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Datasheet for the decision of 23 October 2014

Case Number: T 0244/11 - 3.3.07
Application Number: 01947612.6
Publication Number: 1296651
IPC: A61K9/14, A61K47/26
Language of the proceedings: EN

Title of invention:
METHOD OF MAKING PARTICLES FOR USE IN A PHARMACEUTICAL COMPOSITION

Patent Proprietor:
Vectura Limited

Opponent:
NORTON HEALTHCARE LIMITED

Relevant legal provisions:
EPC Art. 54, 100(a), 104, 111(1)
RPBA Art. 13

Keyword:
Late-filed document - justification for late filing
Novelty - implicit disclosure (no)
Appeal decision - remittal to the department of first instance (yes)
Apportionment of costs - (no)
Case Number: T 0244/11 - 3.3.07

DECISION of Technical Board of Appeal 3.3.07 of 23 October 2014

Appellant: Vectura Limited
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 1 December 2010
revoking European patent No. 1296651 pursuant to
Article 101(3)(b) EPC.

Composition of the Board:
Chairman J. Riolo
Members: D. Semino
D. T. Keeling
Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 13 October 2010 to revoke European Patent 1 296 651. The patent was granted on the basis of 14 claims, claim 1 reading as follows:

"1. A method for making a pharmaceutical composition for inhalation comprising the steps of:
a) making composite excipient particles by milling particles of an excipient material in the presence of an additive material, wherein the milling step involves mechanofusion, ultracentrifugal milling, jet milling, high pressure homogenisation, ball milling, agitator bead milling, air jet milling, pin milling, hammer milling or knife milling; and
b) adding particles of active material;
wherein the composition consists essentially of the composite excipients particles and the particles of active material, and optionally a flavouring agent and wherein the mass median aerodynamic diameter of the composite excipient particles is not more than 50 μm."

II. The patent was opposed under Article 100 (a) EPC on the grounds that its subject-matter lacked novelty and inventive step.

III. The decision was based on six sets of claims filed with letter of 13 August 2010 as main request and auxiliary requests I to V and on the set of claims of the patent as granted introduced as auxiliary request VI during the oral proceedings before the opposition division.
IV. In the decision the following documents were cited inter alia:

D1: WO-A-01/78693  
D2: WO-A-96/23485  
D11: Report entitled "Ball mill studies on inhalation excipients" by B. Nyambura dated 22 March 2010  
D14: Report entitled "Ball mill studies on inhalation excipients" by B. Nyambura dated 17 September 2010  
D15:  
D16: First Declaration from David Ganderton dated 7 October 2010  
D17: "SpheroLac® 100", Meggle - Excipients & Technology, dated 7 October 2010

V. As far as relevant to the present decision, the decision under appeal can be summarised as follows:

a) Document D11, which concerned a reworking of example 3 of D2, was prima facie relevant and therefore admitted into the proceedings. Documents D14, D16 and D17 were prima facie not relevant and therefore not admitted into the proceedings.

b) Claim 1 of the main request and of auxiliary requests I to IV was found not to meet the requirements of Article 84 EPC and claim 1 of auxiliary request V did not meet the requirements of Article 123(2) EPC.

c) Claim 1 of the patent as granted (considered as auxiliary request VI) was new over the compositions of D1, as they comprised coarse carrier particles and therefore did not consist essentially of composite particles with a mass median aerodynamic diameter (MMAD) of not more
than 50 µm. It lacked novelty, however, over D2, as on the balance of probabilities and in view of the results in D11 the milling conditions of example 3 of D2 could result in a considerable reduction of the particle size of the milled particles to a MMAD of not more than 50 µm.

VI. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant resubmitted documents D16 and D17 and submitted for the first time the following piece of evidence:

D18: Protocol of "Studies on inhalation additives (magnesium stearate)", Vectura

VII. With the reply to the statement setting out the grounds of appeal the respondent resubmitted document D14 and submitted for the first time the following documents:

D19: Pharmaterials report entitle "Ball Milling of Lactose and Leucine" dated 22 August 2011
D20: Declaration from G. Buckton dated 19 August 2011

VIII. With letter of 29 June 2012 the appellant submitted the following pieces of evidence:

D21: Vectura Study Report entitled "Studies on milling of carrier with additive particles" dated 1 June 2012
D22: Vectura Study Report entitled "Studies on the resting duration of samples subsequently analyzed using a Malvern Mastersizer 2000" dated 1 June 2012
D23: Graph entitled "Percentage Recovery of Sieved Lactose Fractions"
D24: Graph entitled "Particle Size Analysis of Leucine"
D25: Table entitled "Analysis methods"
D26: Graph entitled "Blend 1 (Sieving alone) - MMAD"
D27: Graph entitled "Blend 2 (Sieving + Brushing) - MMAD"
D28: Graph entitled "Blend 3 (Sieving + Brushing + Vacuum) - MMAD"
D29: Graph entitled "Blend 4 (Sieving + Brushing + Vacuum) no Leucine - MMAD"
D30: Graph entitled "Post Ball Milling - MMAD"
D31: Graph entitled "Sedimentation Analysis - Spherolac 100" with table

IX. In a communication sent in preparation of oral proceedings the Board reviewed the generally applied principle for concluding lack of novelty, namely that "there must be a direct and unambiguous disclosure, either explicit or implicit, in the state of the art which would inevitably lead the skilled person to subject-matter falling within the scope of what is claimed" (paragraph 2.1 of the communication) and indicated that in case "novelty is acknowledged, the question will arise whether the Board decides on inventive step (on which no decision was taken by the opposition division) or the case is remitted to the first instance" (paragraph 3 of the communication).

X. With letter of 24 September 2014 the appellant filed a further experimental report:


XI. Oral proceedings were held on 23 October 2014. During the oral proceedings the respondent filed a further piece of evidence:
D33: Hollow sphere for use in water and oil baths up to 110°C approx. weight of ball 1gm +/- 10%

XII. The arguments of the appellant can be summarised as follows:

Admittance of further evidence

a) Documents D21 to D31 were a genuine attempt to reproduce example 3 of D2. They came in reaction to the decision and required a long time as it was difficult to identify the errors in the tests of the respondent. Moreover, they were very relevant, were filed largely in advance of the invitation to oral proceedings, so that the respondent had ample time to react, and did not change the case, but backed up the arguments of the appellant. Document D32 was a reaction to the communication of the Board, was meant to show the improvement brought by the distinguishing feature and was prima facie very relevant. On that basis D21 to D32 should be admitted into the proceedings.

b) The filing of document D33 at the oral proceedings before the Board took the appellant and the Board by surprise. The document was not relevant and was not suitable to challenge the correctness of the reproduction of D2 made by the appellant. However, if admitted on the basis that it put into doubt those results, then an adjournment of the proceedings would be needed to give time to the appellant to react, e.g. by providing further experiments.
**Novelty**

c) The method of claim 1 differed from the one disclosed in D2 in that the latter did not disclose a MMAD of the composite excipient particles of not more than 50 µm. The teaching of the document was that the purpose of the gentle milling step was to dislodge small grains from the surface of the particles without substantially changing their size. Therefore the size of the particles of example 3, which was well above 50 µm before milling, could not be below 50 µm after milling. The results in the reproduction of example 3 in D11 and D14 were at odds with the teaching of D2 and were not correct due to three sources of error. Firstly, the sieving step undertaken during preparation of carrier particles was accomplished without intermediate brushing, so that clogging of the sieve could take place with a consequent increase of the content of fine particles in the sieved fraction. Secondly, the use of a powerful wetting agent in the method of measuring the MMAD of the sample caused the dissociation of agglomerates present in the dry powder and therefore an alteration of the results. Finally, in the method of particle size analysis used in D11 and D14 sedimentation of the sample took place before the measurement was made, which resulted in a large reduction of the measured MMAD, as larger particles settled at a faster rate than smaller ones. The experiments described in D21 to D31 showed these three effects and also that a proper reproduction of example 3 of D2 resulted in a MMAD of the excipient particles well above 50 µm even without brushing and when using a wetting agent. Indeed out of the mentioned effects
the one of sedimentation was the strongest one. While it was not alleged that the errors were made deliberately, they explained why results were surprisingly obtained which were contrary to the teaching of D2. A MMAD of not more than 50 µm was not therefore the inevitable result of the method of example 3 of D2, which was a necessary condition to conclude lack of novelty in the absence of an explicit disclosure. Indeed employing the criterion of the balance of probabilities, as occurred in the decision under appeal, was in the present situation not correct. A further difference over the method of D2 was the milling step, as the gentle milling of D2 was not a milling in the sense given in the description of the patent.

Remittal

d) The essential function of appeal proceedings being the review of the first instance decision, a remittal should take place after acknowledgement of novelty in order not to deprive the parties of one instance. Whether the remittal could have an impact on the admittance of document D32 into the proceedings, had no relevance on the decision to remit.

Apportionment of costs

e) An apportionment of costs was not justified as the conduct of the appellant did not cause any extra costs for the respondent, did not result in an abuse of the procedure, and was not at any time against the direction of the Board.
XIII. The arguments of the respondent can be summarised as follows:

Admittance of further evidence

a) There was no justification in filing the test data contained in documents D21 to D31 at a late stage of the proceedings. The reproduction of the appellant of their own experiments in D2 could have been provided in opposition or at the latest with the statements setting out the grounds of appeal. The eleven annexes and the complex submission related to that should therefore not be admitted into the proceedings. Document D32 could not be seen as a reaction to the communication of the Board, as the need to support any effect with experimental data is known from the usual application of the problem-solution-approach. Moreover, no time was available to the respondent to file counter-tests. On that basis also that document should not be admitted.

b) Document D33 came very late to the attention of the respondent while trying to understand why the appellant had obtained different results by the reproduction of D2. It showed that the balls used by the appellant were hollow floating balls not suitable for ball milling. That document did not provide new experimental data and could not be surprising for the appellant, as it showed what the appellant had used for its experiments. The fact that it did not bear a date was also of no relevance as it was printed from the site of the company producing the balls used by the appellant. It provided objective information whose analysis did not require an adjournment of the proceedings.
On that basis in should be admitted into the proceedings.

Novelty

c) The method of granted claim 1 lacked novelty over the disclosure of example 3 of D2. Therein all the features of claim 1 were explicitly disclosed with the exception of a MMAD of not more than 50 μm. The reproduction of that example in D11 and D14 showed, however, that the disputed feature was a direct result of the method. In this respect it was not relevant what D2 said about a change in size, but what happened when reproducing its example. In the tests of the respondent that example had been reproduced as faithfully as possible and none of the doubts of the appellant was justifiable. The sieving step was pragmatically accomplished without brushing as long as no clogging took place, so that no alteration of the results was caused by the absence of a brushing step. The use of a dispersant was part of a suitable method for measuring particle size and did not result in a modification of the results. In any case it was acknowledged by the appellant that these two effects had a small impact. As to the crucial source of error according to the appellant, namely the sedimentation in the measuring apparatus, it was not credible that an apparatus was used which, in spite of being a commercial one, systematically gave incorrect result in view of sedimentation. Even if not explicitly mentioned in D14, a recirculation by means of a pump took place in the measuring apparatus, so that sedimentation was avoided. In any case the results in D11 and D14
constituted the only independent reworking of example 3 of D2 as the tests in D21 to D31 were conducted internally by the appellant. As all the objections of the appellant to the tests provided by the respondent had been addressed, there was no credible evidence that those tests were erroneous and the necessary standard of proof was satisfied. The onus of proof was therefore on the appellant to show why example 3 of D2 according to the experiments in D11 and D14 did not fall under granted claim 1, which onus had not been discharged. As to the results of the reproduction of example 3 of D2 provided by the appellant, one could only speculate that the milling step was not done properly, so that they were not a correct reworking of the example. On that basis lack of novelty had to be acknowledged.

Remittal

d) The request to remit was an abusive attempt to introduce the late-filed evidence provided with document D32 into the proceedings. Indeed while the document would be inadmissible in appeal proceedings, having been filed shortly before the oral proceedings, it could be admitted by the opposition division, thereby resulting in a circumvention of the Rules of Procedure of the Boards of Appeal.

Apportionment of costs

e) The late filing of documents D21 to D31 should result in an apportionment of the costs of the respondent to the appellant.
XIV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of the grounds of opposition under Article 56.

XV. The respondent requested that the appeal be dismissed, that the patentee's late-filed submissions be found inadmissible, that documents D21 to D32 not be admitted into the proceedings, that the case not be remitted to the opposition division and that an apportionment of costs be made against the patentee.

Reasons for the Decision

Admittance of evidence

1. While admittance into the proceedings of the documents filed with the statement of grounds and the reply thereto by the opposing parties (D14 and D16 to D20) was not contested, this was the case for all documents filed thereafter, namely D21 to D31 filed by the appellant with letter of 29 June 2012, D32 filed by the appellant with letter of 24 September 2014 and D33 filed by the respondent during oral proceedings before the Board. In addition the respondent requested the patentee's late-filed submissions be found inadmissible.

1.1 Document D32 was not cited by the appellant with regard to novelty, but only with regard to inventive step which is not decided upon in this decision (see points 3 and 4, below). On that basis the Board has only to decide on the admittance of documents D21 to D31 and D33 into the proceedings.
1.2 In the decision under appeal the opposition division decided that granted claim 1 lacked novelty over document D2, as on the balance of probabilities and in view of the results in D11 the milling conditions of example 3 of D2 could result in the required MMAD of not more than 50 μm. At that stage the patent proprietor, now appellant, had chosen as a line of defense to show that the required MMAD was not the inevitable result of example 3 of D2 on the basis of the disclosure of the document itself and of possible deficiencies in the reproduction of the opponent, now respondent, in D11.

1.3 Since that line of defence was not successful, the appellant as a reaction to the decision decided to follow a possibly stronger line of defense on appeal by filing experimental tests in the form of documents D21 to D31, which is considered in the present case an acceptable way of defense, not constituting any abuse of procedure.

1.4 While it is true that D21 to D31 were not filed with the statement of grounds, but only with letter dated 29 June 2012, the experimental data contained therein relate to the crucial issue relevant for novelty of claim 1, which is the only point of the decision under appeal which is disputed, are on that basis prima facie highly relevant, were filed well before oral proceedings were convened by the Board, so that the opposing party had ample time to react to them, and do not cause in view of that any delay in the procedure.

1.5 On that basis the Board finds it appropriate to exercise its discretion according to Article 13 (1) of the Rules of Procedure of the Boards of Appeal by admitting documents D21 to D31 into the proceedings.
The same reasoning applies to the submissions of the appellant filed with letter of 29 June 2012 which discuss documents D21 to D31, which are therefore likewise admitted into the proceedings.

1.6 Document D33 was filed by the respondent during oral proceedings before the Board to provide information on the balls which were used for ball milling in the experiments provided with D21 to D31 and to show that those balls were unsuitable for that purpose and that their usage made the results irrelevant.

1.7 While the balls used in the experiments in D21 to D31 should in principle be known by the party having provided them, namely the appellant, the argument that these balls were unsuitable for ball milling came for the first time at the oral proceedings, which put the appellant in the impossibility of refuting that argument by means of further evidence or further experiments and made it impossible for the appellant and the Board to deal with that argument without adjournment of the oral proceedings.

1.8 On top of that the lack of a date on D33 and the lack of an indication of the source of the document made it impossible for the Board to properly evaluate the evidence, without further investigation which at that stage of the proceedings would not be appropriate.

1.9 In view of that the Board finds it appropriate to exercise its discretion according to Article 13 (1) of the Rules of Procedure of the Boards of Appeal by not admitting document D33 into the proceedings.
Novelty

2. Document D2 discloses a powder for use in a dry powder inhaler, the powder including active particles, carrier particles for carrying the active particles and an additive material on the surfaces of the carrier particles (claim 1). A method of making such pharmaceutical composition for inhalation is disclosed in example 3 which with reference also to example 1 describes the steps of ball milling lactose as carrier and leucine as additive followed by mixing with active particles of beclomethasone dipropionate (page 35, line 21 to page 36, line 14 and page 27, line 1 to page 29, line 1). The lactose particles used as starting material have a diameter ranging from 90µm to 125µm (page 27, lines 7 to 9).

2.1 The appellant was the opinion that the method of granted claim 1 differs from that disclosure in that:

(a) the ball milling of D2 is a gentle ball milling which differs from the one in the patent in suit as defined in paragraph [0016] of the patent;

(b) the MMAD of the composite excipient particles of example 3 of D2 is more than 50µm.

2.2 As far as the first difference is concerned, the Board cannot follow the argument of the appellant. The term "ball milling" is well-known in the art and equally used in granted claim 1 and in example 3 of D2 (page 36, lines 1 to 4). Without any further limitation in the claim, the term cannot be meant to exclude some of the processes which are commonly defined as ball milling (i.e. milling by means of balls) in the art,
such as the one of D2. The presence of a definition of milling in the description as a "mechanical process which applies sufficient force to the particles of excipient material that it is capable of breaking coarse particles (for example, particles of MMAD greater than 100\mu m) down to fine particles of MMAD not more than 50\mu m" (see paragraph [0016]) does not change the scope of the claim, which contains a term known in the art and clear in itself (contrary to the definition in the description which may lead to lack of clarity).

2.3 The crucial point remains therefore whether the MMAD of the composite excipients particles distinguishes the method of granted claim 1 from the method of example 3 of D2. In this respect it was accepted by the parties that the feature is not explicitly disclosed in example 3 of D2.

2.4 According to established case law, a prior art document anticipates the novelty of claimed subject-matter if the latter is directly and unambiguously derivable from that document, including any features implicit to a person skilled in the art. However, a disclosure can only be considered "implicit" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject-matter disclosed (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, I.C.3.3, first paragraph). In a case as the present one, in which a method for the production of a product is described in the prior art and a feature of such a product which is of interest for the claim under analysis is not mentioned in the prior art, lack of novelty can only be concluded on application of the general principle if carrying out the process of the prior art inevitably results in a
product having the required feature (still Case Law, supra, I.C.3.3).

2.5 According to D2 the method of making the carrier particles "includes the step of treating the carrier particles to dislodge small grains from the surfaces of the carrier particles, without substantially changing the size of the carrier particles during the treatment" (page 21, lines 5 to 9, see also page 25, lines 7 to 10), wherein "advantageously, the treatment step is a milling step" (page 23, lines 8 to 13). As a further explanation it is added that where "reference is made to the size of the carrier particles being substantially unchanged during the treatment, it will of course be understood that there will be some change in the size of the carrier particles because portions of the particle are removed as small grains during the treatment" (page 24, lines 18 to 23), but that "that change in size will not be as large as that obtained when particles are milled in a conventional more aggressive way" (page 24, lines 23 to 25), whereby the milling is referred to as a "gentle milling" (page 24, line 26).

2.6 The teaching of D2 points therefore clearly to a maintenance or a slight reduction of the size of the particles after milling, which for example 3 would clearly mean a MMAD well above 50μm. Under such circumstances, in order to conclude that the disputed feature is implicitly disclosed and therefore that there is lack of novelty, even stronger evidence is needed to show that it is not possible to reproduce the example according to the teaching of D2, but that contrary to that teaching any reproduction would necessarily lead to a MMAD of not more than 50μm.
2.7 A reproduction of example 3 of D2 has been provided by the appellant with the documents filed by letter of 29 June 2012 (D21 to D31). In particular in document D21 a number of blends of lactose and leucine were produced (page 6, "Blend Manufacture"), among which blend 2 includes lactose particles sieved with a 125μm sieve placed on top of a 90μm sieve for a total sieving time of 40 minutes in which the sieving step was interrupted by a brushing step (pages 4 and 5, point 2.3.2), whereby the production of lactose with a range of diameters from 90μm to 125μm corresponded to the one of example 3 of D2 (see D2, page 35, lines 22 to 25 with reference to page 27, lines 7 to 22). Blend 2 was thereafter processed according to D21 using a Pascal ball mill in a 2.5 liter porcelain pot containing 1200 ml of 20 mm plastic balls for 6 hours with the mill set at 60 rpm (page 7, point 3), wherein that milling step corresponds to the most aggressive milling according to example 3 of D2 (page 36, lines 1 to 10). The milled blend was then analysed by using 3 measurement methods for the particle size distribution (page 7, point 4 and pages 10 and 11, point 3), which was then used to calculate the value of the MMAD (page 11, last paragraph before point 4). The calculated MMAD values for blend 2 after ball milling are shown in document D27 for the three measurements methods (values on top of the three bars relative to "Ball Mill") and are of 78.4μm, 69.4μm and 103.0μm.

2.8 A reproduction of example 3 of D2 is therefore available which leads to results which are in line with the teaching of the document. The Board considers that reproduction as credible, as there are no objective elements that make it appear unreasonable, nor any manifest defects that disqualify its results. The fact that the experiments were conducted by the appellant is
in itself not a sufficient reason to disqualify the results.

2.9 The availability of a credible reproduction of example 3 of D2 in which a value of the MMAD higher than 50μm is obtained is sufficient to conclude that a MMAD of not more than 50μm is not the inevitable result of the process of the prior art.

2.10 In this respect it is not even necessary to analyse the contrasting results of a reproduction of example 3 of D2 under different conditions and employing different methods of measurement, such as the one in D11 and D14, and investigate which of the differences led to a difference in the results. There is indeed no further burden of proof on the appellant to show why the respondent obtained different results, as long as credible experiments are present which show that the disputed feature is not the inevitable result of the process of the prior art.

2.11 In view of this, novelty of the method of claim 1 with respect to the disclosure of example 3 of D2 must be acknowledged.

Remittal

3. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the
claimed subject-matter have not yet been examined and decided by the department of first instance.

3.1 In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon a particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issue (Article 111(1) EPC).

3.2 The observations made above apply in full to the present case. The opposition division decided that the subject-matter of claim 1 was not patentable on the ground of lack of novelty over D1, but did not consider the issue of inventive step. This issue, however, formed, inter alia, the basis for the requests that the patent be revoked in its entirety and must therefore be considered as an essential substantive issue in the present case.

3.3 None of the specific reasons invoked by the respondent is considered by the Board strong enough to justify a deviation from these principles. In particular, the possibility of a discrepancy in the exercise of discretion in first and second instance proceedings regarding admittance of document D32 into the proceedings cannot have any bearing on the decision of the Board. Moreover, the request of the appellant to have an issue evaluated by two instance is a legitimate (and common) request and cannot be seen as an attempt to circumvent the Rules of Procedure.
4. Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the opposition division for the analysis of inventive step of the granted claims.

*Apportionment of costs*

5. The request that an apportionment of costs be made against the patentee was based solely on the late filing of documents D21 to D31.

5.1 As already detailed when deciding on admittance of documents D21 to D31 into the proceedings (see points 1.2 and 1.3, above), the Board considers it in the present case as an acceptable line of defense the fact that the appellant followed one of the two possible lines of defense against the argument that the required MMAD was the inevitable result of example 3 of D2 in opposition proceedings and the second one on appeal, once it was clear that the first one had not been successful in first instance proceedings.

5.2 This behaviour cannot be considered as an abuse of procedure which could justify for reasons of equity an apportionment of costs different from the standard one in which each party bears the costs it has incurred.

5.3 Moreover, no evidence has been provided by the respondent, nor any argument, that it has incurred further costs due to the fact that the documents were not filed with the statement of grounds, but only with letter of 29 June 2012.

5.4 On that basis the request for apportionment of costs must be refused.
Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.
3. The request for apportionment of costs is refused.

The Registrar: 

The Chairman:

N. Schneider 
J. Riolo

Decision electronically authenticated