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Datasheet for the decision of 30 April 2025

Case Number: T 2403/22 - 3.4.03

Application Number: 19749121.0

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Language of the proceedings: EN

Title of invention:
MAGNETIC PARTICLES

Applicant:
Beckman Coulter, Inc.

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)
Amendment after notification of Art. 15(1) RPBA communication - taken into account (yes)

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

Case Number: T 2403/22 - 3.4.03

D E C I S I O N
of Technical Board of Appeal 3.4.03
of 30 April 2025

Appellant: (Applicant)	Beckman Coulter, Inc. 250 S. Kraemer Boulevard Brea, CA 92821 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 May 2022 refusing European patent application No. 19749121.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Papastefanou
Members:	M. Ley
	T. Bokor

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division to refuse European patent application No. 19 749 121 pursuant to Article 97(2) EPC.

II. The following documents were cited in the impugned decision:

D1 US 2017/216463 A1
D2 US 2013/0130035 Al
D3 US 4 965 007
D4 US 7 476 313 B2
D5 US 2009/289213 A1
D6 KR 101 725 240 B1

III. The examining division decided that the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 4 did not involve an inventive step over document D2 as the closest prior art.

IV. The appellant requests that the impugned decision be set aside and a European patent be granted on the basis of the sole request filed during the oral proceedings before the board as "New auxiliary request 1" and to admit the following document into the appeal proceedings:

D7 Declaration of Mr Evan Farthing (1 page) with appendix (2 pages)

V. Claim 1 according to the sole request has the following wording :

Use of a magnetic particle in a method for processing a biological sample, the magnetic particle comprising: magnetite having a diameter of about 100 nm, a maximum field strength in a range of from about 20 Am^2/kg (emu/g) to about 250 Am^2/kg (emu/g), a remanence in a range of from about 1 Am^2/kg (emu/g) to about 30 Am^2/kg (emu/g), and
an outer surface containing a ligand, wherein the ligand interacts with an analyte of interest in the sample solution; wherein the ligand comprises a carboxyl group, and
wherein the magnetic particle is ferrimagnetic.

VI. The appellant mainly argued that document D3 was the closest prior art and that the subject-matter of claim 1 differed from the teaching of D3 by the claimed use (with the ligand interacting with an analyte of interest in the sample solution) and in that the magnetite had a diameter of about 100 nm. The objective technical problem was to provide an alternative use of ferrimagnetic particles comprising magnetite.

The claimed solution was not obvious over D3 so that an inventive step (Article 56 EPC) should be acknowledged.

Reasons for the Decision

1. Magnetic particles are used for sample analysis and preparation in a variety of contexts, including chemical and biological assays and diagnostics, see paragraph [0002] of the application. In some applications, the surface of magnetic particles can be coated with a suitable ligand or receptor (e.g. antibodies, lectins, oligonucleotides, or other affinity groups), which can selectively bind a target substance or a group of analytes in a mixture.

The present invention aims at the use of a magnetic particle in a method for processing a biological sample. It relates to sample processing methods and systems for mixing, separating, filtering, or otherwise processing a sample (e.g. a fluid sample) by utilizing magnetic particles that are caused to move under the influence of a magnetic assembly disposed about the periphery of a container containing the sample, see paragraph [0015] of the application.

As claimed, the magnetic particles comprise a magnetite (Fe_3O_4) core with a diameter of about 100 nm and a ligand. The particle is thus ferrimagnetic having a maximum field strength and remanence in the claimed ranges.

The "maximum field strength" of the particle is a measure of the magnetic strength generated by the particle upon exposure to a magnetic field, see paragraph [0051] of the application. The term "remanence" refers to the residual magnetism that a material retains after a magnetic field has been removed, see paragraph [0028] of the application.

Ferrimagnetic particles can respond to an external magnetic field (e.g. a changing magnetic field), but can demagnetize when the external magnetic field is removed, see paragraph [0018] of the application.

2. Admittance of D7 - Article 12(4) RPBA

2.1 The appellant argued that the filing of document D7 was in response to the erroneous reasoning of the examining division based on D2 and that D7 was filed at the earliest possible opportunity having considered the impugned decision. D7 showed that particles of similar size (15 to 300 nm) to those exemplified in D2 were inferior to those claimed for the purpose of processing a nucleic acid sample.

2.2 The diameter of (about) 100 nm was claimed for the first time in the set of claims filed on 7 March 2022, i.e. one month prior to the oral proceedings before the examining division. The examining division explained for the first time during the oral proceedings, why it did not acknowledge an inventive step based on the claimed diameter.

Prior to the oral proceedings, there was a telephone conversation between the primary examiner and the appellant's representative. However, the corresponding minutes did not contain any detailed reasoning with respect to the particle diameter.

Hence, the board accepts that document D7 was filed in response to the explanations provided orally for the first during the oral proceedings and then in the impugned decision. D7 could not have been expected to be filed earlier and represents a reasonable reaction to the impugned decision.

The board therefore decided to admit document D7 into the appeal proceedings under Article 12(4) RPBA.

3. Admittance of the sole request - Article 13(2) RPBA

The board decided to admit the sole request filed during the oral proceedings before the board into the appeal proceedings, because it is a reaction to issues raised for the first time by the board in its communication pursuant to Article 15(1) RPBA and because claim 1 substantially corresponds to claim 1 of auxiliary request 2 underlying impugned decision, and therefore the board is not confronted with new issues.

4. Inventive step - Article 56 EPC

4.1 The examining division decided that the subject-matter of claim 1 of then auxiliary request 2 lacked an inventive step over document D2. Documents D1 and D3 were cited to show that it was part of the skilled person's common general knowledge that coated magnetic particles were suitable for biological applications.

4.2 The appellant argued that the allegation of the examining division that the skilled person would have assumed that each and every magnetic particle was useful for nucleic acid purification purposes, apparently irrespective of what had been shown for that particle, was unsupported and misplaced. D2 was not suitable as the closest prior art, as it did not describe that the ferrites for inkjet printers were suitable for use in a method for processing a biological sample. D2 had a entirely different purpose.

As pointed out by the appellant, document D3 might be considered as a suitable starting point for the assessment of inventive step (Article 56 EPC), because it concerned the use of magnetic particles for the separation of biological materials (col. 1, "Field of the invention", col. 7, lines 53 to 55).

The appellant added that D3 contemplated "coacervate coated superparamagnetic particles" or "encapsulated superparamagnetic particles" which comprised magnetite particles having a mean diameter in the range of 5 to 35 nm (col. 7, lines 25 to 31, col. 2, lines 3 to 29). However, the particles which were actually described in the examples were 10 to 15 nm in diameter with a very minor 4 to 5 nm fraction (col. 10, lines 25 to 27). They might be coated with carboxilic acid or sulfonic acid (col. 7, lines 35 to 38, col. 3, lines 9 to 12). Their magnetization was greater than 30 emu/g (col. 7, lines 39 to 42). A remanence was not disclosed in D3.

The claimed particles were bigger and not superparamagnetic (in view of paragraph [0064] of the application). The claimed remanence was not zero.

The particles of D3 were said to be useful "in systems in which the separation of certain molecules, macromolecules and cells from the surrounding medium is necessary or desirable", see col. 1, lines 6 to 10, lines 25 to 43, col. 7 lines 53 to 62 in combination with col. 2, lines 33 to 36.

The use described in D3 relied upon the particles acting as a solid support for biological molecules such as enzymes, antibodies and other bioaffinity adsorbents. Those biological molecules were therefore immobilized on the particles, so that they could bind to their binding partner. The use of magnetic particles facilitated separation of bound from unbound analyte.

This was a fundamentally different use from that of the claimed invention. The claimed invention relied upon using magnetic particles to isolate a nucleic acid from a biological sample solution, i.e. upon the interaction between ligand and analyte of interest. The particles captured e.g. the nucleic acid from the sample, thereby isolating it.

In the statement setting out the grounds of appeal, the appellant argued that a technical effect of these differences was that the claimed magnetic particle was particularly useful for the isolation of nucleic acids, demonstrated by the advantageous properties outlined in Table 2 of the present application. Only the magnetic particle of the invention was magnetically responsive enough to mix well in buffers of polyethylene glycol (PEG) + salt (NaCl), water, 80% ethanol, which were used to precipitate nucleic acids. Polyethylene glycol and salt could be used as a precipitating reagent, which facilitated adsorption of DNA species on to the surfaces of the magnetic particles (paragraph [0033] of the application). The objective problem to be solved by the present invention could be formulated as the provision of an improved magnetic particle for use in processing a nucleic acid containing sample.

Magnetic particles were available with a wide range of diameters, cores and coatings and would not necessarily behave in the same way as particles used in other applications (such as the ones described in D3). The inventors tailored these properties for the specific biological application of interest. Only the claimed particles displayed the requisite combination of properties needed for the isolation of nucleic acids.

The results in D7 complemented those already provided in the present application. The results demonstrated that particles differing from those presently claimed did not mix in water or in a solution comprising PEG and salt (used for nucleic acid precipitation). These further results encompassed particles having diameters both below and above that presently claimed, including those within the range of sizes disclosed in D2. For example, Bead 10 was around 20 nm in diameter and was not magnetically responsive enough to mix. This bead size was comparable to the size of the particles exemplified in D2 (50 nm), D3 (10 to 15 nm) and D1 (16 nm).

In its letter dated 23 December 2024 and during the oral proceedings before the board, the appellant argued that the problem to be solved in view of D3 might also be framed as an alternative use of ferrimagnetic particles comprising magnetite.

D3 provided no motivation to change the combination of properties of the magnetic particles. The focus of D3 was on very small superparamagnetic particles with a narrow particle size distribution and their use as a solid support for biological molecules and none were actually demonstrated to be effective at separating biological molecules. Col. 4, lines 2 to 8 of D3 taught the skilled person that very small particles should be used for the application of D3.

An essential requirement of the disclosure of D3 was that those smaller particles were superparamagnetic (see title, col. 4, lines 18 to 20 and lines 50 to 53, and claim 1 of D3). There were therefore clear directions in D3 for the skilled person to use much smaller superparamagnetic particles (see col. 4, lines 2 to 13) than those in claim 1. The skilled person would not realistically wish to depart from these essential requirements of D3.

D1 contemplated "magnetic nanoparticles" having a maximum dimension of about 20 nm (paragraph [0041]; however, the nanoparticles that were actually described in the examples had an overall diameter of about 16 nm (paragraph [0085]). D1 stated that "a nanoparticle that is too large can be difficult to use to detect small molecules and cells" (see D1, paragraph [0039]).

D2 focused on ferrites used for inkjet printers and not on the processing of a nucleic acid. The skilled person would not consider D2. The claimed diameter was not disclosed, either. Claim 7 of D2 mentioned 10 to 300 nm, paragraphs [0060] and [0064] mentioning around 50 nm.

The focus of D4 was on an apparatus for mixing magnetic particles. The beads used in example 1 of D4 had "uniform size of 4.5 µm" (col. 28, line 43 to 45), i.e. much larger than those claimed. D4 provided no indication of suitable particle properties for isolating nucleic acids.

D5 focused on a fluid droplet comprising magnetically attractable matter (abstract). Although D5 generically described "magnetic particles" (e.g. paragraph [0040]), it provided no teaching towards the presently claimed subject matter and no indication of suitable particle properties for isolating nucleic acids.

D6 focused on nanoparticles having UV-light and pH reactivity, and a drug delivery system comprising the same (English abstract). The skilled person looking to solve the objective technical problem would not have consulted D6.

The combination of D3 with any prior art document presently at hand would not have led to the claimed invention so that an inventive step should be acknowledged in the appellant's view.

4.3 The board does not find the appellant's arguments persuasive and cannot acknowledge an inventive step (Article 56 EPC) for the following reasons.

4.3.1 Claim 1 is directed to the use of magnetic particles comprising magnetite (Fe_3O_4), wherein the term "diameter" suggests a spherical shape. A given magnetic particle made of a specific material and having a specific shape and size has a specific maximum field strength (or mass susceptibility) and remanence.

The application as a whole does not disclose how to modify a given spherical Fe_3O_4 particle with a diameter of 100 nm so that any value of the maximum field strength in a range of from about 20 Am^2/kg to about 250 Am^2/kg or so that any value of remanence in a range of from about 1 Am^2/kg to about 30 Am^2/kg could be obtained.

Paragraphs [0021], [0064] and [0129] (example 2) and [0134] (example 7) discuss magnetite particles without disclosing any value of their maximum field strength or remanence. In addition, paragraph [0064] makes it clear that the claimed particles (with diameter of about 100 nm) are not superparamagnetic particles.

As pointed out by the appellant, it can be assumed that the Fe_3O_4 particles as prepared in example 2 and used in the other examples of the application fulfil the claimed conditions in terms of maximum field strength and remanence.

Whether it is possible (and generally known to the skilled person, as argued by the appellant) that both parameters could be adjusted by changing the crystalline structure and microstructure of the magnetic particle, can thus be left unanswered. The board accepts that a magnetite particle with a diameter of about 100 nm necessarily has a maximum field strength and a remanence within the claimed ranges.

4.3.2 Claim 1 is directed to the use of a magnetic particle in a method for "processing" a sample solution using the claimed magnetic particles and the sample solution containing an analyte of interest in the sample solution. According to paragraphs [0015] and [0065] of the application, "processing" a sample encompasses mixing, separating, filtering e.g. a fluid sample in a container.

According to the wording of claim 1, the only method step explicitly mentioned is that the ligand interacts with the "analyte of interest". The board notes that claim 1 does not contain any method steps of analysing the sample solution or the analyte. In order words, claim 1 does not specify what happens after the ligand interacts with the "analyte of interest".

Hence, the board interprets the term "interact" broadly, which thus encompasses the adhering, adsorbing or binding of molecules of interest to the magnetic particle via the ligand, see e.g. page 10, line 30 of the application, "bind an analyte of interest".

4.3.3 The examining division used document D2 as the starting point in their assessment of inventive step and concluded that there was a lack of inventive step. The board is not convinced by this reasoning.

According to paragraphs [0035] to [0043] of the application as originally filed, a magnetic particle is suitable for processing a sample solution when it is a ferrimagnetic particle of any shape with a diameter from 1 nm to 1 mm. It can be coated with a ligand such as a carboxyl group, see paragraph [0057]. Other coatings are also possible, see paragraphs [0054] to [0058].

As D2 discloses ferrimagnetic particles with a average diameter of 15 to 300 nm ([0053], [0060], [0064] disclosing specifically 50 nm), they might be suitable "for processing a sample solution". More specifically, document D2 discloses a magnetic particle ([0053], MFe_2O_4 with M being Fe), said particle comprising magnetite having an average size between 15 to 300 nm and an outer surface containing a ligand ([0023] [0053], "functionalized nanoparticulate"), wherein the ligand comprises a carboxyl group ([0023], "functionalized by organic materials containing carboxylic groups", [0029]).

Contrary to the appellant's view, paragraph [0053] of D2 discloses MFe_2O_4 with a list of possible metals M. Paragraph [0053] of D2 explicitly discloses possible functionalized magnetic particles made of e.g. $CoFe_2O_4$, $NiFe_2O_4$, Fe_3O_4, $MnFe_2O_4$, etc., one of these materials corresponding to the claimed composition.

D2 thus discloses a plurality of magnetic particles with an average size of the particles between 15 to 300 nm ([0053]). In example 1, of D2, an average size around 50 nm is disclosed, see paragraphs [0057] to [0060].

However, the board concurs with the appellant that starting from document D2, the skilled person would not arrive at the subject-matter of claim 1.

The magnetic particles of D2 can used in a magnetic ink for inkjet printers, see paragraphs [0055], [0008] and [0014]. There is no indication that they could or should be used in a method for processing a biological sample, e.g. for the isolation of nucleic acids. The use of the particles of D2 in a method for processing a biological sample, wherein the ligand interacts with an analyte of interest in the sample solution, is not obvious for the skilled person.

The board shares the appellant's view that the content of e.g. D3 does not imply that the use of magnetic particles in biological applications is part of the common general knowledge and that this would be sufficient to motivate the skilled person to use the magnetic particles of D2 in a method of processing a biological sample.

4.3.4 The board holds that document D3 is a more promising springboard for the assessment of inventive step.

D3 discloses a magnetic particle comprising magnetite (Fe_3O_4, col. 5, line 2) having a diameter of 5 to 35 nm (col. 7, lines 25 to 45, col. 4, lines 50 to 54, abstract), a maximum field strength in a range of from about 20 Am^2/kg to about 250 Am^2/kg (col. 7, lines 25 to 44), a remanence in a range of from about 0 Am^2/kg ("superparamagnetic particles" with zero remanence) to about 30 Am^2/kg.

It is undisputed that D3 does not disclose the claimed diameter of "about 100 nm".

While claim 1 does not explicitly exclude superparamagnetic particles, D3 does not disclose that the remanence is 1 Am^2/kg or more. D3 only states that the superparamagnetic particles of 5 to 35 nm are "*weakly magnetic in the absence of an external magnetic field*", see col. 1, lines 45 to 52. From this passage, the board understands that the remanence is small, e.g. close to zero, but no lower limit is given in or derivable from D3.

4.3.5 In D3, the outer surface contains a ligand (col. 7, lines 33 to 38, col. 4, lines 25 to 36), wherein the ligand comprises a carboxyl group (abstract, "carboxyl containing hydrophilic polymer", col. 4, lines 25 to 31, "carboxilic acid", col. 6, lines 37 to 61, col. 7, lines 35 to 44), and wherein the magnetic particle is ferrimagnetic ("magnetite").

The particles of D3 are used in a method for processing a biological sample (col. 1, lines 6 to 43, example 3, "separation of certain molecules").

D3 discloses the attachment of molecules of interest to the coated particles (col. 1, lines 25 to 28, "*Stability of the coating ... the covalent attachment of molecules thereto*", col. 1, line 32, "*The magnetically responsive particles of this invention may be coupled to biological or organic molecules with affinity for or the ability to adsorb or which interact with certain other biological or organic molecules or with cells.*")

Therefore, in view of section 4.3.2 above, the ligand of D3 thus "interacts" with a molecule or an "analyte" of interest in the sample solution. Hence, for the board, the claimed use of magnetic particles is not a distinguishing feature, contrary to the appellant's view.

4.3.6 Hence, the subject-matter of claim 1 differs from D3 only in that the diameter of the particle is 100 nm and that the remanence is within the claimed range.

4.3.7 The appellant did not specifically discuss a technical effect obtained by remanence of 1 Am^2/kg, when compared to a zero or quasi-zero remanence.

Paragraph [0037] of the application merely states that the remanence of the ferrimagnetic particles can influence the length of time of suspension in the sample after the changing magnetic field is removed, but the application is silent on any effect of a remanence of 1 Am^2/kg; see also paragraph [0052], which discloses that any remanence between 0 and 30 Am^2/kg is appropriate for the present invention.

The board also notes that the application is silent about any synergistic technical effect between the claimed diameter and the claimed remanence.

4.3.8 With respect to the claimed diameter, the technical effect allegedly provided by the diameter of 100 nm (according to the statement of grounds of appeal) concerns a method involving features that were not part of the claimed entity (namely a plurality of magnetic particles to mix well in buffers of polyethylene glycol (PEG) + salt (NaCl), water, 80% ethanol used to precipitate nucleic acids).

Claim 1 requires that the magnetic particle is used for processing a biological sample. The composition of the processed solution is not specified. In particular, claim 1 is not limited to a particular solution (e.g. the one used in example 7 of application) or sample with nucleic acid (e.g. DNA). As claim 1 concerns the use of one single magnetic particle for processing a solution sample, it is doubtful whether its diameter would provide the alleged technical effect. For this reason alone, it is not appropriate to formulate the objective technical problem in the way the appellant did in its statement setting out the grounds of appeal.

4.3.9 Moreover, table 2 of the application concerns Fe_3O_4 particles produced and functionalized in a specific way (examples 2 and 7, paragraphs [0129] and [0134]), see table 1, [0146] to [0150]. An unknown concentration of such particles are used in a specific solution (140 mL) of polyethylene glycol, NaCl and water. A 50 mL sample of DNA was added. The results were compared to magnetic particles having a diameter above 1 µm (see table 1, the diameter of Comparative Bead 1 being indicated in D7 (Bead 8), the diameters of comparative beads 2 and 3 not being indicated). In other words, tables 1 and 2 disclose advantages in particular circumstances for the specific particles according to example 7 of the application, when compared to much larger particles.

In addition, paragraph [0041] of the application states that suitable mean diameters of the ferrimagnetic particles used in the invention are from 1 nm to 1 mm. The first sentence on page 10 even might be considered as to suggest that 1 µm to 10 µm is the most preferred range. There is no indication in the application that 100 nm is particularly advantageous when compared to the lower diameters used in D3.

Hence, the board cannot derive from the application any specific technical effect of the claimed diameter of 100 nm when compared to the particles known from D3 (having an average diameter from 5 to 35 nm).

4.3.10 Document D7 provides results for a specific type of magnetite magnetic particle having a diameter of 100 nm. While table 1 of D7 indicates that Bead 13 has a polymer and silica coating, a functionalization with a carboxyl group is not disclosed. D7 is also silent about the magnetic properties of the particles. It is thus questionable whether Bead 13 is a particle according to claim 1.

In any case, Bead 13 is compared to particles having diameter significantly larger than 100 nm (see Beads 8, 9, 11 and 12). Only Bead 10 (stainless steel) without any functionalization has a diameter of 20 nm, which is close to the diameter used in D3. It is doubtful whether the comparison of Bead 13 (which is apparently not arranged as claimed) with Bead 10, which is made of uncoated stainless steel (and thus not made of magnetite) would allow to conclude that a diameter of 100 nm implied advantageous results over particles with the diameters used in D3.

Again, in the board's view, no specific technical effect of the claimed diameter of 100 nm can be derived from D7.

4.3.11 The board thus opines that the use of a particle of 100 nm in D3 does not provide any unexpected effect.

Starting from D3, it seems that the technical effect of the distinguishing diameter is not more than to provide an alternative diameter of the magnetic particles disclosed in D3.

The objective technical problem associated with the claimed diameter is therefore to provide an alternative magnetite particle for the method of D3.

4.3.12 Turning now to the question whether the skilled person wishing to solve this objective technical problem, would consider a diameter of 100 nm in D3.

It is uncontested that the skilled person is aware of methods to produce magnetic particles with a diameter from several nanometers to of over 1 µm. For example, D3 states that it was known to use particles having a size of 0.8 to 50 µm (see col. 3, line 55 to col. 4, line 15). As already discussed, the magnetite particles of D2 have a diameter from 15 to 300 nm, see paragraph [0053].

The passage in D3 indicated by the appellant, i.e. col. 4, lines 2 to 11, has to be read in the context of col. 3, line 55 to col. 4, line 15. The skilled person would understand from this passage that magnetic particles having a size of 0.8 µm (800 nm) to 50 µm or larger are not suitable of the applications mentioned in D3, e.g. magnetic separation techniques (col. 4, line 13 to 15). However, this does not give an indication to the skilled person that that claimed diameter of 100 nm should not be used.

As pointed out by the appellant, superparamagnetic particles are used in the method of D3. According to col. 1, lines 47 to 51, such particles are "weakly magnetic" in the absence of an external magnetic field. A skilled person thus understands that it is acceptable for the particles used in D3 to have a low remanence. A zero remanence is not required. Hence, the fact that D3 refers to superparamagnetic particles would in itself not discourage the skilled person from considering particle diameters resulting in an non-zero remanence.

In view of these considerations, the board is convinced that the skilled person wishing to solve the objective technical problem would consider a diameter of 100 nm for the functionalized magnetite particles of D3. As pointed out in section 4.3.1 before, the remanence would then be in the claimed range.

It is obvious for the skilled person to solve the objective problem using their common general knowledge. Therefore, the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC)

5. As the sole request is not allowable, the appeal must fail.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero M. Papastefanou

Decision electronically authenticated