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# Datasheet for the decision of 22 November 2021

**Case Number:** T 1146/15 - 3.3.08

**Application Number:** 09174581.0

**Publication Number:** 2236621

**IPC:** C12Q1/68

**Language of the proceedings:** EN

**Title of invention:**
Methods and sequences for detection and identification of methicillin-resistant Staphylococcus aureus

**Patent Proprietor:**
Geneohm Sciences Canada, Inc.

**Opponent:**
Beckman Coulter, Inc.

**Headword:**
Detection methicillin-resistant Staphylococcus aureus/GENEOHM SCIENCES CANADA

**Relevant legal provisions:**
EPC Art. 76(1)
RPBA 2020 Art. 13, 17

**Keyword:**
Main request and auxiliary requests 2, 3 and 5 to 15 - added subject-matter (yes);
Auxiliary request 1 - admission into the appeal proceedings (no);

**Decisions cited:**
G 0009/91, G 0010/91, G 0001/05, G 0001/06, G 0002/10, G 0003/14, T 0190/99, T 2002/13

**Catchword:**

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**Case Number: T 1146/15 - 3.3.08**

# D E C I S I O N
# of Technical Board of Appeal 3.3.08
# of 22 November 2021

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Geneohm Sciences Canada, Inc.<br>2555 Boul. du Parc Technologique<br>Québec, QC G1P 4S5 (CA) |
| **Representative:** | H-R. Jaenichen, C. Schlörb<br>Vossius & Partner<br>Patentanwälte Rechtsanwälte mbB<br>Siebertstrasse 3<br>81675 München (DE) |
| **Appellant:** (Opponent) | Beckman Coulter, Inc.<br>250 S Kraemer Boulevard<br>Brea CA 92821 (US) |
| **Representative:** | M. Spencer, J. Legg<br>Boult Wade Tennant LLP<br>Salisbury Square House<br>8 Salisbury Square<br>London EC4Y 8AP (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 April 2015 concerning maintenance of the European Patent No. 2236621 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | B. Stolz |
| **Members:** | P. Julià |
| | D. Rogers |

## Summary of Facts and Submissions

I. European patent no. 2 236 621 is based on European patent application no. 09 174 581.0, a divisional application of the earlier European patent application no. 02 740 158.7 (published as EP 1 397 510), originally filed under the PCT and published as International patent application WO 02/099034 (hereinafter, "the parent application"). The patent was granted with 40 claims.

II. An opposition was filed on the grounds set forth in Articles 100(a), 100(b) and 100(c) EPC. The opposition division considered the main request to contravene Article 76(1) EPC and auxiliary request 1 to fulfil all requirements of the EPC. Both requests were filed at the oral proceedings before the opposition division.

III. Appeals were lodged by the patent proprietor and the opponent (appellants I and II, respectively). With the statement setting out their respective grounds of appeal, appellant I filed a main request and auxiliary requests 1, 2 and 4 to 14, and appellant II filed new evidence (documents (49) and (50)).

IV. The parties replied to their respective statements of grounds of appeal. In further submissions, appellant II filed new evidence (documents (51) to (66), including several appendices).

V. The board summoned the parties to oral proceedings. In a communication pursuant to Article 17 of the Rules of Procedure of the Boards of Appeal (RPBA 2020), they were informed of the board's provisional opinion on the issues of the appeal.

VI. Both parties replied to the board's communication. Appellant I filed further new evidence (document (67) with annexes).

VII. Oral proceedings were held on 22 November 2021. At these proceedings, appellant I filed a new auxiliary request 1 and renumbered former auxiliary requests 1, 2 and 4 to 14 as auxiliary requests 2, 3 and 5 to 15, respectively.

VIII. Claims 1 and 9 of the main request read as follows:

"1. A method for detecting the presence of MREJ type i, ii, iii and vii methicillin-resistant *Staphylococcus aureus* (MRSA) strains comprising:

a) contacting a sample to be analyzed for the presence of said type i, ii, iii and vii MREJ MRSA strains, each said MRSA strain including a Staphylococcal cassette chromosome mec (SCC*mec*) element containing a mecA gene inserted into chromosomal DNA, thereby generating a polymorphic right extremity junction (MREJ) type i, ii, iii or vii sequence that comprises polymorphic sequences from the SCCmec element right extremity and chromosomal DNA adjoining said polymorphic sequences from the SCCmec element right extremity with a first primer and a second primer for each of said MREJ types i, ii, iii and vii, wherein said first and second primers are at least 10 nucleotides in length, and wherein each said first primer hybridizes with said polymorphic sequences from the SCCmec element right extremity of an MREJ type i, ii, iii or vii sequence selected from the group consisting of SEQ ID NOs: 1, 20, 21, 22, 23,

24, 25, 41 and 199, and complements thereof, for MREJ type i; 2, 17, 18, 19, 26, 40, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 185, 186, and 197, and complements thereof, for MREJ type ii; 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 104, 184, and 198, and complements thereof, for MREJ type iii; and 165 and 166, and complements thereof, for MREJ type vii; and wherein each said second primer hybridizes with said chromosomal sequence of S. aureus to specifically generate (an) amplicon(s) if such MRSA strain of said MREJ types i, ii, iii and vii is present in said sample; and

b) detecting the presence of said amplicon(s).

"9. A kit for detecting the presence or absence of an MREJ type vii MRSA strain in a sample comprising:

a) a first primer which hybridizes with polymorphic sequences from the SCCmec element right extremity of an MREJ type vii sequence selected from the group consisting of SEQ ID NOs: 165 and 166 and complements thereof; and

b) a second primer which hybridizes with a chromosomal sequence of S. aureus adjoining said polymorphic sequences from the SCCmec element right extremity of an MREJ type vii sequence;

wherein said primers of a) and b) consist of at least 10 nucleotides in length and enable the selective generation of an amplicon which comprises sequences from the polymorphic sequences from the SCCmec element right extremity and chromosomal DNA adjoining said right extremity of said MREJ type vii MRSA strain."

Claims 2 to 7 are directed to preferred embodiments of the method of claim 1. Claim 8 is directed to the use of a kit specific for the detection of MRSA strains comprising MREJ types i, ii, iii and vii nucleic acid sequences, for carrying out any one of the methods of claims 1 to 6. Claims 10 to 14 are directed to preferred embodiments of the kit of claim 9.

IX. Claim 1 of the new auxiliary request 1 reads as follows:

"1. A method for detecting the presence of MREJ type i, ii, iii and vii methicillin-resistant *Staphylococcus aureus* (MRSA) strains comprising:

the specific generation of SCC*mec*-chromosome right extremity junction sequence data by

a) ... [as claim 1 of the main request] ..., wherein said first and second primers are at least 10 nucleotides in length, and wherein each of said first and second primer hybridizes with an MREJ type i, ii, iii or vii sequence selected from the group consisting of SEQ ID NOs: ... [as in claim 1 of the main request] ...; and 165 and 166, and complements thereof, for MREJ type vii to specifically generate (an) amplicon(s) if such MRSA strain of said MREJ types ... [as claim 1 of the main request]."

This auxiliary request further contains dependent claims 2 to 6 which read as claims 4 to 8 of the main request with corrected dependencies.

X. The arguments of appellant I, insofar as relevant to the present decision, may be summarised as follows:

*Main request*
*Rule 80 EPC*

The amendment introduced into claim 9 intended to overcome an objection raised under Article 76(1) EPC and it was thus in compliance with Rule 80 EPC. According to the established case law, the amendment had to be a serious attempt to overcome a ground of opposition, but it was not required that it had to be successful in overcoming said ground.

*Article 84 EPC*

The method of claim 1 was based on the method of Hiramatsu *et al*. described in the parent application as background of the invention. This method was known in the art and belonged to the common general knowledge of a skilled person. Claim 1 was read by a skilled person who understood thus the first section of step (a) of claim 1 to describe the generation of a polymorphic right extremity junction (MREJ) which comprised polymorphic sequences from the SCC*mec* element right extremity and chromosomal DNA adjoining said polymorphic sequences. Claim 1 required that the sample to be analysed was contacted with a first and a second primer, wherein the first primer was defined as hybridising with the polymorphic sequences from the SCC*mec* element right extremity which were defined by specific SEQ ID NOs, and the second primer as hybridising with the chromosomal DNA of *S. aureus* adjoining said polymorphic sequences. This was in line with the method described in the prior art and the common general knowledge of the skilled person. Thus, there was no ambiguity in claim 1 as regards the definition of the second primer.

The term "such MRSA strain" at the end of step (a) of claim 1 could not be understood as referring to a methicillin-resistant *Staphylococcus aureus* (MRSA) strain having all four MREJ types i, ii, iii and vii. Such interpretation made no technical sense and ignored the method known by the skilled person from the prior art and described also in the patent. Likewise, no unclarity arose from the term "(an) amplicon(s)". The skilled person would have understood that it referred to each of all possible amplicons generated from the several MREJ types of the MRSA strains present in the sample to be analysed. Moreover, an amplification always involved the generation of a large amount of amplified product, in this case a sole amplicon type or several types of amplicons.

No essential technical features were missing from claim 1. If the skilled person wanted to distinguish the different MREJ types, means were provided in the claim for distinguishing them, such as by the length or sequence of the generated amplicon. Although the first primer could hybridise with more than one MREJ type, the amplicon was specific for each MREJ type. As shown in Figure 2A, the SEQ ID NO: 66 sequence was used as a first primer for both MREJ types i and ii and, as shown in Table 7, the length of the amplicons for MREJ type i (176 bp) and type ii (278 bp) were different, allowing thereby to distinguish each MREJ type. The purpose of the method of claim 1 was to detect MREJ type i, ii, iii and vii MRSA strains, not to type these MRSA strains. The latter (typing method) being only an embodiment of the former (detection method).

*Article 76(1) EPC*

The parent application referred first, as a background of the invention, to the method of Hiramatsu *et al*. which was known to use primers that could specifically hybridise to the polymorphic sequences from the SCCmec element right extremity of MREJ types i, ii and iii. As stated in the summary of the invention, the object of the parent application was to provide a specific, ubiquitous and sensitive method using probes and/or amplification primers for determining the presence of all MRSA strains.

Figure 2A of the parent application showed that the same first primer (SEQ ID NO: 66) was used for detecting MRSA strains of MREJ types i and ii. Table 7 showed that the amplicons generated by this first primer and a second primer (SEQ ID NO: 64 sequence which hybridises with the *orfX* chromosomal sequence of *S. aureus*) were different and thus specific to MREJ type i and type ii MRSA strains. Whilst the length of the amplicon was 176 bp for the former, it was 278 bp for the latter; the sequences of these amplicons were also different and thus specific to each MREJ type. The first primers described in the parent application could be specific and nevertheless hybridise with different MREJ types as shown, for instance, in the wording of claims 1 and 4, wherein some of the specific SEQ ID NOs sequences cited in claim 4 hybridised with different MREJ types, such as for the referred to MREJ types i and ii.

A skilled person knew that the specificity was linked to the PCR amplification, the generated amplicons were always (MREJ type) specific regardless of the first primer used. Typing or identifying the MREJ type of a

MRSA strain, i.e. the characterisation of the generated amplicon, was a further step of the detection method; it was a particular embodiment of the overall detection method. If necessary, it could be done, even though for practical/clinical purposes the detection of the MRSA strains in a sample, regardless of their MREJ type, was most relevant. In this context, the parent application referred to (diagnostic) kits for detecting and identifying MRSA strains, such as claim 17 in combination with claim 13 (SEQ ID Nos: 165 and 166 for MREJ type vii). Claims 1 and 9 of the main request related to a method for detecting the presence of MRSA strains of specific MREJ types in a sample, but not for typing or identifying these MREJ types.

As regards the second primer, there was support in the parent application for a definition of said primer as present in claims 1 and 9 of the main request, such as on page 13, lines 16 to 20 of the parent application, wherein the first and second primers were defined without reference to any specific MREJ type and chromosomal DNA sequence, respectively. A skilled person knew that two primers were required for a PCR amplification and the parent application provided information on the location of the first primer, namely the polymorphic sequence from the SCC*mec* element right extremity (MREJ type), and the second primer, namely the chromosomal DNA sequence of *S. aureus* to the right of (i.e. adjoining) the SCC*mec* integration site, without any further limitation. References to the kit of the invention were at the bottom of page 13 and further on pages 14 to 16 of the parent application.

According to the case law, the requirements of Articles 76(1) and 123(2) EPC had to be assessed from the standpoint of a skilled person on a technical and

reasonable basis avoiding artificial and semantic constructions. The subject-matter of claims 1 and 9 was directly and unambiguously derivable from the parent application and the common general knowledge of the skilled person, as required by the case law (G 2/10, OJ EPO 2012, 376).

*Admission of new auxiliary request 1*

New auxiliary request 1 was identical to auxiliary request 6 on file except for the deletion of all claims directed to a kit. The deletion of these claims was a straightforward response to objections raised against the main request. Auxiliary request 6 was originally filed at first instance and filed again with the statement of grounds of appeal. Thus, this auxiliary request, and all features present therein, had been on file for a long time and could not have taken the other party by surprise.

XI. The arguments of appellant II, insofar as relevant to the present decision, may be summarised as follows:

*Main request*
*Rule 80 EPC*

According to the case law, amendments under Rule 80 EPC are admissible if they represent a serious attempt to overcome a ground of opposition. The amendment introduced into part (b) of claim 9, namely "adjoining said polymorphic sequences from the SSCmec element right extremity of an MREJ type vii sequence", was not a serious attempt to overcome the objection raised under Article 76(1) EPC because it did not impart any limitation on where the second primer hybridised and thus, provided no limitation compared to the original

claims which required the second primer to hybridise with a chromosomal sequence of *S. aureus*.

*Article 84 EPC*

By reference to the antecedents in claim 1, the term "said" - introduced into claim 1 for defining the second primer as hybridising with chromosomal sequences of *S. aureus* - allowed two interpretations, namely chromosomal sequences of *S. aureus* adjoining the polymorphic sequences from the SCC*mec* element right extremity but not limited to the chromosomal sequences within the specific MREJ sequences (SEQ ID NOs) cited in claim 1 (i.e. within and outside these specific sequences), and chromosomal sequences of *S. aureus* limited to the chromosomal sequences within the specific MREJ sequences (SEQ ID NOs) cited in claim 1. Both interpretations were possible; the patent referred to the *S. aureus* chromosome attachment site for SCC*mec* DNA (*attBscc*) and to MREJ as including sequences from chromosomal DNA to the right of the SCC*mec* integration site in general, without any further limitation. In claim 2, the chromosomal sequence of *S. aureus* was limited to the *orfX* sequence. Thus, claim 1 was ambiguous and open to interpretation.

Whilst the preamble of claim 1 referred to the presence of MREJ type i, ii, iii and vii in "MRSA strains" (in plural), the term "such MRSA strain" (in singular) at the end of step (a) of claim 1 implied the existence of a MRSA strain containing all four MREJ types; such a MRSA strain was not supported by the patent. According to the case law, a discrepancy between the claims and the disclosure of the patent was not a valid reason for ignoring the clear linguistic structure of a claim and to interpret it differently. Claim 1 lacked support in

the patent and thus, contravened Article 84 EPC. Likewise, the term "(an) amplicon(s)" introduced ambiguity and lack of clarity in the method of claim 1.

Claim 1 did not require the first primer to be MREJ type specific. Indeed, some of the specific sequences cited in claim 1 for MREJ type i hybridised also with MREJ type ii, i.e. not all the first primers of the MREJ type i were specific to MREJ type i. These first primers could not distinguish MREJ type i MRSA strains from MREJ type ii MRSA strains and thus, they neither allowed a specific detection of these two MREJ types, nor the specific generation of an amplicon as required by claim 1.

*Article 76(1) EPC*

There was no basis in the parent application for the features "specifically generate (an) amplicon(s)" and "selective generation of an amplicon" of claims 1 and 9, respectively. Neither the first primer nor the second primer defined in claims 1 and 9 were required to have any specificity. The first primer was defined as hybridising with the polymorphic sequence from the SCC*mec* element right extremity of a MREJ type, not as being specific to said MREJ type. The second primer was defined as hybridising with the (adjoining) chromosomal sequence of *S. aureus* without any further limitation. Thus, claims 1 and 9 comprised embodiments wherein the first primer was not specific to a MREJ type and the second primer was not limited to the chromosomal sequence *orfX* of *S. aureus* and nevertheless, these primers were required to specifically/selectively generate an amplicon. There was no basis in the parent application for these embodiments.

The parent application disclosed two methods. A first (broad) method for detecting MRSA strains of MREJ types i, ii, iii and vii. No specificity was linked to this method since it required only to detect the presence/absence of these MRSA strains and thus, the first primer could hybridise with any region of a MREJ type sequence. The second (narrow) method was for typing MRSA strains of MREJ types i, ii, iii and vii. This method required MREJ type specificity, i.e. the first primer had to be specific to a particular or determined MREJ type and thus, to hybridise only with those sequences that were specific to said MREJ type. Whilst the first (detection) method required no MREJ type specificity, such specificity was required for carrying out the second (typing) method.

There was no notion of MREJ type specificity, let alone of the specific generation of an amplicon, in any of the references of the parent application to a detection method; neither in claim 1, nor in claim 17 in combination with claim 13 of the parent application. Claim 1 and dependent claims of the parent application were directed to a method of detection of MRSA strains, not to a method of typing. For a typing method, it was necessary to select primers specific for each MREJ type, such as required in claim 12 of the parent application; it was only by using specific primers that an amplicon could be specifically or selectively generated. The fact that some of the primers cited in claim 4 of the parent application could be used for MREJ types i and ii was irrelevant because these primers hybridised only with these two MREJ types and, in this sense, they were thus specific, as indicated in Annex I of the parent application. Whilst the primers used in Example 7 of the parent application were specific to several MREJ types and allowed thus the

detection and identification of MRSA strains of these specific MREJ types, not all amplicons specifically generated by using these primers could be distinguished by size; as shown in Table 7, the amplicons generated by primers 64/112 and 64/79 (MREJ types vii and iv) were, to all effects, of the same size (214 and 215 bp, respectively).

Although claims 1 and 9 of the main request related to a detection method wherein the first primer was not required to have any MREJ type specificity; such MREJ type specificity was required by reference to the specific/selective generation of an amplicon. There was no basis in the parent application for combining features of the (broad) detection method with those of the (narrow) typing method.

As regards the second primer, claims 1 and 9 of the main request required said primer to hybridise with the chromosomal sequence of *S. aureus* adjoining the polymorphic sequences from the SCC*mec* element right extremity without limiting these sequences to those of the *orfX* chromosomal sequence as disclosed in the parent application. This definition represented added subject-matter because there was no disclosure in the parent application of a second primer that could hybridise generally with the chromosomal sequence of *S. aureus* outside the MREJ sequences provided by the parent application.

*Admission of new auxiliary request 1*

Contrary to all auxiliary requests on file, new auxiliary request 1 contained no claims directed to a kit. The late filing of this auxiliary request was an amendment of appellant I's case. According to the

RPBA 2020, for such amendment to be taken into account at this late stage of the proceedings, there were to be exceptional circumstances which were not given in the present case. The objections under Article 76(1) EPC were raised at the beginning of the appeal proceedings and dealt with in the board's communication. No unforeseeable developments and/or circumstances had occurred in appeal proceedings to justify an amendment of appellant I's case. New auxiliary request 1 did not overcome the objections raised against the main request and features introduced into this auxiliary request raised new issues that were addressed in the board's communication in the context of auxiliary request 6.

XII. Appellant I (patent proprietor) requested to set aside the decision under appeal and to maintain the patent upon the basis of the main request or, alternatively, upon the basis of one of auxiliary requests 1, 2, 3 or 5 to 15.

XIII. Appellant II (opponent) requested to set aside the decision under appeal and to revoke the patent.

## Reasons for the Decision

*Main request*

1. The main request, filed by appellant I with the statement setting out the grounds of appeal, is identical to the main request underlying the decision under appeal and thus, it already forms part of the appeal proceedings.

*Rule 80 EPC*

2. According to Rule 80 EPC, amendments must be occasioned by a ground of opposition under Article 100 EPC. The feature introduced into part (b) of claim 9 intends to overcome an objection raised under Article 76(1) EPC and thus, it was occasioned by a ground for opposition (Article 100(c) EPC). For the admission of an amendment, the criterion established in the case law requires the amendment to be a serious attempt to overcome an objection, regardless of whether or not the objection is overcome.

3. The amendment introduced into part (b) of claim 9 relates to the second primer of the claimed kit and defines the chromosomal sequence of *S. aureus* with which said primer hybridises, namely the chromosomal sequence of *S. aureus* "adjoining said polymorphic sequences from the SCC*mec* element right extremity of an MREJ type vii sequence". The amendment intends to limit said chromosomal sequence of *S. aureus* and thereby to overcome the objection raised under Article 76(1) EPC. The amendment is a serious attempt to overcome said objection, even though this objection is not overcome (*infra*).

*Article 84 EPC*

4. According to the case law, the claims must be read with a mind willing to understand and make technical sense of them, ruling out illogical or technically meaningless interpretations (cf. *inter alia*, T 190/99 of 6 March 2001; see also "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, II.A.6.1, 307). The claims are directed to a person skilled in the art who, in the present case, is considered to be that

defined in decision T 2002/13, namely a person skilled in amplification (polymerase chain reaction, PCR) techniques and familiar with MRSA in general, and the detection and identification of MREJ types in particular (cf. T 2002/13 of 17 May 2017, point 4 of the Reasons).

5. Step (a) of claim 1 refers to the insertion of a Staphylococcal cassette chromosome mec (SCC*mec*) element containing a mecA gene into chromosomal DNA, thereby generating a polymorphic right extremity junction (MREJ) type i, ii, iii or vii sequence. Claim 1 defines these MREJ sequences as comprising polymorphic sequences from the SCC*mec* element right extremity and chromosomal DNA adjoining said polymorphic sequences from the SCC*mec* element right extremity. Whilst the first primer is defined as hybridizing with said polymorphic sequences from the SCC*mec* element right extremity of an MREJ type i, ii, iii or vii sequence selected from several specific SEQ ID NOs sequences, the second primer is defined as hybridizing with "said chromosomal sequence of *S. aureus*" without any further characterisation. Therefore, there is no reason to limit the chromosomal sequence of *S. aureus* hybridizing with the second primer to the chromosomal sequences of *S. aureus* within the specific (MREJ types) sequences cited in claim 1; the chromosomal sequence of *S. aureus* may well be beyond (outside) these specific sequences as far as it fulfils the other requirements of claim 1, namely specifically generate (an) amplicon(s) when used with a first primer and if a MRSA strain of MREJ type i, ii, iii and vii is present in the sample. Thus, the definition of the second primer in claim 1 is neither ambiguous nor open to interpretation.

6. Prior to the reference to "such MRSA strain of said MREJ types i, ii, iii and vii" (strain in singular) at the end of step (a) of claim 1, step (a) describes the generation of MREJ type i, ii, iii and vii sequences by insertion of a SCC*mec* element containing a mecA gene into chromosomal DNA of *S. aureus*. This description informs the skilled person - defined as in point 4 above - that the generation of a MREJ type sequence can neither provide nor result in a MRSA strain (in singular) having several MREJ type sequences.

Indeed, this was already known by the skilled person from the prior art, in particular from Hiramatsu *et al.*, which is cited in the patent under the heading "Background of the invention". As explained therein, "the SCC*mec* DNAs are integrated at a specific site in the methicillin-sensitive *S. aureus* (MSSA) chromosome ... the SCC*mec* DNA integration site (i.e. *attBscc* which is the bacterial chromosome attachment site for SCC*mec* DNA). The *attBscc* site was located at the 3' end of a novel open reading frame (ORF), orfX" (cf. page 3, lines 6 to 12 of the parent application). Once the SCC*mec* DNA is inserted into the specific integration site *attBscc* within the MSSA chromosome, generating thereby a specific MREJ type sequence, this integration site is not available anymore for insertion of other, additional SCC*mec* DNAs.

Therefore, in the light of the description of the MREJ generation in step (a) of claim 1 and of the skilled person's common general knowledge, the reference to a MRSA strain (in singular) at the end of step (a) of claim 1 would be understood by the skilled person as related to the presence of a MRSA strain of any one of the MREJ type i, ii, iii and vii in the sample analysed, i.e. the presence of MREJ type i, ii, iii and

vii MRSA strains as stated in the preamble and in the first sentence of step (a) of claim 1. Appellant II's interpretation of this reference is neither supported by the wording of claim 1 nor by the description of the patent. Moreover, in light of the prior art and the skilled person's common general knowledge, such interpretation is technically meaningless.

7. It is also in light of this prior art and the skilled person's common general knowledge - as defined in point 4 above - that the reference to the generated "(an) amplicon(s)" in claim 1 would be understood by a skilled person as referring to the generation of (one type of) an amplicon for each of the MREJ types cited in claim 1, i.e. MREJ types i, ii, iii and vii and, in line with the purpose of amplification, to achieve as many as possible of said amplicon(s) so as to allow thereby the detection of the corresponding MREJ type MRSA strain(s) if present in the sample analysed. There is thus no unclarity associated with the term "(an) amplicon(s)" in claim 1.

8. Claim 1 is directed to a method for detecting the presence of MREJ type i, ii, iii and vii MRSA strains in a sample, which is characterised by steps (a) and (b). Step (a) is carried out using first and second primers to "specifically generate (an) amplicon(s) if such MRSA strain ... is present in said sample". These primers are defined by their length (at least 10 nucleotides) and by the sequence with which they hybridise, namely within the polymorphic sequences from the SCC*mec* element right extremity of an MREJ type i, ii, iii or vii selected from a group of specific sequences (first primer) and the chromosomal sequence of *S. aureus* adjoining said polymorphic sequences (second primer). Step (b) further requires the

detection of said amplicon(s), without limitation to any particular method of detection and thus, it includes detection methods other than those relying on the length and/or the nucleotide sequence of the specifically generated amplicon(s). No unclarity arises from the definition of these primers, nor from their use in the claimed method and the purpose of said method. Likewise, no unclarity arises from the definition of the first and second primers in parts (a) and (b), respectively, of claim 9 which is directed to a kit for detecting the presence or absence of an MREJ type vii strain in a sample, and wherein these primers "enable the selective generation of an amplicon".

9. Appellant II also raised a clarity objection against the terms "specifically generate an amplicon" and "selective generation of an amplicon" in claims 1 and 9, respectively. However, these terms are also present in granted claims 1 and 27, which are directed to a method for detecting the presence of at least one MREJ type vii MRSA strain and a kit for detecting the presence or absence of an MREJ type vii MRSA strain, respectively. In view thereof and according to decision G 3/14 (OJ EPO 2015, A102), these terms are not open to an objection under Article 84 EPC because they were already present in the granted claims and they do not arise from any amendment.

*Article 76(1) EPC*

10. According to Article 76(1) EPC, a divisional patent application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier (parent) application as filed. For assessing compliance with this article, the same principles apply as for Article 123(2) EPC (cf. G 1/05, OJ EPO 2008,

271, point 5.1 of the Reasons). Thus, in line with the so-called "gold standard" for assessing compliance with Article 123(2) EPC, the subject-matter disclosed in the divisional patent application must be directly and unambiguously, using common general knowledge, derivable - either explicitly or implicitly - from the earlier application as filed (cf. G 1/06, OJ EPO 2008, 307, Headnote; and G 2/10, OJ EPO 2012, 376, point 4.3 of the Reasons) (see also "Case Law", *supra*, II.E. 1.3.1, 436). As stated in point 4 above, in the present case, the common general knowledge and the person skilled in the art are those defined in decision T 2002/13 (*supra*).

11. The objections raised by appellant II under this article concern two issues, the first one arising from the features "specifically generate (an) amplicon(s)" and "selective generation of an amplicon" in claims 1 and 9, respectively, and the second one arising from the definition of the second primer in these claims.

*The features "specifically generate (an) amplicon(s)" and "selective generation of an amplicon" in claims 1 and 9, respectively*

12. It is not contested that the features "specifically generate (an) amplicon(s)" and "selective generation of an amplicon" in claims 1 and 9 have no explicit basis in the parent application. Thus, in line with the case law referred to above, it is necessary to assess whether these features are directly and unambiguously derivable from the parent application in an implicit manner.

13. Whilst the term "specific" is used in the parent application, this is not the case for the term

"selective" (except for the references to a "selective culture medium" on page 16, line 15, and a "selective pressure" on page 19, line 15, which however have no direct bearing on the claimed method). Without entering into a discussion of the meaning of these terms and an assessment of their scope and possible overlap, it is agreed in these proceedings that the conclusions achieved for the former are also relevant for the latter, i.e. if no implicit basis is acknowledged for the former, none can be acknowledged for the latter. This is so because, at least to a certain extent, the meaning of the term "selective" in the context of claim 9 ("selective generation of an amplicon") may be equated to that of the term "specifically" in claim 1 ("specifically generate (an) amplicon(s)").

14. In the parent application, the term "specific" is used in two different contexts.

14.1 In the first one, the term "specific" is used in the context of a method for detection of MRSA strains, either in general, without reference to any particular MREJ type (cf. *inter alia*, page 5, lines 20 to 22, and page 13, lines 16 to 23), or more specific with reference to several particular MREJ types (cf. *inter alia*, page 5, line 27, to page 6, line 9). In this latter case, the method requires to detect the presence or absence of (at least some of) these particular MREJ types, but without any further requirement. There is no notion or concept of MREJ type specificity in this latter case, let alone in the former one, because the purpose of the method is not to detect - in the sense of identifying, determining or typing - which particular MREJ types are present in the sample analysed, but whether (at least) one of them, no matter which one, is present in the sample. This detection

method corresponds to that of claim 1 and dependent claims of the parent application, wherein reference is made to primers and/or probes specific for MRSA strains and altogether capable of annealing with at least four MREJ types selected from MREJ types i to x. Indeed, by using the term "at least", this method does not exclude the detection of MRSA strains of a MREJ type other than those explicitly mentioned and/or required in the method claim (at least four selected from MREJ types i to x). It is understood that the primers will be used in an amplification reaction and generate an amplicon. However, there are no conditions or any requirements attached to, or associated with, this amplification reaction and the generation of the amplicon.

14.2 In the second context, the term "specific" does not relate directly to the detection method itself but to the primers and/or probes used in said method. In this context, reference is made to primers and/or probes specific for a determined MREJ type, i.e. having MREJ type specificity, which are used in a detection method (cf. *inter alia*, page 10, lines 15 to 19; page 15, lines 12 and 13; and page 36, lines 4 to 12). Primers specific for a determined MREJ type are used in the examples of the parent application (cf. *inter alia*, page 50, lines 19 to 25 in Example 5; page 52, lines 16 to 27 in Example 7; and page 54, lines 5 to 8 in Example 8). This method corresponds to that of claim 12 of the parent application which requires to reproduce the method of any of claims 1 to 11 using primers and/or probes specific for a determined MREJ type. In this case, the purpose of the method is to detect - in the sense of identify, determine or type - the presence or absence of a specific MREJ type explicitly mentioned and/or required in the method claim. In this case, the detection method is not open, in the sense that it does

not contemplate the detection of any MREJ types other than those explicitly mentioned and/or required in the method claim. This method is a typing method and requires a further step, namely the detection of the annealed probe and/or primer as an indication of the presence of a determined MREJ type.

14.3 It is worth noting here that, as stated by appellant I, the (first) primer of nucleic acid sequence SEQ ID NO: 66 is disclosed in the parent application as specific to the MREJ types i and ii, i.e. to more than one MREJ type, thereby casting doubts on the actual interpretation of the term "specific" when associated with the properties of a primer. However, such doubts and possibly associated interpretations may be relevant, if at all, under Article 84 EPC (cf. point 9 *supra*), but have no bearing on the considerations under Article 76(1) EPC.

15. Appellant I argued that the method of claim 1 is not a typing method and therefore, the basis of the contested feature in the parent application is the references to the term "specific" in the first context referred to above, wherein this term relates to the detection method itself and not to the primers and/or probes used therein. Appellant II argued that the method of claim 1 is not a mere detection method but, by the presence of the contested feature, a method comprising features of both, the detection and the typing methods disclosed in the parent application. According to appellant II, such a method has no basis in, and is not supported by, the parent application.

16. For a skilled person (as defined in point 4 above), the terms "specifically" and "selective" in the context of claims 1 and 9 are technically meaningful in the light

of the disclosure of the parent application summarised in point 14 above, and their presence in these claims cannot be disregarded or ignored.

In claims 1 and 9, these terms do not characterise the amplicons generated by using the first and second primers in an amplification reaction; these amplicons are always specific in the sense that they always have the specific nucleic acid sequence of the MREJ type with which the first and second primers hybridise. In claims 1 and 9, the terms "specifically" and "selective" characterise the generation of the amplicon, i.e. they do not characterise the product generated by the amplification reaction but the action or the process of generating the amplicon. There is an important technical difference between the mere generation of an amplicon and a selective generation of an amplicon, i.e. specifically generating said amplicon. For the amplification to be specific or selective, the use of primers specific to a determined or particular MREJ type is required. This corresponds in fact to what has been referred to in point 14 above as the second context in which the term "specific" is disclosed in the parent application.

Thus, the presence of the terms "specifically" and "selective" in the claims inform the skilled person that the claimed method is actually a method corresponding to that of claim 12 of the parent application. However, since the first primers in claims 1 and 9 are not required to be specific to the MREJ type i, ii, iii or vii, these claims are not supported by, and have no basis in, the parent application.

*The definition of the second primer in claim 1*

17. The second primer is defined in claim 1 as hybridising with "said chromosomal sequence of *S. aureus*". As stated in point 5 *supra*, this chromosomal sequence is identified as the chromosomal DNA adjoining the polymorphic sequence from the SCC*mec* element right extremity, with no further requirement associated therewith. In particular, this chromosomal sequence is not limited to a chromosomal sequence within the specific MREJ type sequences (SEQ ID NOs) cited in claim 1 but includes chromosomal sequences of *S. aureus* outside these specific MREJ type sequences, i.e. it is not limited to the *orfX* portion of the chromosomal DNA within the MREJ type sequences cited in claim 1, as far as the second primer is capable of specifically generating (an) amplicon(s) when used with the first primer.

18. As stated in the board's communication pursuant to Article 17 RPBA, if the first primer (of at least 10 nucleotides in length) is - selected from a sequence of a specific MREJ type (SEQ ID NO) sequence - in a region close to the (integration) junction site between the polymorphic sequence from the SCC*mec* element right extremity and the adjoining chromosomal DNA, the second primer must not be necessarily limited to the *orfX* portion of the chromosomal DNA within this specific MREJ type sequence, not even to the other portion of the *orfX* outside said specific MREJ type sequence. Since the *orfX* gene has a length of about 700 nucleotides, the second primer may also hybridise with a region beyond the *orfX* gene and yet allow the specific generation of (an) amplicon(s) of reasonable (1.2 - 1.4 kb) size (see the amplicon lengths in Table 7 of the parent application). In such case,

claim 2 limits "said chromosomal sequence of *S. aureus*" to the *orfX* gene, both inside and outside the specific MREJ type sequence.

19. Figure 1 of the parent application illustrates the studies of the prior art on MREJ types i, ii and iii, and shows the set of first and second primers used in these studies, wherein the second primers with sequences SEQ ID NOs: 60, 61 and 63 hybridise with the chromosomal sequence of *S. aureus* outside the *orfX* portion (cf. page 3, lines 3 to 5; page 5, lines 1 to 5; and page 22, lines 20 to 24). However, it is stated in the parent application that all second primers designed for carrying out the disclosed methods - and thus including the method of claim 1 - hybridised or annealed on the *S. aureus* chromosome to the right of the SCC*mec* integration site and targeting the *orfX* gene (SEQ ID NOs.: 64, 70 to 76) (cf. Figures 2A to 2C and Figure 3A). It is also further stated that only one (SEQ ID NO: 64) was found to be specific for MRSA based on testing with a variety of MRSA, methicillin-sensitive *S. aureus* (MSSA), methicillin-resistant and methicillin-sensitive coagulase-negative staphylococci (MRCNS and MSCNS, respectively) (cf. page 24, lines 10 to 16). Indeed, the SEQ ID NO: 64 sequence is used as the second primer in all examples of the parent application (cf. page 47, lines 20 to 25 in Example 2; page 49, lines 1 and 26 in Examples 3 and 4, respectively; page 50, lines 19 to 29 in Example 5; page 52, line 26 in Example 7; and page 53, line 26 in Example 8; see also Figures 2A to 2C).

20. Since the second primer defined in claim 1 is limited neither to the *S. aureus* chromosomal sequence of *orfX* adjoining the polymorphic sequences from the SCC*mec* element right extremity, let alone to those chromosomal

sequences within the specific MREJ type (SEQ ID NOs) sequences cited in claim 1, nor to the SEQ ID NO: 64 sequence disclosed in the parent application, claim 1 comprises subject-matter that goes beyond that disclosed in the parent application and thus, it contravenes Article 76(1) EPC.

*Conclusion on Article 76(1) EPC*

21. It follows from the considerations above that claims 1 and 9 of the main request contravene Article 76(1) EPC.

*New auxiliary request 1; admission into the appeal proceedings*

22. New auxiliary request 1 was filed by appellant I at the oral proceedings before the board, after announcement of the board's findings on the non-compliance of the main request with Article 76(1) EPC.

23. New auxiliary request 1 is identical to auxiliary request 6 filed with appellant I's statement of grounds of appeal, except for the deletion of all claims directed to a kit (claims 7 to 10 of auxiliary request 6). New auxiliary request 1 is a late filed request and it is thus an amendment of appellant I's case in the sense of Article 13 RPBA 2020. Therefore, this amendment may be admitted into the proceedings at the discretion of the board.

24. In the method of claim 1 of new auxiliary request 1, each of the first and second primers are required to hybridise with an MREJ type i, ii, iii or vii sequence selected from the same group of specific sequences as in claim 1 of the main request. By this definition, the second primer is limited to those sequences which hybridise with the chromosomal sequence of *S. aureus*

within the specific MREJ type sequences (SEQ ID NOs) cited in claim 1, even though there is no reference in this context to the *orfX* chromosomal sequence of *S. aureus* within these MREJ type sequences. However, the first primers are not required to be specific to a determined MREJ type, i.e. to have a MREJ type specificity and, since the first and second primers are required to "specifically generate (an) amplicon(s)", the objection raised under Article 76(1) EPC against claim 1 of the main request is not overcome by the amendments introduced into claim 1 of the new auxiliary request 1.

25. In the board's communication under Article 17 RPBA, further objections were raised under Articles 84 and 76(1) EPC against the subject-matter claim 1 of auxiliary request 6; these objections arising, *inter alia*, from the feature introduced after the preamble of claim 1, namely "the specific generation of SCC*mec*-chromosome right extremity junction sequence data by". These objections are neither addressed nor overcome by the new auxiliary request 1.

26. In light of these considerations, the board, in the exercise of its discretion (Article 13 RPBA 2020), decides not to admit the new auxiliary request 1 into the appeal proceedings.

*Auxiliary requests 2, 3 and 5 to 15*

27. When filing the new auxiliary request 1, appellant I renumbered auxiliary requests 1, 2 and 4 to 14 - all filed with the statement of grounds of appeal, as auxiliary requests 2, 3 and 5 to 15, respectively.

28. At the oral proceedings before the board, after discussion of the main request and of the admission of new auxiliary request 1 into the proceedings, the board asked appellant I on which basis they desired to continue the proceedings. Appellant I replied that the proceedings were to be pursued on the basis of auxiliary requests 2, 3 and 5 to 15 (former auxiliary requests 1, 2 and 4 to 14, respectively) but referred only to its written submissions.

29. None of the parties replied in substance to the board's communication pursuant to Article 17 RPBA, wherein they were informed of the board's provisional opinion on the issues of the cases.

In this communication, the board observed that appellant II had argued that none of the auxiliary requests addressed all the objections raised in the proceedings and that none of them fulfilled all the requirements of the EPC. The board further questioned whether any of these auxiliary requests overcame all the objections raised against the main request, in particular those raised under Article 76(1) EPC, which appeared to apply also to, and be relevant against, all the auxiliary requests then on file. The parties were also informed that these auxiliary requests appeared to raise additional issues under several articles of the EPC. Moreover, except for auxiliary request 2 (former auxiliary request 1), the admission of auxiliary requests 3 and 5 to 15 (former auxiliary requests 2 and 4 to 14) into the appeal proceedings was also questioned by the board.

30. In light of these considerations and of the established jurisprudence that the appeal procedure is a judicial procedure which thus precludes the board from making a

party's case (cf. "Case Law", *supra*, V.A.1, 1133 and V.A.3.4, 1196; see in particular G 9/91 and G 10/91, OJ EPO 1993, 408 and 420, respectively), the board sees no reason to provide a detailed reasoning on each of these auxiliary requests. None of them was considered to fulfil all the requirements of the EPC because they either contravened Article 76(1) EPC for the same reasons as the main request and/or had further deficiencies under the EPC as expressed in the board's communication pursuant to Article 17 RPBA.

*Conclusion*

31. None of the requests on file fulfils all the requirements of the EPC. Thus, the patent must be revoked.

**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:

L. Malécot-Grob B. Stolz

Decision electronically authenticated