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**Datasheet for the decision  
of 22 November 2021**

**Case Number:** T 2066/17 - 3.2.08

**Application Number:** 11799357.6

**Publication Number:** 2651351

**IPC:** A61F5/445

**Language of the proceedings:** EN

**Title of invention:**

A CONVEX SUPPORTING DEVICE FOR AN OSTOMY APPLIANCE

**Patent Proprietor:**

Coloplast A/S

**Opponent:**

Hollister Incorporated

**Headword:**

**Relevant legal provisions:**

EPC R. 99(2), 101(1)

EPC Art. 100(b), 100(a), 56

RPBA Art. 12(4)

**Keyword:**

Admissibility of appeal - (yes)  
Late-filed facts - admitted (no)  
Late-filed evidence - admitted (no)  
Reimbursement of appeal fee - (no)  
Sufficiency of disclosure - (yes)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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Case Number: T 2066/17 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 22 November 2021**

**Appellant:** Hollister Incorporated  
(Opponent) 2000 Hollister Drive  
Libertyville, Illinois 60048-3781 (US)

**Representative:** FRKelly  
27 Clyde Road  
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**Respondent:** Coloplast A/S  
(Patent Proprietor) Holtedam 1  
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 5 July 2017 rejecting the opposition filed against European patent No. 2651351 pursuant to Article 101(2) EPC.**

**Composition of the Board:**

**Chairman** C. Herberhold  
**Members:** A. Björklund  
Y. Podbielski

## **Summary of Facts and Submissions**

- I. The appeal was filed by the opponent (appellant) against the decision of the opposition division to reject the opposition.
- II. The opposition division decided that the invention was sufficiently disclosed for it to be carried out by the skilled person, that the subject-matter of claim 11 was new and that the subject-matter of claims 1 and 11 involved an inventive step.
- III. Oral proceedings by videoconference were held before the Board on 22 November 2021.
- IV. At the end of the oral proceedings the parties' requests were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. They furthermore requested reimbursement of the appeal fee on the basis of a substantial procedural violation by the opposition division.

The respondent (patent proprietor) requested that the appeal be held inadmissible or, if held admissible, that the appeal be dismissed and the patent be maintained as granted.

- V. Claim 1 of the main request (patent as granted) reads as follows:

"A base plate (100) for an ostomy appliance comprising a skin friendly adhesive with a first through-going passage for receiving a stoma, the passage surrounded

by a first adhesive area protruding from and surrounded by a second adhesive area, **characterized in that** the first adhesive area protrudes at least 7mm from the second adhesive area; wherein the axial compression resistance to moving the first adhesive area towards the second adhesive area axially along the centre axis of the through-going passage is above 10 Newton at 3mm compression, and the bending resistance of the base plate about a horizontally extending bending axis perpendicular to the centre axis of the first through-going passage is below 2.25 Newton at 20mm bending."

Claim 11 of the main request reads as follows:

"A convex supporting device (104) for a base plate (100) of an ostomy appliance, said device (104) having a through-going passage, **characterized in that** the device (104) has a bending resistance about a horizontally extending bending axis, which is perpendicular to a centre axis of the through-going passage, which is below 2.25 Newton at 20mm bending and an axial compression resistance in a direction parallel to the centre axis above 10 Newton at 3mm compression."

VI. The following documents have been addressed in the appeal proceedings:

- D1: WO 2010/054662
- D4: "Principles and techniques in the use of convexity", B.S. Rolstad et al., Ostomy Wound Management, The Journal for Extended Patient Care Management, Vol. 42, No. 1, Jan/Feb. 1996
- D9: "Standard deviations and standard errors", Douglas G. Altman et al., Print-out from

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255808/>

- D10: Affidavit Mr. Mayer including exhibits GCM-1 to GCM-6
- D11: Affidavit Mr. Fenton including exhibits GHF-A to GHF-C
- D12: Photos of Marlen UltraLite products
- D13: Affidavit Mr. Czaplewski including exhibits GJC-1 to GJC-4
- D14: Affidavit Mr. Eakin including exhibits PHL1 to PHL2
- D15: Affidavit Mr. Latoz including exhibits CVL-1 to CVL-4
- D16: US 4,219,023
- D17: US 2005/0054997
- D18: US 5,429,626
- D19: Affidavit Ms Mortensen

VII. The appellant's arguments as far as relevant for the present decision can be summarised as follows:

*Admissibility of the appeal*

The appeal criticised the decision in point 1.1. of the grounds of appeal and further repeated the argument that there was insufficiency of disclosure as the invention could not be performed over the whole range claimed - an objection raised in the opposition proceedings but not addressed in the impugned decision. Moreover, as the patent had been maintained as granted, the objections raised in the opposition proceedings and repeated in the statement setting out the grounds of appeal still applied. The appeal was thus admissible.

*Reimbursement of appeal fee, substantial procedural violation*

The appeal fee should be reimbursed since the opposition division had committed a substantial procedural violation in not considering the opponent's argument that the skilled person could not carry out the invention over the entire range claimed. This objection had been raised in writing in the opponent's letter of 2 March 2017 and the opposition division had not decided that it was not admitted into the proceedings. It should thus have been decided upon by the opposition division.

*Admittance of D9 to D18*

D9 disclosed nothing more than the common general knowledge in the field of statistics and should thus be admitted.

Furthermore, the opposition division had considered that the Welland Flair prior art did not compromise the novelty of claim 11. It thus became evident that it was necessary - as a direct response to that decision - to introduce the public prior uses "Marlen" and "Pelican" corroborated by documents D10 to D15 into the proceedings. These prior uses were *prima facie* relevant to the novelty and/or inventive step of the claimed subject-matter and the evidence submitted with the grounds of appeal was sufficient to fully prove them.

Likewise, D16 to D18 were *prima facie* relevant prior art. They should therefore be admitted into the proceedings.

*Sufficiency of disclosure*

The alleged invention was defined by the parameters in the characterising portions of claims 1 and 11. These parameters were unusual and the patent did not describe a reproducible test method which was, however, particularly important for inventions defined by such unusual parameters.

Furthermore, the skilled person could not carry out the invention over the entire scope since only one limit of the parameter ranges was defined in the claims, but the other was left open. However, there must be an upper limit to the axial compression resistance and a lower limit to the bending resistance which were, nevertheless, not disclosed in the patent.

Finally, the patent did not disclose which changes were needed to be made to the base plate and convex supporting device as disclosed in Figures 1 and 2 of D1, which looked identical to the embodiment in Figures 25 and 26 of the patent, in order to arrive at a base plate and convex supporting device according to claims 1 and 11.

The invention was thus not sufficiently disclosed for the skilled person to put it into practice.

*Novelty and inventive step*

Figures 1 and 2 of D1 disclosed a base plate and a convex supporting device according to claims 1 and 11. These figures were identical to that of the embodiment in Figures 25 and 26 of the patent. It followed that also the features of the characterising portion of claims 1 and 11 were inherently disclosed in D1.



Should these features be seen as not disclosed in D1, the technical problem they solved was to provide a base plate, respectively a convex supporting device which prevented peristomal collapse while improving comfort.

The claimed solution to this problem did not involve an inventive step but was obvious in view of the Welland Flair appliance mentioned in the patent or in view of D4.

VIII. The respondent's arguments as far as relevant for the present decision can be summarised as follows:

*Admissibility of the appeal*

The appeal did not contain any analysis of the specific points of reasoning which were incorrect and essentially contained nothing more than a copy of the grounds of opposition and new objections based upon D9 to D18 raised for the first time in the appeal proceedings. This failure to provide sufficient analysis of the decision under appeal resulted in non-compliance with Rule 99(2) EPC and Art. 12(2) RPBA. The appeal was thus not admissible.

*No reimbursement of appeal fee, no substantial procedural violation*

The objection that the skilled person could not carry out the invention over the entire scope of the claim had first been made as part of a third party observation. The opposition had exercised its discretion correctly in not admitting these observations into the proceedings. There was thus no procedural violation. As the objection which the

appellant now sought to introduce itself was late filed it should also not be admitted into the appeal proceedings.

*Admittance of D9 to D18*

D9 was late filed and had no particular relevance to the proceedings. It should therefore not be admitted.

The appellant had filed objections based on the alleged prior uses "Marlen" and "Pelican" for the first time in the appeal proceedings although the factual and legal situation had not changed. These objections thus could and should have been filed already in the opposition proceedings. Furthermore, the evidence filed was *prima facie* not sufficient to prove the prior uses, which was required especially at this late stage of the proceedings.

Likewise, no justification had been given for the late filing of D16 to D18, nor any proof that they were *prima facie* more relevant than D1. They should therefore also not be admitted.

*Sufficiency of disclosure*

The appellant had not submitted any verifiable facts which supported their allegation that the skilled person could not carry out the invention on the basis of the information found in the patent.

The patent disclosed how the testing was to be carried out, the ambient parameters of the testing, testing data obtained from both the claimed and prior art devices, as well as figures showing the geometry of the claimed base plates and convex supporting devices, and

the materials to be used. Several appliances had been actually made and measured, with the respective axial compression resistance and bending resistance being in the claimed range. This was sufficient for the skilled person to carry out the invention.

Regarding the ranges, even if only one limit was defined for the parameters, the skilled person would work within reasonable ranges. As the defined parameters were interrelated, it was clear to the person skilled in the art that a minimum axial compression resistance excluded a bending resistance close to zero. The objection that the claim could not be put into practice over the whole range claimed thus relied on a literal interpretation which technically did not make sense.

*Novelty and inventive step*

Firstly, the objections under Articles 54 and 56, being raised in a copy and paste exercise without addressing the appealed decision, were non-substantiated and should not be admitted into the appeal proceedings.

Secondly, they were also not convincing on the merits.

The features of the characterising portion of claims 1 and 11 were not inherent from the schematic drawings in Figures 1 and 2 of D1 and thus not disclosed.

The differing features of the axial compression resistance and the resistance to bending were interacting. Normally, a base plate or supporting device was therefore stiff in all directions or soft in all directions, whereas those of claims 1 and 11 were

stiff towards compression and soft with regard to bending.

These distinguishing features solved the technical problem to prevent collapse and improve comfort.

D1 was concerned with the precise location at which a base plate should bend, namely at the ridges 10 to 13 shown in Figure 2, and did not address or hint at the problem solved by the claimed invention. The person skilled in the art thus had no reason to modify the D1 product towards a solution of the technical problem.

The Welland Flair appliance did not provide any teaching regarding the claimed parameters, and these were anyway measured to be outside of the claimed ranges.

D4 contained no pointer to the claimed solution and in particular did not indicate the claimed parameter ranges.

While the skilled person could have transferred a teaching from the Welland Flair appliance or D4 to the base plate or convex supporting device of D1, there was no teaching prompting them to do so. And even if they did modify the appliances of D1 according to the Welland Flair appliance or D4, they would not arrive at base plate or convex supporting device having the values as claimed.

The subject-matter of claims 1 and 11 thus involved an inventive step.

## **Reasons for the Decision**

1. Admissibility of appeal
  - 1.1 As the appeal is not allowable for the reasons given below, there is no need to elaborate on its admissibility in greater detail. Generally, the admissibility of an appeal can only be assessed as a whole (Case Law of the Boards of Appeal of the European Patent Office, Ninth Edition, 2019, V.A. 2.6.8). Where the appellant is an opponent, as in the case in hand, it suffices that the appellant sets out why the decision is wrong on one of the grounds for opposition.
  - 1.2 Point 1.1. of the grounds of appeal contains a statement of one specific point in which the appealed decision is incorrect. Further, on page 4, last paragraph of the statement setting out the grounds of appeal, it is argued that the invention could not be performed over the whole range claimed. This objection had already been raised by the appellant in the opposition proceedings (letter dated 2 March 2017, page 4, second paragraph). The objection had not been admitted by the opposition division as originating from a late filed third party submission. However, whether the objection should now be admitted is a matter for the Board to consider. In the present circumstances, the Board regards the objection as a legitimate response to the impugned decision.

The appeal thus fulfils the requirements of Rule 99(2) EPC and is admissible (Rule 101(1)EPC).
2. Reimbursement of appeal fee, no substantial procedural violation

According to Rule 103(1)(a) EPC, the appeal fee shall be reimbursed in full if the Board of Appeal deems an appeal to be allowable, and if such reimbursement is equitable by reasons of a substantial procedural violation.

In the present case, the appeal is dismissed for the reasons set out below. The appeal fee is thus not to be reimbursed for this reason alone.

With respect to the alleged procedural violation by not considering the opponent's argument that the skilled person could not carry out the invention over the entire range claimed, it is uncontested that said objection was originally part of a third party observation, from which the then opponent took it up in the letter dated 2 March 2017. Also uncontestedly, both, the third party observation and the opponent's letter were filed after the 9 month opposition time limit, the opposition division thus having a discretion not to admit the respective facts (Art. 114(2) EPC) into the proceedings. According to point 15 of the impugned decision, the opposition division decided not to admit the third party observations into the procedure as they were late filed and were seen not to be prima facie relevant. During the oral proceedings before the opposition division the chairman asked the parties to present their arguments concerning Article 83 EPC without referring to the documents of the third party (see minutes, point 2). The appellant's objection that the opposition division had not decided that the objection was not admitted into the proceedings is thus not convincing. As to the discussion of the objection on the merits, see point 4.3 below).

3. Admittance of D9 to D19

3.1 D9 is an article explaining the difference between standard deviation and standard error, which is a representation of the common general knowledge. It relates to the appellant's argument that the parameters determined with respect to the Welland Flair specimens were not sufficiently far removed from the parameter ranges claimed. The Board thus decided to admit D9 into the appeal proceedings.

3.2 The alleged prior uses "Marlen" and "Pelican"

3.2.1 The appellant alleges that the subject-matter of claims 1 and 11 lacks novelty in view of the prior use "Marlen". D10 to D13 have been filed to support this allegation.

They also allege that the subject-matter of claim 11 lacks novelty and the subject-matter of claim 1 does not involve an inventive step in view of the prior use "Pelican". D13 to D15 have been filed to support this allegation.

According to the submitted evidence, the alleged prior uses took place well in advance of the filing of the opposition on 17 February 2016. The appellant has not provided any reason as to why these alleged prior uses could not have been filed in the opposition proceedings.

3.2.2 The Board notes in this regard that according to the affidavit D10, samples of "Marlen" products (and of products of other competitors) were kept by the appellant, and at least one of the products was received already in August 2005.

The appellant therefore admittedly had in its possession all the relevant evidence and thus could have raised the objections based on the alleged prior use "Marlen" already in the opposition proceedings.

3.2.3 With regard to the prior use "Pelican", it is noted that the only evidence for the public availability of the products is the statement of Mr. Eakin in the affidavit D14. No sales receipt or other evidence of a sale has been provided. The Board thus finds that this prior use is not *prima facie* sufficiently proven on the basis of the documents filed with the grounds of appeal.

3.2.4 Furthermore, the argument that the filing of D10 to D15 was a reaction to the opposition division's assessment of the "Welland Flair" specimens is not convincing. The appellant has not established any relation between the assessment of the "Welland Flair" specimens in the decision and the alleged further prior uses. There was also no surprising change during the opposition proceedings which could justify the late filing of D10 to D15. The fact that the opposition division did not consider a certain attack persuasive is not a "development" which justifies the submission of a new line of attack.

The Board therefore decided not to admit the objections based upon the alleged prior uses "Marlen" and "Pelican" into the appeal proceedings under Article 12(4) RPBA 2007 in conjunction with Article 25(2) RPBA 2020.



3.3 D16 to D18

With the present main request being the claims as granted, the Board can see no reasons why the inventive step objections based on D16 to D18 could not have been filed during the proceedings before the opposition division. Furthermore, the attacks do not appear prima facie more relevant than those starting from D1 as closest prior art.

The Board therefore decided not to admit documents D16 to D18 into the proceedings under Article 12(4) RPBA 2007 in conjunction with Article 25(2) RPBA 2020.

3.4 D19

D19 is only of relevance to the discussion of the test results of the alleged public prior use "Pelican". Since this alleged public prior use was not admitted into the proceedings, the admittance of D19 into the proceedings is moot.

