technology in the context of the pharmaceutical industry. However, D3 and D4 did not disclose the specific process steps of claim 1 of both the main and first auxiliary requests.

The appellant argued that D2 disclosed a process for transporting pharmaceutical containers which were

carried in pucks. These pucks were labelled with an RFID. D2 appeared to use data on the puck for identifying the puck rather than for storing compliance data as claimed. Error data, i.e. a (non-)compliance data item, referred to on page 18 of D2, were stored only on the database.

With respect to the first auxiliary request, the appellant argued that D1 did not disclose or suggest writing a compliance data item to the identifier for any further operation either. D2 disclosed ordering or identifying the sequence of pucks procedure. D2 did not disclose or suggest storing a compliance data item on the RFID of the puck in this respect. D3 thus disclosed the possibility of recording a "service history" of a container to which an RFID tag is applied. However, D3 did not disclose or suggest writing a compliance item on a tag attached to a container as claimed. The "service history" might equally be stored on a central database.

X. Oral proceedings were held as scheduled on 14 October 2014. At the end of the oral proceedings the Chair announced the board's decision.

Reasons for the Decision

1. Admissibility

The appeal complies with the provisions of Articles 106 to 108 EPC. Therefore it is admissible.

2. Non-attendance at oral proceedings

By letter dated 2 September 2014 the appellant submitted amended new main and first auxiliary requests and informed the board that the appellant would not be attending oral proceedings. The board nonetheless considered it expedient to maintain the date for oral proceedings. Nobody attended on behalf of the appellant.

Article 15(3) RPBA stipulates that the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

Hence, the board was in a position to announce a decision at the end of the oral proceedings.

3. Articles 84 and 123(2) EPC

The board refrains from treating these points since the appeal is clearly unallowable the reasons set out below.

4. Articles 52(1) and 56 EPC

4.1 Main request

The appellant argued that the claimed subject-matter differed from D1 which is considered to be the closest prior art document in that all claim steps were performed automatically, that the label was checked against the compliance criterion and that a compliance data item indicating compliance with this compliance criterion was written to the tag (cf. letter of 2 September 2014, page 3, penultimate paragraph and page 4, fourth paragraph).

As stated in point 18.13 of the board's communication, automated verification systems e.g. OCV for checking labels in the context of pharmaceutical containers were known from D2. Moreover, the appellant submitted that at the date of filing in 2002 the application methods were known in the art for automatically validating the operation of applying a label (cf. letter of 2 September 2014, page 2, penultimate paragraph). Thus, the skilled person would have been aware that some or all steps in a method of automatically validating the operation of applying a label may be performed automatically. It would lie within the competence of the skilled person to choose that all the steps are performed automatically. In the board's judgment, this difference does not involve an inventive step.

It is common ground (see letter of 2 September 2014, last paragraph and paragraph 18.11 of the board's communication), that, starting from D1, the technical problem underlying the claimed subject-matter is that of further reducing error during labelling of pharmaceutical containers.

The claimed solution consists of performing some kind of "checking" in order to determine whether or not the labelling operation has been performed correctly and recording information indicative of the results of said "checking" by writing an associated compliance data item to the relational database and to the memory of the identifier.

Claim 1 does not specify the technical details of how the checking of the labelling operation is to be performed. However, the board notes that at the filing date of the present application it was known per se in

the context of pharmaceutical packaging to perform verification checks on labels applied to containers. In particular D2 (see e.g. page 18, 3rd paragraph to page 20, 2nd paragraph) discloses the performance of a verification check following the labelling of a container having an associated RFID.

With respect to the claim features pertaining to the recording of information indicative of the results of said "checking" (i.e. the "compliance data item"), the board does not consider that these features contribute to inventive step for the reasons which follow.

The board finds that the recording of information indicative of the results of "checking" is a measure having an essentially administrative character in regard to what technical considerations are only relevant in respect of the data storage arrangements.

According to D1, the RFID tag may be used to store "any other production process ... details deemed appropriate" (cf. D1, page 5, lines 6 to 10). D1 further discloses the writing of data to and reading from "a tag or its associated database" for the purpose of recording details and status of materials and, likewise, the interrogation and update of the database or tag required (cf. sentence bridging pages 5 and 6).

Based on the foregoing considerations, the board finds that D1 discloses that both the database and the RFID tag are appropriate locations for the storage of data relating to "details and status of materials". Whether a particular item of data is to be stored in one or both of these available data storage locations is considered to be a matter of design choice. Storing data in the database means that it is centrally

accessible to any device with online access to the database. Storing data in the RFID tag means that it is locally available and can be accessed even when the database is not accessible. The board judges that the skilled person would not require the exercise of inventive skill to recognise the respective advantages of each of the aforementioned data storage locations and to choose one or both of said storage locations for specific data items as required.

Moreover, the board notes that D2, page 24 teaches that, upon determining that an operation (here: bottle fill) was properly performed, an appropriate flag is stored in the data storage element of the puck (cf. first paragraph). This flag indicating that the bottle is properly filled, which represents a compliance data item in the same sense as in the claimed invention, is considered to be a fail-safe feature of the invention (cf. third paragraph). Thus, D2 discloses the recording of a compliance data item in the data storage element which may be an RFID tag.

As to the appellant's argument that D1 saw no need for a compliance check, the board notes that D1 states in the concluding paragraph on page 6 that all aspects of clinical trial packaging, including labelling, can be "controlled and verified with the use of RFID tags". The board considers that the explicit reference to possible control and verification using RFID tags implies the option of compliance checks.

As to the appellant's argument with respect to D2, the board notes that, contrary to the appellant's view that the data on the puck was only used for identifying the puck and that error data, i.e. compliance data items, were only stored on the database, the board refers to

the flag indicating the result of determining that the bottle is properly filled, i.e. a compliance data item, which is stored in the storage element, i.e. RFID tag, (see D2, page 24, 1st and 3rd paragraphs).

In view of the foregoing, the board finds that claim 1 of the main request does not involve an inventive step over D1.

4.2 First auxiliary request

Claim 1 of the first auxiliary request adds to claim 1 of the main request that it additionally specifies the performance of one or more further operations, i.e. second or third operations, relating to the container and the recording of further compliance data items relating to these further operations.

Any industrial process such as a pharmaceutical trial typically involves a plurality of clearly defined process steps or "operations". In this context, it is not considered to involve the exercise of inventive skill to extend the method of claim 1 of the main request to record a plurality of data items relating to the completion of further operations following an initial operation.

In this regard, D1 refers to writing to and reading from the RFID tag "at all stages" of a clinical trial process (cf. D1, paragraph bridging pages 5 and 6).

Further, D2 discloses that a plurality of "flags" may be written to the memory of an RFID tag associated with a container as it passes through the system (cf. D2, page 25, lines 10 to 22).

Moreover, D3, page 1/3, second paragraph discloses the use of an RFID tag for recording a "service history" of a tagged item.

With respect to the claim specification to the effect that a compliance data item is read prior to performing a further operation, the board notes that in any situation where a sequence of operations is to be performed it is considered to be an obvious measure to check that a preceding operation has been satisfactorily completed before proceeding to the next operation in the sequence. Such an approach is disclosed in D2 (cf. D2, page 32, lines 1 to 30; Fig. 5).

The appellant's arguments with respect to the first auxiliary request do not convince the board for the reasons set out above with regard to the main request, as they are related to the writing of the compliance data item on the identifier, i.e. RFID tag. No specific arguments with respect to the additional steps of the first auxiliary request were submitted in the letter dated 2 September 2014.

Thus, claim 1 of the first auxiliary request does not involve an inventive step over D1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated