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Datasheet for the decision of 26 June 2014

Case Number: T 1907/10 - 3.3.07

Application Number: 01992358.0

Publication Number: 1343480

IPC: A61K9/16, A61K9/50

Language of the proceedings: EN

Title of invention:
INDUCED PHASE TRANSITION METHOD FOR THE PRODUCTION OF MICROPARTICLES CONTAINING HYDROPHOBIC ACTIVE AGENTS

Patent Proprietor:
Alrise Biosystems GmbH

Opponent:
Alkermes Inc.

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(c), 123(2)

Keyword:
Amendments - added subject-matter (yes) - main request
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)

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Case Number: T 1907/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 June 2014

Appellant: (Opponent)	Alkermes Inc. 852 Winter Street Waltham MA 02451 (US)
Representative:	Chapman, Paul William Kilburn & Strode LLP 20 Red Lion Street London WC1R 4PJ (GB)
Respondent: (Patent Proprietor)	Alrise Biosystems GmbH Robert-Rössle-Strasse 10 13125 Berlin (DE)
Representative:	Vossius & Partner Siebertstrasse 4 81675 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 July 2010 rejecting the opposition filed against European patent No. 1343480 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies against the decision of the opposition division announced at the oral proceedings on 1 June 2010 to reject the opposition against European patent 1 343 480. The patent was granted with 34 claims, of which claims 1 and 2 were independent and read as follows:

"1. A process for the production of polymeric microparticles comprising dissolving a polymer in a halogen-free solvent that is at least partially water-miscible to form a polymer solution, adding a non-water-soluble active agent to the polymer solution to form a drug phase contained in a vessel; adding a predetermined amount of an aqueous surfactant phase to the vessel containing the drug phase with mixing, said predetermined amount being sufficient to (i) result in a volume fraction of the surfactant phase of at least 60%, and (ii) provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of said solvent from said drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without requiring removal of the solvent from the vessel.

2. A process for the production of polymeric microparticles comprising dissolving a polymer in a halogen-free solvent that-is at least partially water-miscible to form a polymer solution; adding in the form of an aqueous suspension, an active agent selected from calcitonin, erythropoietin (EPO), Factor VIII, Factor IX, ceredase, cerezyme, cyclosporin, granulocyte colony stimulating factor (GCSF), alpha-1 proteinase inhibitor, elcatonin, granulocyte macrophage colony

stimulating factor (GMCSF), growth hormones including human growth hormone (HGH) and growth hormone releasing hormone (GHRH), heparin, low molecular weight heparin (LMWH), interferons including interferon alpha, interferon beta, interferon gamma, interleukin-2, luteinizing hormone releasing hormone (LHRH), goss erelin, insulin, somatostatin, octreotide, vasopressin, follicle stimulating hormone (FSH), insulin-like growth factor, insulintropin, interleukin-1 receptor antagonist, interleukin-3, interleukin-4, interleukin-6, macrophage colony stimulating factor (M-CSF), nerve growth factor, parathyroid hormone (PTH), thymosin alpha 1, llb/llla inhibitor, alpha-1 antitrypsin, VLA-4, respiratory syncytial virus antibody, cystic fibrosis transmembrane regulator(CFTR) gene, deoxyribonuclease (Dnase), bactericidal/ permeability increasing protein (BPI), anti-CMV antibody, interleukin-1 receptor, vaccines, 13-cis retinoic acid, pentamidine isethiouate, albuterol sulfate, metaproterenol sulfate, beclomethasone dipropionate, triamcinolone acetamide, budesonide acetonide, fluticasone, ipratropium bromide, flunisolide, cromolyn sodium and ergotamine tartrate to the polymer solution to form a drug phase contained in a vessel; adding a predetermined amount of an aqueous surfactant phase to the vessel containing the drug phase with mixing, said predetermined amount being sufficient to (i) result in a volume fraction of the surfactant phase of at least 60%, and (ii) provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of said solvent from said drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without requiring removal of the solvent from the vessel."

II. A notice of opposition was filed against the granted patent requesting revocation of the patent in its entirety on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step in accordance with Article 100(a), (b) and (c) EPC.

III. During opposition proceedings the following documents *inter alia* were cited:

D1: WO-A-97/19676
D1a: US-A-6 294 204
D3: WO-A-01/15799
D4: US-A-5 049 322
D5: US-A-4 389 330
D6: US-A-6 291 013
D7: WO-A-00/40221
D8: WO-A-99/24061
D11: Hongkee Shaa et al., Pharmaceutical Research, vol. 13, no. 3, 1996, pages 360-367.

IV. The decision of the opposition division can be summarised as follows:

a) The patent as granted met the requirements of Article 123(2), as claim 2 was based on original claim 1 in combination with the teachings in the description regarding the addition of a suspension of a hydrophobic agent to a polymer solution and a list of suitable hydrophobic agents. The patent as granted was also sufficiently disclosed, as claim 1 provided sufficient guidance as to the volume of the aqueous surfactant phase to be used and defined specific steps to be performed to prepare polymeric microparticles.

b) The processes of claims 1 and 2 were novel, as D6 was not prior art, D3, D4 and D5 did not disclose the correct order of addition of the drug phase and the aqueous phase and the use of an aqueous suspension of the specific agents of granted claim 2, D1 did not disclose a non-water-soluble active agent, nor an aqueous suspension of insulin, D7 involved the simultaneous mixing of the aqueous phase and the drug phase and D8 did not disclose the volume of the aqueous surfactant phase and required addition of the drug phase to the aqueous surfactant phase.

c) Claim 1 involved an inventive step over D11, which was the closest prior art, the distinguishing features being the order in which the aqueous surfactant phase and the drug phase were added to each other, and the requirement in D11 that a transient stable oil-in-water emulsion be formed. The problem solved was the provision of a simplified process for the production of polymeric microparticles containing non-water-soluble active agents and the proposed solution was not made obvious by D11 either alone or in combination with D1 or D4. Inventive step was also acknowledged starting from D4 as the closest prior art in an *obiter dictum*, although this was not the correct choice. The difference was the order in which the aqueous surfactant phase and the drug phase were added together, the problem solved was the provision of a process for the production of microparticles containing non-water-soluble active agents which was more versatile and the proposed solution was not obvious, as no pointer to it existed in the available prior art.

d) Claim 2 as granted involved an inventive step over D8 as closest prior art, the latter being identified as the only document on file dealing with the encapsulation of suspensions of active agents, and differing from claim 2 in both the solvent used and in the order in which the drug phase and the aqueous surfactant phase were added together. The problem solved was the provision of a process for the production of microparticles involving an aqueous suspension of the active agent which was simplified and did not require the use of toxic solvents and the proposed solution was not made obvious by D8 either alone or in combination with D1.

V. The appellant lodged an appeal against that decision, and filed a statement of grounds in due time. With the statement setting out the grounds of appeal, the appellant submitted *inter alia* the following documents:

D17: WO-A-00/00610
D19: Fischel-Ghodsian et al, Proc. Nat. Acad. Sci. USA, vol. 85, 1988, pages 2403-2406
D20: WO-A-02/49619
D21: Technical annex including experiments 1 to 3

VI. With the reply to the statement setting out the grounds of appeal, the respondent (patent proprietor) filed further sets of claims as auxiliary requests 1-5. Auxiliary request 1 differed from the main request (the claims as granted) in the deletion of independent claim 2 and the renumbering of subsequent claims.

VII. In a communication sent in preparation of oral proceedings, the Board reviewed the submissions of the parties and in particular made reference the

possibility that claim 2 of the main request extended beyond the content of the application as filed.

VIII. Oral proceedings were held on 26 June 2014.

IX. The arguments of the appellant, as far as relevant to the present decision, may be summarised as follows:

Main request - added subject-matter

a) The reference in the description whereby an aqueous suspension of the hydrophobic active agent is to be added to the polymer solution (page 12, lines 1-4 of the application as filed) cannot be considered to be applicable wholesale to the list of compounds described as examples of hydrophobic active agents provided in a further section of the description (page 15, lines 6-24). The skilled person, aware of the hydrophilic character of some of the agents comprised within the list (such as insulin), would rather contemplate only those agents he would consider as being suitable for forming the required aqueous suspension, i.e. those which would be considered as being clearly hydrophobic. There is no teaching in the application as filed which would suggest to the skilled person that active agents not normally considered as hydrophobic should be forced into suspension. Consequently, the application as filed does not disclose the process for preparing a drug phase by addition of a suspension when the active agent is one which the skilled person would normally consider as being hydrophilic despite being chosen from the list provided and claim 2 therefore comprises added matter.

Auxiliary request 1 - novelty

b) Claim 1 is not novel with respect to D1 (reference is made to the disclosure of the English language family member D1a) and with respect to D20, the latter due to the invalidity of the priority date. Accordingly, both D1a (example 20) and D20 (example 10) disclose processes for producing microparticles comprising insulin. According to the evidence provided by D19 and D21, the insulin preparations of the respective examples of D1a and D20 are inevitably aqueous suspensions, since under the conditions described, the limits of solubility of insulin has been surpassed. Under the conditions of suspension formation disclosed, insulin is a "non-water-soluble active agent" as required by claim 1.

Auxiliary request 1 - inventive step

c) The opposition division's choice of D11 as the closest prior art was incorrect. D4 (see example 2) is the closest document, as it also avoids the use of a halogenated solvent and it differs from the process of claim 1 only in the order of addition of the drug phase and the aqueous phase. Furthermore, the choice of D11 as closest prior art was erroneous due to the position of opposition division that according to the process of D11 a transient emulsion was formed, a process which is clearly different from the process of the patent. All of the alleged advantages associated with the difference are provided by the disclosure of D4; nothing has been shown to depend on the order of addition and no evidence to this effect has been presented. The size range of the

particles produced according to the process of D4 overlaps with that of the examples of the disputed patent, and in any case, particle size is not recited in claim 1. The problem solved is consequently the provision of an alternative method for preparing microparticles having the morphology shape and size distribution as provided by D4. The skilled person starting from example 2 of D4 in view of the known advantage of avoiding halogenated solvents, would simply change the order of mixing in the expectation that the resultant process would be equally effective in producing the desired microparticles, thereby arriving at the process of claim 1 without exercising inventive activity. The allegation of the respondent that it was unpredictable that changing the order of mixing would still produce the desired microparticles has not been supported by any evidence. The facts that the examples of the patent are written in the present tense and that examples 1-4, in which different active agents are used, share exactly the same values of active agent content (2.2%) and encapsulation efficiency (85%) render the examples not credible and lead to the conclusion that the examples were not carried out and that the patent lacks any evidence that the desired microparticles are provided by the claimed process.

X. The arguments of the respondent, as far as relevant to the present decision, may be summarised as follows:

Main request - added subject-matter

a) It is clear to the skilled person that all of the active agents listed in the application as filed

(page 15, lines 6-24), even if not considered non-water-soluble *per se*, would be suitable for producing an aqueous suspension of the drug phase as claimed. On page 12 of the description as filed, three embodiments of the invention are listed: the drug phase may be prepared by adding an aqueous suspension of the active agent (lines 1-5), it may be prepared by dissolving the active agent in the organic polymer solution (lines 15-16) or it may be prepared by suspending insoluble hydrophobic active agents in the organic polymer phase (lines 30-31). In order to arrive at the subject-matter of claim 2, the skilled person must make a selection from this short list of embodiments and combine it with the list of active agents described as being suitable for use in the invention. With respect to the alleged hydrophilicity of many of the active agents listed, many of said agents are proteins, for which the skilled person is aware of the ease with which solubility can be manipulated, an example of which is the pH-dependency of insulin solubility demonstrated in figure 1 of D19. Proteins are regularly purified by precipitation from aqueous solution, and thus the skilled person would use the same techniques to form an aqueous protein suspension for the purpose of claim 2. Additionally, if the skilled person were interested in a high drug concentration, it would be possible to saturate an aqueous solution with the active agent after which the addition of further agent will inevitably lead to the formation of a suspension. Using such common general knowledge, the skilled person would not refrain from using any of the active agents listed on page 15 of the description in a process for the

preparation of an aqueous suspension of the drug phase, and consequently claim 2 does not comprise added subject-matter.

Auxiliary request 1 - novelty

b) D1a (example 20) and D20 (example 10) disclose insulin as a water-soluble active agent and the formulation thereof in aqueous solutions, which thereby differs from claim 1 in that the latter requires the presence of a non-water-soluble drug.

Auxiliary request 1 - inventive step

c) D11 is the most appropriate starting point for the invention and is consequently the closest prior art. Although D4 is an artificial starting point for the skilled person, the skilled person nevertheless knowing the disclosure of D4 would not arrive at the subject-matter of claim 1. A difference between the process of D4 and that of claim 1 is the way in which the polymer phase and the surfactant phase are combined. In order to effect the immediate precipitation of nanoparticles aimed at in D4, it is important to add the polymer phase to the surfactant phase which is non-solvent for the polymer. The process of claim 1 relies on a different mechanism whereby it is necessary to add the surfactant phase to the polymer phase and as a result, a phase transition occurs during the mixing process. There is no reason for the polymer to immediately precipitate because an initial amount of non-solvent for the polymer is dissolved in a large quantity of a solvent for the polymer. Only once a sufficient amount of surfactant phase has been added to the

polymer phase, will the environment for the polymer be such that it can no longer remain in solution. In D4 such a process would not be desirable, since the instantaneous formation of the particles is emphasised (column 2, lines 49-50). Indeed, it would not have been predictable for the skilled person from the information provided in D4 that such a delayed precipitation would provide microparticles at all, and if so, whether they would have the desired shape, size and active agent content. Thus even if the process of the patent is seen as an alternative to that of D4 (which the respondent does not concede), there is no obvious route for the skilled person therefrom to the process of claim 1.

XI. The appellant requested that the decision under appeal be set aside and the European patent be revoked.

XII. The respondent requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of the claims of one of auxiliary requests 1-5, all filed on 14 June 2011.

Reasons for the Decision

Main Request - added subject-matter

1. Claim 2 as granted corresponds to claim 1 as originally filed except that addition of a non-water-soluble active agent to the polymer solution has been replaced with the addition "in the form of a suspension" of "an active agent selected from" a long list of compounds and it is specified that the added amount of aqueous surfactant results "in a volume fraction of the surfactant phase of at least 60%".

1.1 While a basis for a volume fraction of the surfactant phase of at least 60% is to be found in original claim 7, a formal basis for the other two features is to be found separately in a specific reference on page 12 (lines 1-5) to an embodiment whereby the drug phase is prepared by adding an aqueous suspension of the hydrophobic active agent to a polymer solution and in the general list of active agents said to be suitable for use in the invention, disclosed in a non-adjacent section of the description (page 15, lines 6-24), which reads as follows: "The present invention can be practised to encapsulate a wide range of hydrophobic active agents. Examples of agents suitable for use in this invention include but are not limited to..", after which the same agents as listed in claim 2 are provided.

1.2 The question to be answered is therefore whether also the combination of the two separately disclosed features is directly and unambiguously derivable from the application as filed.

1.3 The Board considers that notwithstanding the fact that the application as filed offers a number of agents conventionally considered hydrophilic, such as insulin, as being examples of hydrophobic agents, the skilled person knows from common general knowledge that this is not correct. Although the Board does not dispute the assertion of the appellant that the water solubility of certain active agents listed such as proteins can be controlled to a certain extent, this does not render said agents hydrophobic in the conventional sense of the term. On that basis, the skilled person wishing to put into practice the embodiment in which a hydrophobic active agent is added to a polymer solution as an

aqueous suspension, would not contemplate agents conventionally considered as being hydrophilic in nature disclosed in a different part of the original description as being suitable for said process. In other words, the skilled person would apply his common general knowledge when deciding which of the active agents listed in the separate passage may be employed in the preparation of an aqueous suspension of a hydrophobic active agent, and would thereby exclude those agents, such as *inter alia* insulin, which are not conventionally hydrophobic.

1.4 In view of that the combination of an aqueous suspension of the active agent with the whole list of agents disclosed on page 15 is not directly and unambiguously derivable from the application as filed.

1.5 The fact that the skilled person may be aware of methods to make a suspension of conventionally hydrophilic compounds among those listed does not change that conclusion, since the application as filed comprises no suggestion or teaching that in order to prepare an aqueous suspension of the hydrophobic agent, active agents conventionally considered hydrophilic should be manipulated to render them partially water-insoluble, such as by adjusting the pH or by adding quantities of the agent beyond the saturation point.

1.6 On that basis, it is concluded that granted claim 2 extends beyond the content of the application as filed.

Auxiliary request 1 - novelty

2. Both parties agreed that example 20 of D1 (page 18, line 23 - page 19, line 7; similarly in D1a, column 9, lines 30 to 49, as referred to by the parties) and

example 10 of D20 (page 24, lines 5 to 23) disclose a process with all the features of claim 1 of auxiliary request 1 apart from the active agent being non-water-soluble. The active agent in both examples is insulin.

2.1 The appellant has argued that under the reaction conditions described in said examples, the aqueous solution of insulin is inevitably a suspension and consequently insulin can be considered as a non-water-soluble active agent.

2.2 The Board cannot follow that argument and considers that, independently of whether a suspension is or is not formed when carrying out the examples of D1 and D20, the fact remains that according to said examples, at least a non-insignificant portion of the insulin provided is dissolved in the aqueous phase (in both cases a solution of insulin is mentioned, see D1, page 18, lines 25 to 30 and D20, page 24, lines 7 to 10). Furthermore, it is part of the common general knowledge of the skilled person that insulin is a hydrophilic hormone and evidence in this regard has been provided by the appellant as D17 (page 10, lines 12-17) in which insulin and vasopressin are described as hydrophilic hormones.

2.3 The Board must therefore conclude that insulin cannot be considered as a "non-water-soluble active agent" as indicated in granted claim 1. This conclusion is also consistent with the findings of the Board with respect to the main request.

2.4 It follows that claim 1 is novel over both D1 and D20. Neither of the parties has considered D1 as relevant for the purposes of inventive step (see points 3 to 5, below). Since alleged prior right D20 is not relevant

for novelty, the Board does not need to decide upon the priority issue raised by the appellant.

Auxiliary request 1 - inventive step

3. *Closest prior art*

3.1 While in the decision under appeal D11 was chosen as the closest prior art for the subject-matter of granted claim 1 and arguments starting from D4 were given only in an *obiter dictum*, the appellant has challenged in appeal the decision on inventive step only starting from document D4 as the closest prior art. Under these circumstances the Board has only to decide whether the arguments relating to the alleged lack of inventive step of claim 1 starting from document D4 are sufficient to overturn the decision on inventive step or not.

3.2 D4 discloses a process for the production of microparticles which comprises combining a first liquid phase consisting essentially of a solution of the substances A and B in a solvent and a greater amount of a second liquid phase consisting essentially of a non-solvent for A and B and including one or more surfactants, the particles comprising a core of B surrounded by a layer of A (claim 1). The addition of the first phase to the second phase is done with gentle agitation so as to produce a colloidal suspension of the particles (column 2, lines 39 to 41), which are formed practically instantaneously (column 2, lines 49 to 50). Substance A is typically a polymer (column 2, line 58 - column 3, line 15); substance B is a substance to be encapsulated in substance A (column 3, lines 16 to 18), in particular an active medical ingredient (column 3, lines 24 to 27). Several examples

of suitable solvents for the polymer are given, including many non-halogenated solvents (column 3, lines 47 to 55) and water is indicated as a typical non-solvent for the polymer (column 3, lines 59 to 61). Example 2 (column 5, line 40 - column 6, line 13) describes a process with a first phase comprising a polymer (polyisobutylcyanoacrylate), a non-halogenated solvent (acetone) and a non-water-soluble drug (indomethacin) and a second aqueous phase including a surfactant (a mixed polymer of ethylene oxide and propylene glycol), in which with reference to example 1 (column 5, lines 11 to 38) the acetone phase is poured into the aqueous phase.

3.3 This analysis is agreed by the parties, as it is agreed that an undisputed difference between the disclosure of D4 and claim 1 of auxiliary request 1 is the manner in which the polymer (drug) phase and the surfactant phase are added to each other. According to D4, the polymer phase is added to the surfactant phase, while the reverse is true for the process of claim 1.

4. *Problem solved*

4.1 Although the respondent has submitted that the acknowledged difference leads to certain specific advantageous technical effects such as the availability of a number of parameters which can be manipulated to produce particles of the desired morphology and size, the Board will first assess inventive step without examining whether said effects are indeed present or not, i.e. by formulating the problem as the mere provision of a *further* process for the production of microparticles. Should the solution to this problem be considered non-obvious in the light of D4, then the same conclusion would apply *a fortiori* to the case in

which the presence of particular advantageous effects linked to the difference were acknowledged. In this case it can be concluded that an inventive step is present.

4.2 That the problem of providing a further process for the production of microparticles is actually solved is shown by the examples in the patent. In this respect the argument of the appellant that the examples in the patent were not carried out, so that the patent lacks any evidence that the desired microparticles are provided by the claimed process, cannot be accepted, as the Board has no concrete element to put into question the fact that the examples were indeed carried out by the respondent and no evidence has been provided by the appellant that they cannot be carried out as described in the patent.

5. *Obviousness*

5.1 The main argument of the appellant for lack of inventive step is that the skilled person, starting from example 2 of D4, would simply change the manner in which the phases are mixed in the expectation that such a process would be equally effective in producing the required microparticles. Since this argument implies that the respective possibilities are technically equivalent and that the skilled person would arbitrarily choose one option as an alternative to the other in the expectation of achieving the same result, the Board must investigate whether the respective possibilities may indeed be considered as technical equivalents.

5.2 As noted by the respondent, in the process according to D4 in which the polymer phase is added to the (aqueous)

surfactant phase, the first drop of the former which comes into contact with the latter is surrounded by a large volume of liquid which is a solvent for the organic solvent of the polymer phase, but a non-solvent for the polymer. The organic phase is quickly extracted into the aqueous phase, and the polymer, which is now without solvent, immediately precipitates and encapsulates the drug (column 2, lines 49 and 50). In contrast, when the polymer and surfactant phases are mixed according to claim 1 of auxiliary request 1 by adding the surfactant phase to the polymer phase, there is no reason for the polymer to immediately precipitate: only once a sufficient volume of the surfactant phase has been added, will the solvent for the polymer be extracted in a quantity sufficient to cause the formation of polymer particles. During this process, a phase transition from a continuous polymer phase to a continuous surfactant phase occurs, whereas in the process according to D4, no such transition takes place. Thus by changing the manner in which the respective phases are added to each other, the formation of microparticles is from a mechanistic point of view inherently different.

5.3 In view of said distinct mechanistic differences, the respective methods of microparticle formation cannot be considered as technical equivalents. It follows that the skilled person, starting from D4 and wishing to provide a further process for the production of microparticles, would not arbitrarily choose to change the way in which the phases are mixed in the expectation of achieving the same result, since he would realise, using his common general knowledge, that doing so would not lead to the immediate precipitation of particles as described in D4. Indeed the Board agrees with the argument of the respondent that it

would not have been easily predictable for the skilled person, based on the information provided in D4 (in particular that the addition of the drug phase to the surfactant phase leads to the instantaneous formation of the particles, see column 2, lines 22 to 50), whether by changing the order of addition there would be any precipitation of particles at all. In conclusion, the process described by claim 1 would not have been arrived at by the skilled person starting from D4 without exercising inventive skill.

5.4 On that basis the process of claim 1 of auxiliary request 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 to 33 of auxiliary request 1, filed on 14 June 2011, and a description to be adapted.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated