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Datasheet for the decision of 3 March 2020

Case Number: T 1684/16 - 3.3.02

Application Number: 06774184.3

Publication Number: 1902029

IPC: C07D215/54, A61K31/4709

Language of the proceedings: EN

Title of invention:
CRYSTALLINE FORMS OF 4-[(2,4-DICHLORO-5-METHOXYPHENYL)AMINO]-6-METHOXY-7-[3-(4-METHYL-1-PIPERAZINYL)PROPOXY]-3-QUINOLINECARB-ONITRILE AND METHODS OF PREPARING THE SAME

Patent Proprietor:
Wyeth LLC

Opponents:
Fresenius Kabi Deutschland GmbH
Generics [UK] Ltd (trading as Mylan)

Headword:

Relevant legal provisions:
EPC Art. 100(c), 56
RPBA Art. 13(1), 13(3)

Keyword:
Grounds for opposition - amendments
New allegation of facts
Inventive step

Decisions cited:
T 0777/08

Catchword:
The fact that the skilled person is taught in the prior art to investigate polymorphs in order to isolate the crystalline form having the most desirable properties is in itself not necessarily sufficient to consider a specific polymorphic form having a certain desired property obvious (see point 4.3.4 of the Reasons).

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Case Number: T 1684/16 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 3 March 2020

Appellant: (Opponent 2)	Generics [UK] Ltd (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1 AG (GB)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
Respondent: (Patent Proprietor)	Wyeth LLC 235 East 42nd Street New York, NY 10017-5755 (US)
Representative:	Pfizer European Patent Department 23-25 avenue du Docteur Lannelongue 75668 Paris Cedex 14 (FR)
Party as of right: (Opponent 1)	Fresenius Kabi Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Borkenberg 14 61440 Oberursel (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 May 2016 rejecting the opposition filed against European patent No. 1902029 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 1 902 029 was opposed under Article 100(a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, and extended beyond the content of the application as filed.

II. The appeal by opponent 2 (hereinafter "appellant") lies from the decision of the opposition division to reject the opposition.

III. The opposition division came, *inter alia*, to the following conclusions:

- Claim 1 of the patent as granted fulfilled the requirements of Article 123(2) EPC.
- The subject-matter of the patent as granted involved an inventive step in view of D1, D2 or D3 as the closest prior art.

IV. The following documents are referred to in the present decision:

D1	WO 2005/047259 A1
D2	WO 03/093241 A1
D3	WO 2005/019201 A2
D4	Federal Register, vol. 65, 2000, 83041-83063
D5	S. Byrn et al., Pharm. Res. 12(7), 945-954 (1995)
D7	WO 01/51919 A2
D16	Affidavit of K.R. Leeman dated 31 January 2013

D18 D. Braga et al., Chem. Comm., 2005, 2513-2514

V. The patent as granted contains 22 claims, with independent claim 1 reading as follows:

"*An isolated crystalline Form 1* [sic] *of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile monohydrate having an x-ray diffraction pattern wherein all of the 2θ angles (°) of the significant peaks are at about: 9.19, 11.48, 14.32, 22.33 and 25.84.*"

4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile is also known as bosutinib. This name is used hereinafter.

VI. In its statement of grounds of appeal, the appellant contested the reasoning of the opposition division and submitted that claim 1 of the patent as granted had not been originally disclosed in the application as filed. It further submitted that the subject-matter of the claims did not involve an inventive step, taking into consideration any one of D1, D2 and D3 as the closest prior art.

VII. In its reply to the grounds of appeal, the patent proprietor (hereinafter "respondent") provided counter-arguments to the appellant's objections of added subject-matter and lack of inventive step. It also submitted first, second and third auxiliary requests.

VIII. Opponent 1 did not submit any arguments or comments.

IX. Oral proceedings before the board were held on 3 March 2020.

X. The appellant's case, where relevant to the present decision, may be summarised as follows.

Main request - Added subject-matter:

- Form I of bosutinib monohydrate as defined by the five peaks in claim 1 of the patent as granted had not been originally disclosed in the application as filed. The combination of the five peaks had not been originally described as an alternative in a claim or as an embodiment explicitly set out in the description. The data in table 1 of the patent were insufficient to allow the combination of the five peaks to be derived directly and unambiguously from the disclosure of the application as filed. Figures 1, 4, 10 and 11 did not show that the five peaks were the only significant peaks. It was irrelevant whether the peaks in claim 1 of the patent as granted distinguished Form I from other forms of bosutinib.

First auxiliary request - Inventive step:

- The closest prior art was any one of D1, D2 or D3.

- The feature distinguishing Form I of bosutinib monohydrate from the bosutinib samples in each of D1, D2 and D3 was the specific crystalline form.

- The data in D16 were not convincing and should not be taken into account for the further reason that the effect shown in D16 had not been plausibly demonstrated in the application as filed. Considering the tests in D16, the technical effect

resulting from the claimed crystalline form was a stable solid form that did not change significantly during stability testing.

- In view of D16, the objective technical problem was therefore to provide a form of bosutinib that was more stable.

- The scientific guidance in D5 and regulatory incentives in D4 would have prompted the skilled person to investigate for polymorphs. D7 taught that crystalline species should be provided for increasing stability since amorphous solids were physically and/or chemically unstable. D7 also taught that different polymorphs of a given compound had different properties.

- The skilled person, faced with the objective technical problem and knowing that the physical properties vary with the type of polymorphic form, would have been motivated by D4, D5 or D7 to provide and test different crystalline species/ polymorphic forms of bosutinib for stability, and so would have arrived at the claimed Form I of bosutinib monohydrate in an obvious way.

XI. The respondent's case, where relevant to the present decision, may be summarised as follows.

Main request - Added subject-matter:

- Claim 1 of the patent as granted characterised only Form I of bosutinib monohydrate. The basis for claim 1 of the patent as granted was to be found in paragraph [0005] when read in combination with figures 1 (Pattern A), 4, 10 and 11 of the application as filed. This basis supported the

assertion that the combination of the five claimed peaks for Form I of bosutinib monohydrate could not be present in the other polymorphic forms of bosutinib monohydrate identified in the patent. Therefore, this five-peak restriction characterised only Form I of bosutinib monohydrate, and did not cover other polymorphic forms of bosutinib. Therefore, claim 1 of the patent as granted did not add subject-matter.

First auxiliary request - Inventive step:

- The closest prior art was any one of D1, D2 or D3, which all disclosed solid/crystalline forms of bosutinib.

- D16 established in a comparative stability study that Form I was a stable crystalline polymorphic form and was non-hygroscopic, whereas the closest prior art compounds from each of D1, D2 and D3 were unstable solid forms and were very hygroscopic.

- The problem to be solved was to provide a form of bosutinib that was more stable but still had a high degree of solubility.

- The skilled person would have realised that this was a very challenging problem to solve, as illustrated by the teachings of D4 (p. 83055) and D5 (p. 945, left-hand column; p. 946, right-hand column; figure 1). D4 and D5 disclosed in those passages that it was not possible to predict whether a polymorph of a compound could exist, let alone what its properties would be if it did.

- Predicting the formation and properties of a crystalline hydrated form provided a far higher

level of complexity since it introduced an additional significant solvation factor, as stated in D18 (p. 3640, right-hand column, lines 3-7).

- Case law exemplified by T 777/08 made it clear that, if any unexpected property existed, an inventive step could be recognised for a novel crystalline form of a known pharmaceutically active compound. Stability and non-hygroscopicity were not inherent characteristics of crystalline materials, unlike the position in T 777/08.

- The claimed subject-matter involved an inventive step.

XII. The parties' final requests were as follows:

- The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

- The respondent requested, as its main request, that the appeal be dismissed and that the patent be maintained as granted. Alternatively, it requested that the patent be maintained on the basis of one of the sets of claims of the first, second or third auxiliary request, filed with its reply to the statement of grounds of appeal.

Reasons for the Decision

1. The party as of right (opponent 1) was duly summoned but did not attend oral proceedings. The board decided that the proceedings would be continued in the absence of opponent 1 pursuant to Rule 115(2) EPC and Article 15(3) RPBA 2020.

Main request (patent as granted)

Added subject-matter - Article 100(c) EPC

2. The appellant objected to claim 1 of the patent as granted on the grounds that it was not based on the application as filed.

2.1 Claim 1 of the patent as granted relates to Form I of bosutinib monohydrate as a crystalline form. This form is characterised by an x-ray diffraction pattern, the 2θ angles (°) of the significant peaks being at about: 9.19, 11.48, 14.32, 22.33 and 25.84 (V, *supra*).

2.2 The board agrees that claim 1 of the patent as granted is not based on the application as filed, for the following reasons.

The respondent cited paragraph [0005] of the application as filed as a basis. This paragraph discloses the following: *"This invention is directed to isolated polymorphs of crystalline 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile including Form I, Form II, Form III, Form IV, Form V and Form VI having a x-ray diffraction pattern as shown in Figure 1 and Figure 11. A particular preferred polymorph is a monohydrate (Form I) having an x-ray diffraction pattern wherein at least one or more, and most preferably all, of the 2θ angles (°) of significant peaks are at about: 9.19, 11.48, 14.32, 19.16, 19.45, 20.46, 21.29, 22.33, 23.96, 24.95, 25.29, 25.84, 26.55, 27.61, and 29.51."*.

Similarly to paragraph [0005], paragraph [0031] of the application as filed discloses that *"Form I has at least one, preferably a majority and most preferably*

all, of the following characteristic 2 theta angles (°) peaks: 9.19, 9.98, 11.48, 14.32, 14.85, 15.64, 19.16, 19.45, 19.71, 20.46, 21.29, 22.33, 22.58, 23.96, 24.95, 25.29, 25.84, 26.55, 27.61, 28.42, 29.51, 30.32, 31.40, and 32.39.".

Claim 1 of the patent as granted differs from these disclosures in that its five peaks were selected from the list of fifteen 2θ angles given in paragraph [0005] or from the list of twenty-four 2θ angles given in paragraph [0031]. The list of the five peaks in claim 1 of the patent as granted is not directly and unambiguously disclosed in the application as originally filed. There is no dependent claim, preferred embodiment or figure that discloses the list of the five peaks as the only peaks. The information provided in paragraph [0005] or [0031] covers two alternatives: the first is that at least one or more of the peaks may be selected, and the second is the disclosure of the whole list of the peaks. There is no teaching in paragraph [0005] or [0031] relating to the selection of only five peaks. The remaining part of the description as filed does not provide any teaching relating to the selection of a number of five peaks, let alone any teaching relating to the selection of the five specific peaks in claim 1 of the patent as granted (9.19, 11.48, 14.32, 22.33, 25.84). Lastly, figures 1, 4, 10 and 11 show x-ray diffraction patterns (XRDP) of different forms of bosutinib (Forms I to VI) and do not teach the selection of the five peaks of claim 1 of the patent as granted, since those peaks are, for instance, not the most significant peaks in terms of intensity.

In the absence of any teaching relating to the selection of the number of five peaks given in claim 1 of the patent as granted in order to characterise Form I, the skilled person is presented with

information which is not directly and unambiguously derivable from the whole content of the application as filed.

2.3 The respondent further argued that the compound claimed in claim 1 as granted, characterised by the five peaks, was the same as the compound in paragraph [0005] of the application as filed, which is identified by 15 peaks, and that the claim therefore did not contain added subject-matter. In fact these five peaks not only sufficiently identified Form I, but distinguished it from the other forms disclosed in the application as filed. More specifically, according to the respondent, "*... the claimed combination of five specified "significant" XRDP peaks uniquely characterises the Form I polymorph of the named compound (monohydrate) since no other polymorph of the named compound (monohydrate) is known having these characteristics*". Reference was made to table 1 and the XRDPs of Forms II, III, IV and V (patterns B, C, D and E).

2.4 However, it is irrelevant to establish whether the five peaks in claim 1 identify the same compound as the compound characterised by the fifteen peaks of paragraph [0005]. The question to be answered with regard to an allowable amendment is whether or not the skilled person is presented with technical features or information which are directly and unambiguously derivable from the whole content of the application as filed. As established above, the list of five peaks in claim 1 of the patent as granted, and more specifically the fact that Form I can be characterised (and possibly distinguished) by just these five specific peaks, amounts to technical information which is not directly and unambiguously derivable from the whole content of the application as filed.

2.5 For the above reasons, claim 1 of the patent as granted contains subject-matter which extends beyond the content of the application as filed (Article 100(c) EPC).

First auxiliary request filed with the reply to the grounds of appeal

3. Article 123(2) EPC

Claim 1 of the first auxiliary request corresponds to a combination of the features of claims 1 and 2 as granted, i.e. claim 1 of the first auxiliary request refers to Form I having an XRDP wherein all the 2θ angles are the fifteen peaks listed in paragraph [0005] of the application as filed. No objection of added subject-matter was raised by the appellant against either claim 2 as granted or claim 1 of the first auxiliary request and the board is convinced that claim 1 of the first auxiliary request is based on paragraph [0005] of the application as originally filed. This paragraph discloses the whole list of 15 peaks mentioned in claim 1 of the first auxiliary request.

Therefore, claim 1 of the first auxiliary request meets the requirements of Article 123(2) EPC. The same applies to claims 2-21 of the first auxiliary request.

4. Inventive step

4.1 New allegations of facts

4.1.1 Plausibility

When formulating the objective technical problem, the respondent relied on an effect that was derived from post-published data contained in D16. As regards D16,

the board observed the following in its communication (point 11.5):

"The technical effect associated with the distinguishing feature is a stable crystalline form as shown by D16. [...] ***The technical effect evidenced by D16 does not appear to be disputed by the parties."*** (emphasis added)

Even after having received the board's communication, the appellant did not challenge the effect demonstrated by D16.

Only during the oral proceedings did the appellant argue, for the first time, that this effect had not been plausibly demonstrated in the application as filed and that, therefore, the post-published data contained in D16 could not be taken into account in the evaluation of the effect achieved by the claimed subject-matter.

This allegation of fact was new, deviated completely from the appellant's line of argument presented before the oral proceedings, which did not challenge the taking into account of D16, and was filed at the latest possible time during the appeal proceedings.

Had this new allegation of fact been admitted, there would have had to be a discussion for the first time as to whether the improved stability of the claimed compound had been plausibly demonstrated in the application as filed.

Furthermore, not taking the effect shown in D16 into account would have meant reformulating the objective technical problem in a less ambitious manner and there would then have had to be a discussion for the first time as to whether the solution proposed by the claims

would have been obvious in view of this less ambitious technical problem.

The allegation of fact submitted by the appellant thus raised complex new issues which had not previously been addressed during the written proceedings.

Lastly, the respondent itself underlined that it was not prepared to contest the appellant's allegation of facts within the short time available during the oral proceedings.

The board therefore decided not to admit the allegation of fact that the content of the application as filed did not plausibly demonstrate the effect on which the respondent relied and that post-published documents thus could not be taken into account (Article 13(1) and (3) RPBA 2007).

4.2 Challenging the data in D16

Following this decision of the board, the appellant argued during the oral proceedings that the results in D16 were not convincing since it did not contain any comparison with an embodiment reflecting the form of claim 1 of the first request. For this reason, the results in D16 should not be taken into account in the formulation of the objective technical problem. This amounted to a second allegation of facts.

Like the allegation of facts on plausibility, this second allegation of facts was new, deviated completely from the appellant's line of argument presented before the oral proceedings, which did not challenge the validity and relevance of the data in D16, and was filed at the latest possible time during the appeal proceedings.

In the same way as discussed previously, not taking the effect shown in D16 into account would have meant reformulating the objective technical problem in a less ambitious manner and there would have had to be a discussion for the first time as to whether the solution proposed by the claims would have been obvious in view of this less ambitious technical problem.

The board therefore decided not to admit the second allegation of facts into the proceedings (Article 13(1) and (3) RPBA 2007).

4.3 Inventive step in view of D1, D2 or D3 as the closest prior art

4.3.1 As set out above, the compound in claim 1 of the first auxiliary request is a specific crystalline form of bosutinib monohydrate ("Form I"). The patent aims to provide methods for preparing this form and pharmaceutical compositions containing this form for the treatment of pancreatic and prostate cancer (paragraph [0001] of the patent).

4.3.2 Closest prior art

D1, D2 and D3 disclose solid/crystalline forms of bosutinib.

In accordance with the parties' submissions, any of D1, D2 and D3 may be regarded as the closest prior art.

In D1, D2 and D3, the products are described as a "light pink solid" having a melting point of 116-120°C in D1 (example 1), a solid having a melting point of 125-128°C in D2 (example 50) and a crystalline solid in D3 (example 45). There is no indication that the crystalline form is obtained in D1 and D2, and no indication of the specific nature of the crystalline

form obtained in D3. The distinguishing feature is thus the specific crystalline form of bosutinib monohydrate ("Form I"), as defined in claim 1.

4.3.3 Technical problem

The technical effect associated with the distinguishing feature is a stable crystalline form as shown by D16. Table 1 of D16 in conjunction with figure 1 shows that Form I maintained its appearance, purity, water content and crystallinity after being exposed to a temperature of 70°C and 75 % relative humidity for two weeks (points 9 and 15 of D16). Under the same conditions, the crystalline forms of example 1 of D1 (table 2 and figure 2), example 50 of D2 (table 3 and figure 3) and example 45 of D3 (table 4 and figure 4) changed significantly during stability testing and were hygroscopic (points 8, 16-18 of D16).

For these reasons, the objective technical problem is to provide a form of bosutinib that is more stable. Following the board's decision not to admit the appellant's new allegations of facts and to take D16 into account, this was not challenged by the appellant.

4.3.4 Obviousness

The appellant submitted that the claimed solution was obvious since screening of polymorphs was a routine task as demonstrated by D4, D5 and D7. It submitted that there was a reasonable expectation of success for the skilled person as regards whether Form I of bosutinib monohydrate would maintain its stability in terms of appearance, purity, water content and crystallinity after being exposed to 70°C and 75 % relative humidity for two weeks.

D4 (p. 83055) discloses a flow chart for investigating the need to set acceptance criteria for polymorphism in drug substances and drug products. The chart shows the steps of conducting polymorphism screening on drug substances and characterising the form by X-ray powder diffraction, DSC/thermoanalysis, microscopy and spectroscopy (step 1) and of establishing the different properties (solubility, stability and melting point) of the forms (step 2).

D5 (p. 945, first paragraph) discloses that "*Interest in the subject of pharmaceutical solids stems in part from the Food and Drug Administration's (FDA's) drug substance guideline that states "appropriate" analytical procedures should be used to detect polymorphic, hydrated, or amorphous forms of the drug substance. These guidelines suggest the importance of controlling the crystal form of the drug substance. The guideline also states that it is the applicant's responsibility to control the crystal form of the drug substance and, if bioavailability is affected, to demonstrate the suitability of the control methods*". D5 (p. 946, paragraph A; figure 1) also refers to a flow chart outlining the investigations of the formation of polymorphs, the analytical tests available for identifying polymorphs and studies of the physical properties of polymorphs.

D7 (abstract) purports to provide rapid screening methods to identify solid forms with enhanced properties. Like D4 and D5, D7 refers to the need for screening to identify polymorphs, but it proposes only a general method for producing and screening them. The last paragraph of point 4.8 of D7 (p. 34) teaches that different polymorphs of a given compound are different

in structure and properties and that solubility and stability, *inter alia*, vary with the polymorphic form.

The board acknowledges that, in view of their disclosures, D4, D5 and D7 teach the investigation of polymorphs in order to isolate the crystalline form having the most desirable properties. This in itself is not sufficient to deny inventive step, however. Only if the prior art contains a clear pointer that it is the claimed subject-matter that solves this problem or where it at least creates a reasonable expectation that a suggested investigation will be successful, can inventive step be denied. In this case, however, there is no clear pointer in any of D4, D5 or D7 that it is the specific crystalline Form I as defined in claim 1 that is the most stable form. There is in particular no teaching in the cited prior art that Form I of bosutinib monohydrate would have maintained its appearance, purity, water content and crystallinity after being exposed to 70°C and 75 % relative humidity for two weeks, in contrast to other crystalline forms.

D4 (p. 83055, first question in point 2) and D5 (figure 1) question whether newly discovered polymorphs have different properties. Therefore, and without there being any indication in D7, it is entirely unpredictable which crystalline form is the most stable one. This unpredictability is confirmed by D18. D18 (p. 3640, right-hand column, first sentence) states that "*The problem is further complicated by the possibility of obtaining different solvate forms. One can say that if the formation of polymorphs is a nuisance for crystal engineers,* ***solvate formation can be a nightmare, because it is extremely difficult to predict whether a new species may crystallize from solution with one or more molecules of solvent.***" (emphasis added by the board). D18 emphasises

the difficulty of predicting the formation of solvates, which constitutes an additional factor in the unpredictability taught by D4 and D5. Therefore, the unpredictability of polymorphism screening does not represent a reasonable expectation that the specific crystalline Form I as defined in claim 1 would be the most stable form.

The skilled person, starting from the solid bosutinib disclosed in any one of D1, D2 and D3, would thus have found no incentive in D4, D5 and D7 to prepare Form I of bosutinib monohydrate (which is a solvate) in order to provide a form of bosutinib that is more stable nor could he derive a reasonable expectation that a more stable form of bosutinib would be found as a result of the suggested screening.

The appellant submitted that the solution was obvious in the light of T 777/08; however, the present case differs from the situation at issue in decision T 777/08.

In T 777/08, "*the skilled person in the field of pharmaceutical drug development would have been aware of the fact that instances of polymorphism were commonplace in molecules of interest to the pharmaceutical industry, and have known it to be advisable to screen for polymorphs early on in the drug development process. Moreover, he would be familiar with routine methods of screening. Consequently, in the absence of any technical prejudice and* ***in the absence of any unexpected property****, the mere provision of a crystalline form of a known pharmaceutically active compound cannot be regarded as involving an inventive step. When starting from the amorphous form of a pharmaceutically active compound as closest prior art, the skilled person would have a clear expectation that*

a crystalline form thereof would provide a solution to the problem of providing a product having improved filterability and drying characteristics. ***The arbitrary selection of a specific polymorph from a group of equally suitable candidates cannot be viewed as involving an inventive step"*** (headnote 1 and 2, emphasis added by the board).

Hence, the decision in T 777/08 is concerned with the arbitrary selection of any crystalline form and considers it obvious that any arbitrary crystalline form has better filterability and drying characteristics than the corresponding amorphous form. This is entirely different from the present case. The present case is NOT about the selection of **any** crystalline form but about the selection of **one specific** crystalline form, namely Form I of bosutinib monohydrate. Furthermore, the selection of this specific crystalline form is not arbitrary, but rather this form has **unexpected properties**, namely an improved stability when compared with the other crystalline forms in D1, D2 and D3.

4.3.5 Based on the above considerations, the board comes to the conclusion that, having regard to the cited prior art, it was not obvious to the skilled person to isolate Form I of bosutinib monohydrate and to arrive at the compound as defined in claim 1 as granted.

Therefore the subject-matter of claim 1 and, by the same token, of all remaining claims of the first auxiliary request 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 with the following claims and a description to be adapted thereto:
claims 1 to 21 of the first auxiliary request, filed with the reply to the statement of grounds of appeal.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated