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Datasheet for the decision of 1 July 2009

Case Number: T 0462/06 - 3.3.01

Application Number: 01997102.7

Publication Number: 1347755

IPC: A61K 31/335

Language of the proceedings: EN

Title of invention:
Benzopyrancarboxylic acid derivatives for the treatment of diabetes and lipid disorders

Applicant:
Merck & Co., Inc.

Opponent:
-

Headword:
Benzopyrancarboxylic acid/MERCK

Relevant legal provisions:
EPC Art. 82, 113(1), 111(1)
EPC R. 116
RPBA Art. 15(3), 15(6)

Relevant legal provisions (EPC 1973):
EPC R. 68(2), 67

Keyword:
"Unity of invention (yes)"
"Substantial procedural violation (no)"

Decisions cited:
G 0010/93, T 0241/95, T 0763/04

Catchword:

-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0462/06 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 1 July 2009

Appellant: Merck & Co., Inc.
P.O. Box 2000
126 East Lincoln Avenue
Rahway
NJ 07065-0907 (US)

Representative: G. Buchan
Merck & Co., Inc.
European Patent Department
Merck Sharpe & Dohme Limited
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 26 August 2005 refusing European application No. 01997102.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

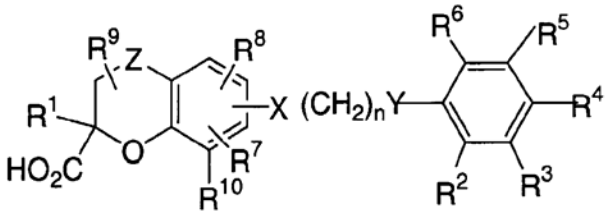
Chairman: P. Ranguis
Members: G. Seufert
R. Menapace

Summary of Facts and Submissions

I. The Appellant lodged an appeal on 24 October 2005 against the decision of the Examining Division dated 26 August 2005 refusing the European patent application No. 01997102.7 and filed a written statement setting out the grounds of appeal on 22 December 2005.

II. Claim 1 of the set of claims on which the refusal was based and which corresponds to claim 1 as originally filed reads as follows (the definition of the substituents being reproduced as far as necessary for the purpose of the present decision):

1. A compound having the formula (I)



I

or a pharmaceutically acceptable salt or prodrug thereof, wherein:
Z is selected from the group consisting of CH_2 and C=O;
R^1 is selected from the group consisting of H, -OH, C_{1-7}alkyl, C_{2-7}alkenyl, C_{2-7}alkynyl, -OC_{1-3}alkyl, -OC_{2-3}alkenyl, -OC_{2-3}alkynyl, F, Br, Cl, and Ar,
or alternatively,
R^1 is a group —$CR^{11}R^{12}$- which bridges between the carbon to which R^1 is attached in Figure I and the adjacent carbon on the heterocyclic ring, yielding a cyclopropane ring;

X and Y are independently selected from the group consisting of O, S, SO, SO_2, NR^a and CH_2;
n is an integer from 1-6;
R^4 is selected from the group consisting of Benzoheterocycle, C_{3-8}Cycloalkyl, Hetcyc, $-OC_{3-8}$-Cycloalkyl and R^c, with the proviso that if R^4 is R^c, then either (1) R^1 is not H, and no more than one of R^2, R^6, and R^{10} is alkyl, or (2) R^2 is Cl, Br or F, and R^{10} is not alkyl;
wherein R^C is selected from the group consisting of halogen, -OH, $-OSO_2C_{1-8}$alkyl, $-OSO_2C_{3-8}$Cycloalkyl, $-OSO_2$Ar, C_{1-8}alkyl, C_{2-8}alkenyl, C_{2-8}alkynyl, $-OC_{1-8}$alkyl, $-OC_{2-8}$alkenyl, $-OC_{2-8}$alkynyl, and Aryl;

Independent claims 35, 36-38 and 39 of the application, which were filed on 23 April 2003 with the request for entry into the European regional phase, refer to a pharmaceutical composition comprising the compounds of claim 1, various therapeutic uses of the compounds of claim 1 and a pharmaceutical composition comprising the compound of claim 1 in combination with additionally defined active ingredients.

III. In the decision under appeal, the Examining Division relying on document

(1) WO-A-00/16798

held that the application lacked unity of invention contrary to the requirement of Article 82 EPC in combination with Rule 30 EPC (1973).

The Examining Division held in particular that a single inventive concept linking the compounds of formula (I)

was not present, as the compounds, although exhibiting a common property or activity, namely an anti-diabetic activity due to their PPAR agonistic activity, did not have a common structural part, which distinguished them from the compounds of the prior art. The structural element common to the claimed compounds, namely the benzopyran-2-carboxylic acid ring attached via a linker to a phenyl group, is already disclosed in document (1) for compounds which exhibit the **same** anti-diabetic activity. No common feature was left that could link the individual compounds of the formula (I).

The Examining Division did not consider the peroxisome proliferator activated receptor (PPAR) agonistic activity, which is not disclosed in document (1), as a common special technical feature defining the contribution over the state of the art, because it considered this activity as merely a newly discovered mechanism of action underlying the known anti-diabetic use. The newly discovered effect might have already taken place when the known compounds of document (1) were administered for the same purpose, i.e. for their anti-diabetic activity.

Furthermore, compounds of document (1) might be either agonists or antagonists of the insulin receptor without restriction as to their specific structural features. This finding was confirmed by example 5 referring to a compound having a benzopyran-2-carboxylic acid core structure attached to a phenyl ring, i.e. compound IM 132.

Equally, none of the other mentioned diseases or disorders was viewed as a unifying concept. The

application is focused on the treatment of diabetes and the biological assays have been run only with regard to this activity. In addition, these other diseases/disorders are mostly known to be associated with diabetes as acknowledged in the application page 1, lines 14-34 and document (1), page 9, lines 16-27.

IV. With his statement of the grounds of appeal the Appellant submitted an auxiliary request. Furthermore, the Appellant requested the reimbursement of the appeal fee under Rule 67 EPC (1973) based on the allegation that substantial procedural violations were made by the Examining Division.

V. In a communication dated 6 April 2009 accompanying the summons to oral proceedings requested by the Appellant the Board expressed its preliminary view that the requirement of Article 82 EPC was fulfilled and indicated its intention to set the decision of the Examining Division aside and to remit the case to the first instance for further prosecution. With regard to the alleged violations the Board came to the preliminary conclusion that no substantial procedural violation, justifying reimbursement of the appeal fee, had been committed by the Examining Division. The Board also indicated that the sole remaining point to be discussed during the oral proceedings would be the requested reimbursement of the appeal fee.

VI. In response the Appellant informed the Board with letter of 12 June 2009 that he would not attend the oral proceedings scheduled for the 1 July 2009 and

submitted further arguments in support of the alleged procedural violations.

VII. With regard to the main request, i.e. the claims on which the refusal was based, the Appellant argued that the compounds of formula (I) of claim 1 share a common property/biological activity, i.e. the PPAR agonistic activity, and a common utility, i.e. treatment of diseases/disorders related to the PPAR agonistic activity. Furthermore, they have a significant structural element in common, which distinguishes them from those compounds known in the art having the same PPAR agonistic activity, for example the PPAR agonists referred to on page 5, lines 11-33 of the application. The criteria of unity are therefore fulfilled.

The Appellant contested the approach of the Examining Division to disregard the PPAR agonistic activity as a common novel property, and to consider only the therapeutic utility, namely the use in the treatment of diabetes, as a common property or activity in relation to criteria of unity. The Appellant also contested the relevance of the decision T 241/95 which was cited by the Examining Division in support of its approach, since contrary to the present application, this decision was concerned with a clarity issue of a second medical use claim.

The Appellant further argued that the PPAR agonistic properties are not only useful for the treatment of diabetes, but also for the treatment of a variety of other diseases not mentioned in document (1) and having no obvious link to diabetes. Any of these diseases could be considered as a special technical feature for the purpose of Rule 30(1) EPC (1973).

In addition, the Appellant disagreed with the analysis of document (1) by the Examining Division. According to him document (1) does not disclose the use of benzopyrans of the type as presently claimed for the treatment of diabetes, but is concerned with the use of non-peptidyl compounds which through binding to insulin receptors modulate the activity of theses receptors. This modulation can take the form of agonism and antagonism, whereby antagonists are not suitable for the treatment of diabetes. Document (1) discloses only 14 compounds and all the Benzopyran-type compounds are listed as antagonists. They are therefore not suitable for the treatment of diabetes.

VIII. The Appellant also contended that substantial procedural violations were made by the Examining Division.

He argued that his right to be heard under Article 113(1) EPC had been violated by the manner in which the Examining Division conducted both the written and oral proceedings. In particular the Appellant pointed out that after the Appellant's reply to the Examining Division's first communication stating lack of unity, the Examining Division immediately issued a summons to oral proceedings without providing any feedback to the Appellant's arguments or setting out the points to be discussed in the accompanying letter. The Examining Division also did not react to the Appellant's submission of 27 June 2005, i.e. one month before the oral proceedings, in which he repeated his earlier arguments in greater detail, provided further arguments, protested at the lack of feedback and

requested such a feedback before oral proceedings took place. According to the Appellant the Examining Division provided its interpretation of property or activity in the context of pharmaceuticals only at a very late stage during the oral proceedings and it was also at this very late stage that the Examining Division switched its attention to compound IM 132, i.e. example 5 of document (1), thus depriving the Appellant of an adequate opportunity to assess the relevance and significance of the Examining Division's arguments.

Furthermore, in the Appellant's opinion the Examining Division violated the requirement of Rule 68(2) EPC (1973) that a decision shall be reasoned, in that it failed to explain why the various therapeutic utilities other than diabetes cannot support a finding of unity. Additionally, he considered the fact that the Examining Division had completely disregarded these other therapeutic utilities as a breach of Article 113(1) EPC.

Finally, the Appellant was of the opinion that point 4 of the written decision contained arguments referring to the wording of claims in document (1) which were not mentioned at all in the proceedings and on which, therefore, the Appellant has had no opportunity to comment.

IX. The Appellant requested that the decision under appeal be set aside and the examination be resumed on the basis of claims 1-34 as originally filed and claims 35-39 as filed with letter of 23 April 2003 for entry into the European Phase, or, alternatively, on

the basis of claims 1-39 of the auxiliary request filed with the statement of grounds of appeal. The Appellant further requested that the appeal fee be reimbursed in view of the substantial procedural violations made by the Examining Division.

X. At the end of the oral proceedings, which were held before the Board on 1 July 2009 in the absence of the Appellant, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Absence of the Appellant at the oral proceedings before the Board*

2.1 In accordance with Article 15(3) RPBA (Rules of Procedure of the Boards of Appeal), the Board relied for its decision only on the appellant's written submissions set out in the statement of grounds of appeal and the letter of 12 June 2009. The Board was in a position to decide at the conclusion of the oral proceedings, since the case was ready for decision (Article 15(6) RPBA) and the voluntary absence of the appellant is not a reason for delaying a decision (Article 15(3) RPBA).

Main request

3. *Lack of unity of invention*

3.1 In accordance with Article 82 EPC the European patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. According to Rule 44(1) EPC the requirement of unity for a group of inventions is fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those features which define a contribution which each of the claimed inventions considered as a whole makes over the prior art.

3.2 Claim 1 of the present application refers to compounds of the general formula (I). Such a formula defines an invention or group of inventions in the sense of Article 82 EPC.

3.3 The compounds of formula (I) are PPAR agonists and as such are useful in the treatment of diabetes and conditions directly or indirectly associated with it as well as various other diseases and disorders (see application page 1, lines 14-25, page 6, lines 1-6 and claim 38). In this context it may be worth mentioning that the present application is not merely related to the treatment of diabetes, but of Type 2 diabetes, which is a particular form of diabetes requiring a different treatment compared to Type 1 diabetes.

3.4 The question to be examined is therefore whether the subject-matter of claim 1 defining a group of inventions lacks unity a posteriori in view of the disclosure in document (1).

3.4.1 Document (1) refers in general to the treatment of insulin related ailments by administering a compound which is a biological modulator of the insulin activity (see claim 1 of document (1)). The compound has ionic and hydrophobic chemical moieties located so as to mimic certain amino acids of insulin, which are associated with the binding of insulin to its receptor. Suitable modulators are non-peptidyl compounds of a very general formula $AXYXZ_n$ (see claim 7 of document (1)). In claim 11 and the description of document (1) fourteen compounds are explicitly mentioned. Examples 1, 3, 5 (IM 132), 6 (IM 134) and 10 (IM 171) of document (1) describe benzopyran-2-carboxylic acid compounds connected via a linker of at least three atoms to a phenyl group. The compounds of document (1) are not included in the present claims due to the fact that the substituent corresponding to R^4 of the presently claimed compounds differs, or that the compounds fall within the area that is disclaimed.

3.4.2 The modulation of the activity in document (1) can take the form of agonism or antagonism of insulin or insulin-like activity. Diabetes, Type 1 as well as Type 2, characterised by hyperglycaemia, i.e. elevated levels of glucose in the blood, is described as **one** of the ailments to be treated, but the description of document (1) also mentions **other** clinical conditions like hyperinsulinism, insulinomas, characterised by hypoglycaemia, i.e. low levels of glucose in the blood (see page 9, line 22 - page 11, line 2, page 12, line 4 - page 13, line 5). According to document (1) antagonists of insulin would be suitable to treat conditions involving hyperinsulinism and hypoglycaemia (see page 14, lines 5-10). Their effect would be to

reduce the hypoglycaemic action of insulin, i.e. they would increase the blood glucose levels, which would be clearly contra-indicated for patients with a high blood glucose level. These facts have not been denied by the Examining Division.

3.4.3 Document (1) discloses fourteen examples which have been identified as modulators for the insulin receptor. Eleven of these compounds have been identified as antagonist (see page 56, line 9 - page 64, line 2) and three as agonists (see page 64, line 3 - page 69, line 6). **All compounds** with a benzopyran structure have been characterised as **antagonist** in document (1). Thus, these compounds, according to document (1), would not be suitable for the treatment of diabetes, let alone Type 2 diabetes.

3.4.4 The Examining Division is of the opinion that the teaching of document (1) is not limited to the examples, but discloses that the compounds mentioned in document (1) may be either agonists or antagonists of insulin receptors without restriction as to specific structural features, thus being useful in the treatment of hyperglycaemia (diabetes) or hypoglycaemia. Apparently, the Examining Division assumed that benzopyrans, although being insulin antagonists according to document (1), which would render them unsuitable for the treatment of diabetes, may also be agonists. In this context the Examining Division pointed to claim 11 of document (1), which refers to the compounds of the examples. Since this claim refers back to claim 1, document (1) describes these compounds suitable for any insulin related disease. To support its view the Examining Division referred to example 5 of document

(1), i.e. IM 132, which is described as an antagonist, but, in the presence of insulin, shows significant synergism with insulin in the glucose transport. The Examining Division came to the conclusion that this example shows that the compound of example 5 is useful in the treatment of diabetes, especially Type 2 diabetes, wherein patients exhibit normal or even elevated plasma insulin levels.

3.4.5 The Board does not share the Examining Division's point of view. Example 5, i.e. IM 132, which has a benzopyran-2-carboxylic acid ring attached via a linker to a phenyl group, and thus shares the common structure with the presently claimed compounds, is clearly listed under the **heading "antagonist"**, and thus is basically unsuited for the treatment of diabetes. In one particular assay a synergistic activity with insulin has been found for this single compound, increasing the effect of a **submaximal** dose of insulin (2 nM) to levels obtained by 100 nM. The conclusion drawn in document (1) was that this compound may be interacting in a more complex manner with the insulin receptor at the insulin binding site. Contrary to the Examining Division's view, this finding cannot lead to the conclusion that IM 132, undisputedly characterised as antagonist, shows anti-diabetic activity. Furthermore, it is against the proper reading of document (1) to conclude from such a single compound, which differs from the presently claimed compounds as well as from the other clearly antagonistic benzopyran compounds by virtue of the substituent in position four of the phenyl ring, that benzopyran-2-carboxylic acid compounds attached via a linker to a phenyl group with anti-diabetic activity, particular of Type 2, are known.

The Board also notes that example 5 in document (1) refers to a synergistic effect of the compound with a **submaximal** dose of insulin. In Type 2 diabetes the level of insulin is usually the same or elevated compared to non-diabetic subject (see the present application page 1, line 28-30). It would not be described as submaximal.

3.4.6 Furthermore, the Examining Division argued that the PPAR activity, being merely a newly discovered mechanism of action of known compounds for a known use, cannot be used as the basis for unity of invention. As document (1) does not disclose benzopyran-2-carboxylic acid compounds attached via a linker to a phenyl group for the treatment of Type 2 diabetes (see point 3.4.5 above), this argument of the Examining Division must fail. It is also to be remarked that claim 1 of the main request is directed to compounds (see point II of this decision), not to a second medical use claim as in the decision T 241/95 which the Examining Division cited in support for its interpretation.

3.5 For the reasons set out above the Board comes to the conclusion that the property or activity of benzopyran-2-carboxylic acid compounds attached via a linker to a phenyl group to treat diabetes of Type 2 due to their PPAR agonistic activity, as well as other diseases and disorders known to be related to the PPAR agonistic activity, can be considered as the special technical feature defining the contribution over the prior art. The application therefore meets the requirement of Article 82 EPC.

4. *Procedural violations*

4.1 The Appellant considered the failure of the Examining Division to provide in its communication accompanying the summons to oral proceedings an indication as to the points to be discussed, including a feedback on the applicant's response of 28 April 2004 and an indication as to why the objection of lack of unity is maintained, a serious breach of the Appellant's right under Article 113(1) EPC, particularly due to the fact that during the oral proceedings the Examining Division focused its attention for the first time on a different example and some particular case law (see point VII above). In this context the Appellant referred to the first sentence of Rule 71(a) EPC (1973, now Rule 116 EPC), which reads:

"When issuing the summons, the EPO shall draw attention to the points which in its opinion need to be discussed for the purpose of the decision to be taken"

4.2 The Board does not share the Appellant's point of view. Article 113(1) EPC requires parties to be given the opportunity to present their comments on the grounds or evidence on which the European Patent Office bases its decision. For the purpose of this Article the oral and the written procedure enjoy the same status. They are equivalent alternatives having the same value in preparing the basis for arriving at a decision, and it is at the discretion of the Examining Division to chose between them. Thus, even if further aspects for an objection, which has been communicated beforehand, are presented for the first time during oral proceedings, this does not amount to a breach of Article 113(1) EPC

provided that when the decision is taken the parties have been given an adequate opportunity to comment on these aspects. It follows that the requirement of Rule 116 EPC does not means that already in the communication all lines of arguments or a detailed reasoning for the decision should be set out.

4.2.1 In the present case, the Examining Division appointed oral proceedings as requested by the Appellant, thus providing a further opportunity for an exchange of arguments and comments before taking a decision. In its communication accompanying the summons to oral proceedings the Examining Division indicated the point to be discussed, namely the lack of unity, and referred to its first communication where it was indicated that no common element was present in view of document (1). This position was also maintained in the decision (see Reasons for the decision point 1.). A further detailed explanation of the objection was not required, although, that may have been helpful in the present case.

4.2.2 During the oral proceedings the Examining Division provided further arguments for its position, namely its interpretation of utility and activity as well as the relevance of the compound IM 132. These arguments did not amount to an introduction of new facts or evidence, but were in fact explanations and reasons as to why the Appellant's arguments were not considered convincing. In these circumstances the Appellant was in a position to deal with any such explanations offered by the Examining Division during oral proceedings which included the grounds on which the decision under appeal was based within the meaning of Article 113(1) EPC.

4.2.3 The Board also observes that, although it is in general the purpose of oral proceedings to settle as far as possible all outstanding issues relevant to a decision, the Examining Division is not required to render an immediate decision at the end of these oral proceedings. The Appellant could have asked for an interruption or an adjournment of the oral proceedings in order to be able to carefully consider the Examining Division's arguments, which were apparently crucial to the decision, if he had felt that he was not in a position to adequately address these points and needed time for further reflection. According to the minutes the Appellant did not request such an interruption or adjournment, and it was never alleged and there is no indication whatsoever that the Examining Division refused to hear the Appellant on these points.

4.3 With regard to the feedback requested by the Appellant with his written submissions filed one month before the date of the oral proceedings, the Board observes the following:

The Examining Division had decided to continue the procedure orally in accordance with the Appellant's request, and, therefore, had set a date for oral proceedings. Although, in accordance with Rule 116 EPC, the applicant may make written submissions in preparation for the oral proceedings within the time limit set by the Examining Division, here one month before the oral proceedings, he cannot expect to be sent a further written communication in reply to his submission, which would be at variance with the Examining Division's decision to continue the procedure

orally (and often, as a matter of fact, not possible in view of the time left).

4.4 In conclusion, no substantial procedural violation occurred by the way the Examining Division conducted the procedure. Whether that way was the optimal one, is not a matter to be considered by the Board.

4.5 The Appellant further contended that the Examining Division had failed to consider all the facts and arguments provided by the Appellant in support of his case, in particular the therapeutic uses mentioned in addition to the anti-diabetic use, which qualified a violation of Rule 68(2) EPC (1973) and Article 113(1) EPC. In this context he referred to the decision T 763/04, where it was held that Article 113(1) EPC is not complied with where facts and arguments central to the appellant's case are **completely** disregarded in the decision in question and where there is **no trace** in the file that such comments were indeed heard and considered by the deciding instance.

Furthermore, according to the Appellant, point 4 of the reasons for the decision contained reasoning related to the claim wording in document (1) on which the Appellant had no opportunity to comment.

4.6 The Board does not agree with the Appellant's view.

According to Rule 68(2) EPC 1973 decisions which are open to an appeal shall be reasoned, which means they must contain a logical chain of facts and reasoning in order to enable the appellants and the boards of appeal

to examine whether the decision was justified or not. In the present case the decision sets out the objection of the Examining Division based on the analysis of document (1). It contains the arguments brought forward by the Appellant and gives reasons why the examining division did not accept these arguments.

It is also apparent that the Examining Division considered the arguments put forward by the Appellant with respect to the various other therapeutic uses and provided reasons why it did not accept them (see point 3 of the decision). According to the Examining Division the decisive fact was that both the application and the document (1) targeted the same disease with compounds of the same core structure. Since the PPAR activity, according to the interpretation of the Examining Division, was not considered as the unifying feature, the Division had no reason to go into a more detailed discussion of disorders related to this feature. The question of whether the Examining Division correctly assessed the disclosure of document (1) or the nature of the claimed invention, or whether its interpretation with regard to the PPAR activity was correct, is a substantive and not procedural issue and, therefore, cannot give raise to a procedural violation.

Furthermore, the case underlying the decision T 763/04 differs from the present situation. In T 763/04 the Examining Division in its decision merely referred to its own final communication and apparently did not consider **any** of the facts and arguments provided by the appellant in response to this communication.

With regard to the issue of the new arguments presented for the first time in the decision, the Board observes that the reasoning of the Examining Division in point 4 of the reasons of the decision is based on the relevance it attributed to the example 5 of document (1). According to the minutes this example was discussed during the oral proceedings and, therefore, the Appellant had an opportunity to present his comments. Whether the Examining Division correctly assessed the importance of this example or "inflated" it by referring to the claims of document (1), which included this example anyway, is again a substantive matter, and not a procedural issue.

4.7 For these reasons no substantial procedural violations, justifying the reimbursement of the appeal fee (Rule 67 EPC 1973) occurred in the present case.

5. *Remittal*

In accordance with Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case for further prosecution. While this Article gives the Boards of Appeal the power to include fresh issues in ex-parte cases, proceedings before the Boards of Appeal in ex-parte cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons).

The Examining Division refused the application on the sole ground of lack of unity. Other issues have not yet been considered.

In these circumstances the Board considers it appropriate to remit the case to the Examining Division so that the Appellant has the opportunity to defend his case without loss of an instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance for further prosecution of the substantive examination on the basis of claims 1-34 as originally filed and 35-39 as filed with letter of 23 April 2003.

3. The request of reimbursement of the appeal fee is rejected

The Registrar: The Chairman:

M. Schalow P. Ranguis