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Datasheet for the decision of 20 January 2015

Case Number: T 1122/11 - 3.3.07

Application Number: 07754043.3

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Language of the proceedings: EN

Title of invention:
METHOD AND SYSTEM FOR DETERMINING WHETHER A DRUG WILL BE EFFECTIVE ON A PATIENT WITH A DISEASE

Applicant:
Biodesix Inc.

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
Amendments - added subject-matter
Inventive step - closest prior art

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Case Number: T 1122/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 January 2015

Appellant: (Applicant)	Biodesix Inc. 2790 Wilderness Place, Suite 100 Boulder, CO 80301 (US)
Representative:	Webber, Philip Michael Dehns St Bride's House 10 Salisbury Square London EC4Y 8JD (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 December 2010 refusing European patent application No. 07754043.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Semino
	D. T. Keeling

Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division announced at oral proceedings on 1 December 2010 refusing European patent application No. 07 754 043.3.

Claim 1 of the application as originally filed read as follows:

"1. A method of determining whether a patient will be responsive to a drug or treatment, the method comprising:
obtaining a test spectrum produced by a mass spectrometer from a serum produced from a patient having a disease;
processing the test spectrum to determine a relation to a group of class labeled spectra produced from respective serum from other patients having a same or similar clinical stage disease and known to have responded to or not responded to a drug or treatment; and
determining, based on the relation of the test spectrum to the group of class labeled spectra, whether the patient will be responsive to the drug or treatment."

II. The decision was based on the set of claims of the main request filed with a letter of 28 October 2010, the sets of claims of auxiliary requests 1 and 2 filed with a letter of 29 November 2010, and the set of claims of auxiliary request 3 filed during oral proceedings on 1 December 2010.

Claim 1 of auxiliary request 2 read as follows:

"1. A method of identifying a non-small cell lung cancer patient as being likely to benefit from treatment with a drug targeting an epidermal growth factor receptor pathway or not likely to benefit from treatment with said drug, comprising the steps of:

a) obtaining a mass spectrum from a blood-based sample from the patient (1502);

b) performing one or more predefined pre-processing steps on the mass spectrum obtained in step a) (1504);

c) obtaining values for integration ranges in said spectrum at positions corresponding to one or more differentiating peaks obtained from a training set of class-labelled spectra produced from samples from other patients having a same or similar clinical stage disease after the pre-processing steps on the mass spectrum in step b) have been performed, wherein an integration range is the interval around the m/z position of the differentiating peak with a width corresponding to the peak width at the m/z position of the differentiating peak;

d) using the values obtained in step c) in a classification algorithm using said training set to identify the patient as being either likely or not likely to benefit from the said drug (1506)."

In addition to an independent method claim, all requests included an independent apparatus claim (claim 10 for auxiliary request 2).

III. In the decision under appeal, the following documents were cited *inter alia*:

D1: WO-A-2005/098445

D2: US-A-2005/164218

IV. According to the decision under appeal:

a) The main request did not fulfill the requirements of Article 123(2) EPC. Auxiliary request 1 was not admitted into the proceedings under Rule 137(3) EPC, as no convergence towards meeting the requirements of Article 123(2) EPC was seen.

b) Auxiliary request 2 did not fulfill the requirements of Article 56 EPC. D1 was the closest prior art, since it was from the same technical field of data analysis for medical classification using molecular data from patient samples, the purpose of the classification involved the response to drug treatments, and the method thereof involved the similar structural features of using mass spectra from blood-based samples. Claim 1 differed from the disclosure of D1 in part of the definition of the class label, namely that the drug used for treatment of non-small cell lung cancer (NSCLC) targets an epidermal growth factor receptor (EGFR) pathway, and was therefore novel. D1 disclosed in particular the prediction of the success of a treatment, before the drug was administered (page 19, paragraph 2 - page 20, paragraph 1 and page 55, paragraph 2). The problem to be solved was the selection of a drug suitable for treating NSCLC. The solution, namely selecting a drug targeting the EGFR pathway, did not involve an inventive step, since, as illustrated by D2, it was well known that this pathway is associated with NSCLC, and drugs targeting it were known from common general knowledge.

c) Alternatively, starting from D2, considered as closest prior art by the applicant, the conclusion

with respect to inventive step was the same. Claim 1 differed from D2 in the steps of obtaining the data from blood-based samples and using ranges defined by peak widths instead of protein names for the data obtained by mass spectrometry. The problem to be solved was to improve the technique of prediction of drug response. A team working on improving such techniques would include a bioinformatician who, should the data obtained from gene expression data not be enough to obtain a good result, would request other types of data, such as those from mass spectra, as exemplified in D1. Using blood-based samples was well known to the skilled person and would be seen as a straightforward possibility. Independent claim 10 was not inventive for similar reasons.

d) Claim 1 of auxiliary request 3, which differed from that of auxiliary request 2 in that it specified a particular set of m/z peak ranges, did not involve an inventive step, since the ranges defined were not associated with an unexpected effect and were among those that would have been chosen by the skilled person.

V. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted by letter of 4 May 2011 six sets of claims as main request and auxiliary requests 1 to 5.

The main request corresponded to auxiliary request 2 on which the impugned decision was based.

Claim 1 of auxiliary request 1 differed from claim 1 of the main request by the addition of "wherein said one or

more differentiating peaks comprise one or more m/z ranges selected from the group of m/z ranges consisting of", after which a list of numerical m/z peak ranges was provided.

Claim 1 of auxiliary request 2 read as follows:

"1. A method of determining whether a non-small cell lung cancer patient will be responsive to a drug or treatment, the method comprising:

a) obtaining a test spectrum produced by a mass spectrometer from a blood-based sample produced from the patient;

b) processing the test spectrum to determine a relation to a group of class labeled spectra produced from respective blood-based samples from other patients having a same or similar clinical stage disease and known to have responded to or not responded to the drug or treatment; and

c) determining, based on the relation of the text spectrum to the group of class labeled spectra, whether the patient will be responsive to the drug or treatment."

VI. In a communication sent in preparation of oral proceedings, the Board emphasised *inter alia* that the wording of the independent claims of the main request and auxiliary request 1 did not resemble that of the corresponding claims of the application as filed, and that a clear basis therefor was not easily derivable from the description as originally filed. It was noted that the same requests appeared to infringe Article 123(2) EPC at least in respect of the features "a drug targeting an epidermal growth factor receptor pathway" and "blood-based sample". Since claim 1 of auxiliary

request 2 also comprised the latter feature, the same conclusion appeared to apply.

VII. With a letter of 7 January 2015, the appellant filed amended auxiliary requests 3' and 5' to replace auxiliary requests 3 and 5 previously on file. Auxiliary request 4 was withdrawn.

Claim 1 of auxiliary request 3' differed from claim 1 of auxiliary request 2 by the deletion of the term "or treatment" throughout the claim, by the replacement of "blood-based sample" with "serum" and by the addition of "wherein the drug is an anti-cancer drug which targets the epidermal growth factor receptor pathway".

Claim 1 of auxiliary 5' differed from claim 1 of auxiliary request 2 by the deletion of the term "or treatment" throughout the claim, by the replacement of "blood-based sample" with "serum" and by addition of "wherein the drug is gefitinib or erlotinib".

While the main request and auxiliary requests 1 and 2 included a second independent claim directed to an apparatus with further claims dependent thereon, auxiliary requests 3' and 5' did not comprise such claims.

VIII. Oral proceedings took place on 20 January 2015 in the absence of the appellant as announced with a letter of 7 January 2015.

IX. The appellant's arguments, insofar as relevant to the present decision, can be summarised as follows:

All requests - inventive step

D2 was the closest prior art. The examining division's choice of D1 did not represent an appropriate starting point for the skilled person. The closest prior art must address the same technical problem as the invention in suit; the number of features common to the invention and the closest prior art must be considered as a secondary assessment criterion. D2 related to a method of predicting cancer patient responses to drugs, while D1 related to methods of diagnosis of lung cancer. Consequently D2, which related to the same objective or purpose as the invention, had to be chosen as the closest prior art. The problem to be solved starting from D2 was the provision of an alternative method of identifying whether NSCLC patients would respond to treatment with a drug targeting an EGFR pathway, such as gefitinib and erlotinib. Starting from the teachings of D2, there were numerous possible ways of improving the method thereof, but there was no teaching or motivation to move away from the RT-PCR-based methods of D2 to the mass spectrometry-based methods of D1, particularly given that neither D1 nor D2 suggested that the claimed combination of features could produce a practical test, nor that m/z peaks from serum samples would be predictive. Consequently, the independent claims of the respective requests involved an inventive step.