4. Sufficiency of disclosure

4.1 The appellant submitted that since the alleged invention lies in the parameters of the characterising portions of claims 1 and 11 and these parameters were unusual in the art, a consistent method of determining the parameters must be disclosed in the patent, but such methods were missing in the patent.

They further submitted that the skilled person could not carry out the invention over the entire range claimed. An upper limit of the axial compression resistance was necessary, otherwise the base plate and convex supporting device would be too stiff to achieve

the claimed bending resistance. Conversely, a lower limit of the bending resistance was necessary in order to achieve the claimed axial compression resistance, while the claim encompassed even the extreme cases of the bending resistance being zero.

Finally, the features required for a base plate and a convex supporting device to have the claimed parameters were not disclosed in the patent. In particular the modifications required to the base plate and convex supporting device in Figures 1 and 2 of D1, which were identical in geometry to the embodiment in Figures 25 and 26 of the patent, in order for them to have the claimed parameters were not indicated in the patent.

The invention was therefore not sufficiently disclosed for it to be carried out by the skilled person.

- 4.2 Paragraphs [0071] to [0077] in combination with figures 4 to 7 of the patent disclose how the claimed parameters are to be measured. In addition, paragraph [0172] discloses the device used for the testing and the ambient parameters used during testing.

The appellant submitted that this information was not sufficient, but did not indicate the exact information which was missing or put forward any evidence for this allegation. The appellant's submission is not convincing in view of the detailed information regarding the measurements given in the patent.

The Board is thus of the view that the skilled person would not have any difficulty measuring the claimed parameters of a base plate or convex supporting device on the basis of this information.

4.3 The appellant is correct in that the definitions of the ranges for the axial compression resistance and bending resistance in claims 1 and 11 are open. However, the reader of the claim is a skilled person who would not interpret the ranges to encompass values which may be encompassed in a strictly literal reading of the claim, but which are unattainable in practice or make no technical sense, like a bending resistance of zero or infinite axial compression resistance.

Furthermore and more importantly, for the very reason that the axial compression resistance and the bending resistance interact as pointed out by the appellant, the ranges are only in theory open ended. A low bending resistance counteracts a high axial compression resistance and therefore an upper limit of the bending resistance limits - to a certain extent - the maximum axial compression resistance. Conversely, a lower limit of the axial compression resistance limits the minimum bending resistance.

The "open" ranges of claims 1 and 11 would therefore not prevent the skilled person from carrying out the invention.

4.4 Further, again with respect to the question of sufficiency of disclosure, the appellant has not submitted any verifiable facts which support their allegation that the skilled person would not know how to modify the base plate or convex supporting device in Figures 1 and 2 of D1 to achieve a base plate or a convex supporting device with an axial compression resistance and a bending resistance according to claims 1 and 11.

As pointed out by the respondent, the patent not only discloses how to measure the claimed parameters, but further discusses several examples (paragraph [0079] ff) as to their geometry (see Figs. 9 ff) and as to the materials being used in the prototype products (e.g. paragraph [0174]). Measurements have been performed on the prototype specimen as well as on comparative examples (see Table 1), which demonstrate that the claimed properties could be reached.

The Board is thus convinced that the skilled person reading the patent has the knowledge of suitable materials and geometries which allow them to provide the claimed base plates and convex supporting devices, possibly with the need for a limited amount of experimenting.

- 4.5 For the above reasons, the invention is sufficiently disclosed for it to be carried out by the person skilled in the art.

The ground for opposition under Article 100(b) EPC does therefore not prejudice the maintenance of the patent.

5. Novelty and inventive step

- 5.1 Admittance of the objections against novelty and inventive step starting from document D1

Inventive step starting from document D1 as closest prior art was objected to in opposition proceedings and discussed in the impugned decision. The Board sees no reason to exclude this objection - which was again timely raised with the statement setting out the grounds of appeal - under Article 12(4) RPBA 2007.

Furthermore, while novelty of the subject-matter of claim 1 over D1 was indeed not an issue during the opposition proceedings and was raised for the first time in the grounds of appeal, which features are disclosed in D1 must in any event be established for the assessment of whether the subject-matter of claims 1 and 11 involves an inventive step starting from D1 as closest prior art. The Board will thus in the following assess the disclosure of document D1.

- 5.2 It is common ground that Figures 1 and 2 of D1 disclose a base plate and a convex supporting device according to the preamble of claim 1, and claim 11.

The appellant submitted that since these figures were identical to Figures 25 and 26 of the patent, it was inherent that they also showed the features of the characterising portion of claims 1 and 11.

- 5.3 However, drawings in figures of patent documents are in general schematic and this is also the case in D1. It can therefore not be established from the figures alone that the first adhesive area indicated by reference 22 protrudes at least 7 mm from the second adhesive area indicated by reference 20.

Furthermore, the mechanical properties of the claimed base plate and convex supporting device result from the interaction of the specific material properties and the specific geometry. While the embodiments in Figures 25 and 26 of the patent look very similar to the base plate and convex supporting device in Figures 1 and 2 of D1, it cannot be deduced therefrom that they have the same mechanical properties.

The features of the characterising portions of claims 1 and 11 are therefore not disclosed in D1.

- 5.4 Since the features common to the characterising portions of both claims 1 and 11 are the axial compression resistance and the bending resistance, the assessment of inventive step will be made first on the basis of these distinguishing features, without taking the additional distinguishing feature of the 7 mm protrusion of the first adhesive area from the second adhesive area of claim 1 into account.
- 5.5 The appellant submits that these features solve the technical problem of providing a base plate, respectively a convex supporting device which prevents peristomal collapse while improving comfort.
- 5.6 In their view, the claimed solution would have been obvious in view of the Welland Flair appliance discussed in the patent or in view of D4.

According to the appellant, most prior art devices, including the known Welland Flair appliance, had the claimed axial compression resistance as it was evident from paragraph [0180] and Figure 27 of the patent. The knowledge of the flexible "Welland Flair appliance" would thus point the skilled person towards a reduction in the bending resistance of the base plate and convex supporting device of D1 in order to solve the problem posed. The bending resistance of the Welland Flair appliance was just above that claimed, as indicated in Table 2 of the patent. The skilled person would have no reason not to select an even lower bending resistance and would thus arrive at the base plate of claim 1 or convex supporting device of claim 11 without involvement of inventive skills.

Furthermore, D4, page 29, third column and page 31, first column disclosed that the degree of support, or stiffness, should be adapted to the users abdominal characteristics. This teaching would also point the skilled person towards reducing the bending resistance of the base plate and convex supporting device of D1 and they would then also arrive at the base plate of claim 1 or the convex supporting device of claim 11 without involvement of inventive skills.

- 5.7 However, the mere knowledge of the axial compression resistance and bending resistance of the Welland Flair appliance, of which no further characteristics such as e.g. its structure or geometry are on file, does not as such represent a teaching to the skilled person that these properties would solve the problem posed. The skilled person therefore has no pointer towards a corresponding modification of the base plate and convex supporting device of D1 in order to solve the problem posed.

Furthermore, even if the skilled person would modify the base plate and convex supporting device of D1 such that they would have the axial compression resistance and bending resistance of the Welland Flair appliance, they would still not have the bending resistance according to claims 1 or 11 (see Table 2, giving the respective mean value and standard deviation). No reference was made in this context to document D9.

Document D4, page 29, third column and page 31, first column, teaches that the support and thus the stiffness and bending resistance of face plates should be adapted to the patient, and that in some cases the face plate should be soft. However, D4 does not indicate any

values of the axial compression resistance or the bending resistance of these face plates. It also does not teach that the axial compression resistance should be above a lower limit while the bending resistance should be below an upper limit. Indeed the prior art devices measured in the patent as comparative examples consistently show a higher bendability resistance (see Figure 27 and Table 2). The skilled person is thus not provided with any teaching which would incite them to modify the base plate or convex supporting device of D1 such that they would have an axial compression resistance and bending resistance falling in the ranges claimed in claims 1 or 11.

5.8 The subject-matter of claims 1 and 11 is thus not obvious to the skilled person.

It follows that the ground for opposition under Article 100(a) EPC in conjunction with Article 56 EPC does not prejudice the maintenance of the patent.



**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



C. Moser

C. Herberhold

Decision electronically authenticated