Auxiliary requests 3' - Article 123(2) EPC

Support for the amendment to claim 1 of auxiliary request 3' "wherein the drug is an anti-cancer drug which targets the epidermal growth factor receptor pathway" was to be found in the application as originally filed on page 5, lines 21-22. The skilled person would understand therefrom that gefitinib and

erlotinib were preferred drugs of the invention and that "anti-cancer drugs which target the epidermal growth factor receptor pathway" were an intermediate generalisation of preferred drugs which fell within the general term "drug" as provided in claim 1.

X. 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 as filed by letter of 4 May 2011 or, in the alternative, on the basis of the claims of auxiliary requests 1 or 2 as filed by letter of 4 May 2011 or auxiliary request 3' or 5' as filed by letter of 7 January 2015.

Reasons for the Decision

Main request - amendments

1. With respect to claim 1 as originally filed, claim 1 of the main request includes *inter alia* the following amendments:
   a) the drug is defined as "a drug targeting an epidermal growth factor receptor pathway"; and
   b) the test spectrum is not obtained from a "serum", but from a "blood-based sample".

1.1 In the context of reducing or eliminating the ability of cancer cells to grow and divide, the description as originally filed makes reference to one of the signalling pathways which control cell growth, whereby a chemical in the body, called epidermal growth factor, binds to a receptor found on the surface of many cells, known as the epidermal growth factor receptor (EGFR). This receptor is said to send signals to the cells through the activation of tyrosine kinase, found within the cells (page 1, lines 23-32). Two specific anti-

cancer drugs are identified, namely gefitinib and erlotinib, and it is stated that "these anti-cancer drugs target the EGRF pathway..." (page 1, line 33 - page 2, line 1). Later, in the context of anti-cancer drugs which have been used in clinical trials for patients suffering from NSCLC, it is stated that "these anti-cancer drugs may include gefitinib and erlotinib that target the epidermal growth factor receptor pathway" (page 5, lines 18-22). Thus while gefitinib and erlotinib are identified as targeting the EGFR pathway, the application as filed makes no reference to a generalised group of drugs which target said pathway. Consequently, amendment a) is not directly and unambiguously derivable from the application as filed.

1.2 The term "blood-based sample" does not appear verbatim in the description as originally filed. The detection of differentiating peaks of a spectrum produced by a mass spectrometer from serum extracted from a patient's blood is discussed (page 2, lines 23-24). Although serum, red blood cells and white blood cells are included in a long list of tissue or fluid from which the relevant biomarkers can be measured (page 40, lines 11-14), "blood-based sample" cannot be considered as an umbrella term limited to these constituents, as blood may comprise further components or combinations. Consequently, amendment b) is not directly and unambiguously derivable from the application as filed.

1.3 It follows that claim 1 of the main request does not fulfill the requirements of Article 123(2) EPC.

Auxiliary requests 1, 2 and 3' - amendments

2. Since claim 1 of auxiliary request 1 comprises amendments a) and b) of claim 1 of the main request and claim 1 of auxiliary request 2 comprises amendment b), the same conclusions with regard to Article 123(2) EPC as reached for the main request apply.

2.1 Auxiliary request 3' comprises the feature "wherein the drug is an anti-cancer drug which targets the epidermal growth factor receptor pathway", which differs from amendment a) above by the specification that the drug is "anti-cancer". While the description as originally filed provides support for "anti-cancer drugs" (claim 2), the specific sub-group of anti-cancer drugs which target an EGFR pathway is not directly and unambiguously derivable from the application as originally filed as outlined for amendment a) of claim 1 of the main request (see point 1.1, above). Thus, for the same reasons as provided for the main request the subject-matter of claim 1 of auxiliary request 3' does not fulfill the requirements of Article 123(2) EPC.

Auxiliary requests 5' - amendments

3. Claim 1 of auxiliary request 5' finds a basis in claim 1 of the application as filed with the deletion of "treatment" out of the two options "drug or treatment" and the specifications that the patient is a non-small cell lung cancer patient (original claim 3) and that the drug is gefinitib or erlotinib (page 4, lines 2-4). Claim 2 finds support in claims 5 as well as in the description (page 2, line 22 to 24; page 3, lines 4 to 14), where it is mentioned that the determination of whether a patient will respond to a particular drug is made by detecting differentiating peaks of a mass spectrum from the serum of a patient, called the test

spectrum. Claim 3 find a basis in Table IV on page 35 of the description as originally filed, while claims 4-12 correspond to claims 5, 6, 10-14, 17 and 18 as originally filed.

3.1 It follows that auxiliary request 5' fulfills the requirements of Article 123(2) EPC.

Auxiliary request 5' - inventive step

4. *Closest prior art*

4.1 According to the decision under appeal, D1 represents the closest prior art, while the appellant submits that D2 is the correct starting point for the skilled person.

4.2 According to established case law (Case Law of the Boards of Appeal, 7th edition 2013, I.D.3), in selecting the closest prior art, a central consideration is that it must be directed to the same purpose or effect as the invention, otherwise it cannot lead the skilled person in an obvious way to the claimed invention. The closest prior art is that most suitable for the purpose claimed by the invention, not that showing the largest number of similarities with the claimed subject-matter. The aim of the assessment process is to start from a situation as close as possible in reality to that encountered by the inventor.

4.3 A detailed analysis of documents D1 and D2 is necessary in order to come to a choice which respects these criteria.

4.4 D1 discloses a method for aiding in the diagnosis of lung cancer in a patient comprising obtaining a biological sample from a patient suspected of suffering

from lung cancer and detecting at least one protein biomarker in said sample (claim 1). Said protein biomarkers are differentially present in the samples of patients with lung cancer and in the samples of control subjects, and are characterised by molecular weight via mass spectroscopy, preferably Surface-Enhanced Laser Desorption/ionization ("SELDI") mass spectrometry (page 5, lines 8-20). According to example 2 of D1 (page 48 and following), serum samples from lung cancer patients and from healthy patients were processed for SELDI analysis. The spectra were subsequently analysed and normalised (page 50, "peak detection"). Construction of a decision tree classification algorithm and further analysis yielded peaks that were found to have significant differential expression levels between lung cancer and control serum, allowing a correct identification of 83.3% of the "normal" samples and 81.0% of lung cancer samples (page 50, line 8 - page 53, line 14).

4.5 According to the appealed decision, the examining division, referring to specific passages (page 19, paragraph 2 - page 20, paragraph 1 and page 55, paragraph 2), interpreted D1 as also disclosing the prediction of the success of a treatment before the drug is administered, and equated this with the identification of a lung cancer patient as being likely or not likely to benefit from said drug (reasons, section 3.4). The Board cannot agree with this reading of D1.

4.6 D1 refers to a form of the invention in which the "drug responder status of a biological sample of a lung cancer patient may be determined". The drug responder state is described as "a state of a biological sample in response to the use of a drug" (page 19, lines 19-21). In the

example provided (page 20, lines 1-12), mass spectra of samples from lung cancer patients who were treated with a drug of known effect are created. The drug of known effect and drugs of the same or similar type might all regulate the same biochemical pathway in a person to produce the same effect on a person. Characteristics of the biological pathway may be reflected in the mass spectra.

4.7 This alternative embodiment of D1, rather than disclosing the diagnosis of lung cancer, merely illustrates that the same method may be used to determine whether, after treatment with the chosen drug, or drugs or a similar type, a patient is responding thereto. This is distinct from the determination of whether a patient will be responsive to a drug, which has a predictive quality and must take place before administration of the drug.

4.8 D1 further discloses that in "addition to being an important diagnostic tool, SELDI protein profiles can also be utilized before, during and after treatment of lung cancer in order to determine whether or not a particular cancer treatment is successful and to enable the monitoring of patients for persisent [*sic*] or recurrent disease" (page 55, lines 10-13). This disclosure merely amounts to the provision of a means of determining whether a particular treatment is effective or not. Claim 90 of D1, which appears to correspond to this embodiment, refers to a method of monitoring the effectiveness of lung cancer treatment in a patient.

4.9 Neither the above-cited passages in D1, nor any other disclosure therein can be understood, either explicitly or implicitly, to disclose a method for determining

whether a patient will be responsive to any particular treatment.

4.10 The method of claim 1 of auxiliary request 5' differs therefore from the disclosure of D1:

a) in the purpose of the method, namely that it is for detecting whether a patient will be responsive to a drug;

b) in that steps b) and c) are consequently meant to determine whether a patient is responsive to a drug and not whether he has lung cancer or whether a treatment has been effective;

c) in that the method is specific to non-small cell lung cancer and the drug is specifically gefitinib or erlotinib.

4.11 D2 concerns a method for predicting the likelihood that a cancer patient will respond to treatment with EGFR inhibitors, comprising determining the expression level of one or more prognostic RNA transcripts or their expression products in a biological sample comprising tumour cells, wherein the prognostic transcript is that of one or more genes chosen from a specific group (paragraphs [0010] and [0011]). In the "example" (page 8), tissue samples from NSCLC patients who did or did not respond to treatment with EGFR inhibitors were embedded in paraffin, mRNA was extracted and gene expression analyses were carried out by molecular assay using RT-PCR (paragraph [0109]). The result was the identification of statistically significant genes, greater expression of which was either indicative of patients who were likely to benefit from anti-EGFR treatment, or alternatively, unlikely to benefit

therefrom (paragraphs [0118] and [0119]). Mass spectrometry is mentioned in D2 only in connection with quantifying the cDNA present (paragraph [0074]), or generally to detect the products of the "prognostic markers" of the invention (paragraph [0089]). Gefitinib and erlotinib are mentioned as known EGFR inhibitors (paragraph [0093]).

4.12 Thus document D2 discloses a method with the same objective as the one of claim 1 of auxiliary request 5', namely to determine whether a NSCLC patient will be responsive to gefitinib or erlotinib.

4.13 The method of claim 1 of auxiliary request 5' differs therefrom in the choice of the sample ("serum") and in the technique used to measure its properties (mass spectrometry) and consequently in the details of steps a), b) and c) depending on these choices.

4.14 The rationale for the examining division's choice of D1 as closest prior art may largely be attributed to the interpretation that it discloses a method for identifying whether a patient will be responsive to a particular treatment. As mentioned above (points 4.5 - 4.9), D1, in the opinion of the Board, does not disclose such a method and on that basis is not suitable as closest prior art.

4.15 D2 on the other hand discloses a method for predicting the likelihood that a cancer patient will respond to treatment with EGFR inhibitors (claim 1), and as such, is clearly directed to the same purpose and objective as the present application. Consequently D2 represents the most appropriate starting point for the skilled person.

5. *Problem solved*

5.1 Despite the absence of data directly comparing the method of D2 with that of claim 1, it is plausible that some features of the claimed process, such as the use of blood serum samples rather than tumour tissue may be seen as less invasive and thus advantageous (see in particular the application, page 9, lines 1-8). Nevertheless, it cannot be concluded that the method of claim 1 is an improvement over the method of D2, since it cannot be excluded that one method may be superior to the other according to the circumstances, e.g. in terms of the specificity or sensitivity. Thus the problem to be solved is the provision of a less invasive alternative method for determining whether a NSCLC patient will be responsive to gefitinib or erlotinib.

5.2 That the problem is solved is demonstrated in the patent application. With reference to serum sampling for detecting whether a drug will be effective on NSCLC, several groups of patients were tested (Italian 1, Italian 2, Japanese 1, Japanese 2). Each patient was treated with gefitinib and information, including survival times, was recorded (page 33, lines 18-21 and Table III). Ultimately, processing the information by applying the data analysis techniques set out in the application led to the identification of a set of specific differentiating m/z peak ranges (Table IV on page 35) from which conclusions could be drawn with respect to the patients being likely or unlikely to respond to said treatment (page 36, lines 17 - page 37 line 2). The results of the classification of patients according to the application were verified by testing the classifier trained on Italian 1 samples on the Japanese 1 and 2 samples (page 39, lines 1-8 and figure 12), testing the classifier trained on Japanese samples 1 and 2 on the Italian 1 set (page 39, lines 9-15 and

figure 13) and testing the validated classifier blindly on the Italian 2 samples, i.e. without knowledge of the survival data (page 39, lines 16-24). The results of the tests were consistent with the actual clinical test, thus demonstrating that the problem as posed has been solved when the drug is gefitinib.

5.3 It is established case law that if the inventive step of a claimed invention is based on a given technical effect, the latter should, in principle, be achievable over the whole area claimed. In this context the Board notes that while claim 1 refers to a method of determining whether a NSCLC patient will be responsive to gefitinib or erlotinib, the successful application of the method is demonstrated only with respect to gefitinib. Consequently it must be determined whether the technical effect (of providing a method as claimed) can be considered as plausibly achievable also for erlotinib.

5.4 The m/z peak ranges identified in the application as differentiating whether NSCLC patients will be responsive to gefitinib correspond to biomarkers present in the blood serum of said patients which, albeit of unknown nature, are significant for this differentiation. As noted in the application, there may be many unknown factors that involve a patient's ability to respond (page 2, lines 5-12). Since the serum samples of patients are taken, analysed and test spectra generated before administration of the drug, the differentiating peak ranges (which arise from differentiating biomarkers) must be attributable to physiological factors which are either inherent to the physiology of the patient, to the nature of the NSCLC suffered by said patient, or to a combination of both,

but which clearly do not result from the administration of the drug itself.

5.5 Thus it is reasonable to assume that the differentiating biomarkers are either directly or indirectly associated with the EGFR pathway, since their variability influences whether a drug targeting this pathway will be effective or not. Consequently, it is plausible, and indeed to be expected that differentiating peak ranges corresponding to differentiating biomarkers will also be identifiable in respect of class-labelled spectra generated from patients treated with erlotinib, which also acts via the EGFR pathway, thus allowing the determination, via processing of a test spectrum, of whether a NSCLC patient will be responsive thereto.

5.6 It follows that the posed problem can be considered as plausibly solved over the whole area claimed.

6. *Obviousness*

6.1 In order to determine whether the solution provided by claim 1 would be obvious to the skilled person, the question to be answered is whether the skilled person, starting from D2 and aiming at solving the problem as formulated above, would be led to the claimed method by the available prior art and in particular by D1.

6.2 According to the method of D1, the protein biomarkers are differentially present in the samples of patients with lung cancer and in the samples of control subjects who do not have cancer (page 5, lines 8-14). The process according to claim 1 however requires the existence of differences in the mass spectrum (typically differentiating peaks) of NSCLC patients who have not yet been treated with the relevant drug. Thus said peaks

must correspond to further distinct (unidentified) biomarkers defining physiological factors which do not necessarily differentiate cancer from non-cancer, since the identification of said peaks is carried out by comparing spectra from patients at a similar stage of disease progression known to have responded to the drug or not (the class-labelled spectra). Rather the spectra properties according to claim 1 define whether a NSCLC patient will be responsive to gefitinib or erlotinib, which is an entirely different matter.

6.3 D2, for its part, teaches the skilled person that prediction of the benefit of a drug requires genomic tests on tumour samples.

6.4 There is neither teaching nor suggestion in either D1 or D2 that blood serum samples could be used to identify spectra properties which are predictive of the response to gefitinib or erlotinib and thus offer a less invasive alternative to the method of D2.

6.5 Consequently, the subject-matter of claim 1 of auxiliary request 5' involves an inventive step.

7. It follows that the requirements of the EPC have been fulfilled in respect of auxiliary request 5'.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of the claims of auxiliary request 5' as filed by letter of 7 January 2015 and a description to be adapted.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated