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Datasheet for the decision of 1 February 2008

Case Number: W 0018/07 - 3.3.04

Application Number: PCT/EP 2006/004314

Publication Number: WO 2007/115582

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Language of the proceedings: EN

Title of invention:
HPV detection and quantification by real-time multiplex amplification

Applicant:
BIO-RAD PASTEUR

Opponent:
-

Headword:
HPV detection and quantification/BIO-RAD PASTEUR

Relevant legal provisions:
PCT Art. 16, 17
PCT R. 13, 22, 39, 40, 42
EPC Art. 113(1)

Relevant legal provisions (1973):
EPC Art. 154

Keyword:
"Unity of invention (yes)"
"Procedural violation by a statement of the ISA (no)"

Decisions cited:
G 0001/89, W 0013/87, W 0001/97, W 0017/00, W 0020/06

Catchword:
- see points 14 to 29

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Case Number: W 0018/07 - 3.3.04

International Application No. PCT/EP 2006/004314

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 1 February 2008

Applicant: BIO-RAD PASTEUR
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Decision under appeal: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 15 January 2007.**

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
T. Bokor

Summary of Facts and Submissions

I. International patent application no. PCT/EP2006/004314 published as WO 2007/115582 and having the title "HPV detection and quantification by real-time multiplex amplification" was filed on 11 April 2006 with 49 claims.

Claim 1 read as follows:

"1. Process for detecting in a sample at least one HPV, which can be oncogenic for the mucosal epithelia, wherein said detection comprises the determination of whether at least one amplicon has been, or is, produced from said sample, or from nucleic acid material thereof, by amplification by means of amplification primers, whereby the production of at least one amplicon indicates that at least one HPV, which can be oncogenic for the mucosal epithelia, is present in said sample, characterized in that said amplification primers comprise:

- at least two primers, which are intended for targeting oncogenic HPV of group A6, wherein said at least two A6-targeted primers are oligonucleotides, which consist of 14-30 nucleotides, the sequences of which are suitable for use as forward and reverse primers, respectively, in the amplification of at least one A6 reference template sequence, wherein said at least one A6 reference template sequence is a fragment consisting of positions 413-791 (SEQ ID NO:337) of the HPV56 sequence of SEQ ID NO:420 (accession NC_001594.1), or of a conservative sub-fragment thereof, which has retained the property of being a suitable reference

template sequence, to construct and produce A6-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia,

and/or

- at least two primers, which are intended for targeting oncogenic HPV of group A5, wherein said at least two A5-targeted primers are oligonucleotides, which consist of 14-30 nucleotides, the sequences of which are suitable for use as forward and reverse primers, respectively, in the amplification of at least one A5 reference template sequence, which is a fragment consisting of positions 678-902 (SEQ ID NO:326) of the HPV51 sequence of SEQ ID NO:421 (accession NC_001533.1), or of a conservative sub-fragment thereof, which has retained the property of being a suitable reference template sequence, to construct and produce A5-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia,

and/or

- at least two primers, which are intended for targeting oncogenic HPV of group A9, wherein said at least two A9-targeted primers are oligonucleotides, which consist of 14-30 nucleotides, the sequences of which are suitable for use as forward and reverse primers, respectively, in the amplification of at least one A9 reference template sequence, which is:

- a fragment consisting of positions 2707-2794 (SEQ ID NO:122) of the HPV16 sequence of SEQ ID NO:422 (accession NC_001526.1), or a conservative sub-fragment thereof, which has retained the property of being a suitable reference template sequence, to construct and produce A9-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia, or
- a fragment consisting of positions 3600-3840 (SEQ ID NO:377) of the HPV16 sequence of SEQ ID NO:422 (accession NC_001526.1), or of a conservative sub-fragment thereof, which has retained the property of being a suitable reference template sequence, to construct and produce A9-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia,

and/or

- at least two primers, which are intended for targeting oncogenic HPV of group A7, wherein said at least two A7-targeted primers are oligonucleotides, which consist of 14-30 nucleotides, the sequences of which are suitable for use as forward and reverse primers, respectively, in the amplification of at least one A7 reference template sequence, wherein said at least one reference template sequence is:

- a fragment consisting of positions 1895-2103 (SEQ ID NO:48) of the HPV18 sequence of SEQ ID NO:423 (accession NC_001357.1), or of a conservative sub-fragment thereof, which has

retained the property of being a suitable reference template sequence, to construct and produce A7-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia, or
- a fragment consisting of positions 916-1044 (SEQ ID NO:65) of the HPV18 sequence of SEQ ID NO:423 (accession NC_001357.1), or of a conservative sub-fragment thereof, which has retained the property of being a suitable reference template sequence, to construct and produce A7-targeted primers, which allow for a real-time multiplex detection of those HPV, which can be oncogenic for the mucosal epithelia,

said A6, A5, A9 and A7 reference template sequences sharing the special technical feature of being group-based reference template sequences, which are suitable to construct and produce primers and amplicon-annealing probes, which allow for a real-time multiplex amplification of at least the five most common HR HPV (HPV16, 18, 45, 31, 33), preferably of at least 7 HR HPV, still preferably of the five most common HR HPV as well as at least two other HR HPV, advantageously at least two other HR HPV belonging to groups A6 and/or A5 (e.g., HPV 56, 51, 33, 31, 16, 45, 18), more preferably of at least the 13 HR HPV (HPV56, 51, 58, 33, 52, 35, 31, 16, 68, 39, 59, 45 and 18), and more particularly for a real-time quantitative multiplex amplification of such HPV."

II. On 15 January 2007, the European Patent Office (EPO), acting in its capacity as International Searching Authority (ISA) under Article 16 PCT and Article 154

EPC, informed the applicant that the application did not comply with the requirement of unity of invention (Rule 13.1 PCT) and invited the applicant to pay within a time limit of one month twelve additional search fees in accordance with Article 17(3)(a) PCT and Rule 40.1. PCT.

III. In the invitation to pay additional fees, the ISA defined inventions 1 to 13 to which the application related as follows:

"Invention 1 (claims 1-49 all partially)

A process for the detection in a sample of at least one HPV, which can be oncogenic for the mucosal epithelia, by amplification, the polynucleotide of SEQ ID NO:337, the primers therein contained, the primer systems comprising at least one of these primers, amplicons obtainable thereby, probes and beacon probes to detect said amplicons, primer and probe systems comprising said primers and probes, amplification compositions comprising said amplicons, kits comprising said primers and probes.

Inventions 2-10 (claims 1-49 all partially)

The same as invention 1, wherein the polynucleotide is one of the SEQ ID NOs: 25-29, 334-336, and 338 wherein
invention 2 = SEQ ID NO:25
.....
invention 10 = SEQ ID NO:338

Invention 11 (claims 1-49 all partially)

Process and sequences and to detect HPV group A5. These include the process for the detection in a sample of at least one HPV, which can be oncogenic for the mucosal epithelia, by amplification, the polynucleotide of SEQ ID NOs:1-5 and 320-333, the primers therein contained, the primer systems comprising at least one of these primers, amplicons obtainable thereby, probes and beacon probes to detect said amplicons, primer and probe systems comprising said primers and probes, amplification compositions comprising said amplicons, kits comprising said primers and probes.

Invention 12 (claims 1-49 all partially)

Process and sequences to detect HPV group A9. These include the process for the detection in a sample of at least one HPV, which can be oncogenic for the mucosal epithelia, by amplification, the polynucleotide of SEQ ID NOs:122-210 and 359-419, the primers therein contained, the primer systems comprising at least one of these primers, amplicons obtainable thereby, probes and beacon probes to detect said amplicons, primer and probe systems comprising said primers and probes, amplification compositions comprising said amplicons, kits comprising said primers and probes.

Invention 13 (claims 1-49 all partially)

Process and sequences to detect HPV group A7. These include the process for the detection in a

sample of at least one HPV, which can be oncogenic for the mucosal epithelia, by amplification, the polynucleotide of SEQ ID NOs:46-67 and 339-358, the primers therein contained, the primer systems comprising at least one of these primers, amplicons obtainable thereby, probes and beacon probes to detect said amplicons, primer and probe systems comprising said primers and probes, amplification compositions comprising said amplicons, kits comprising said primers and probes."

IV. The invitation made reference to the following documents:

(1) Prado et al., Virology (2005) 340: 95-104

(2) De Villiers et al., Virology (2004) 324: 17-27

(3) Moberg et al., J. Clin. Microbiol. (2003) 41: 3221-3228

The ISA stated that the technical problem of the application was a PCR amplification process for the simultaneous detection of different oncogenic HPV types from a sample. The proposed solutions were oligo-nucleotide primers and reference templates adapted to the multiplex PCR process. However, this concept was known from document (3), which disclosed a real-time PCR based system for simultaneous amplification of HPV types associated with high risk of cancer and primers thereof. In view of this prior art, the technical problem solved by the application now was the provision of further multiplex PCR primers for detecting HPV.

The classification of HPV types in phylogenetic groups (A6, A5, A9, and A7) was not new, in that document (2) showed the same phylogenetic groups that were the subject-matter of the application and provided a list of all the HPV types therein included with the respective GenBank sequence IDs. Since designing amplification primers for a multiplex real-time PCR process from known sequences represented a methodology of common routine for the person-skilled-in-the-art, no common inventive concept linking the different alternative solutions provided in the application could be identified.

Since no other special technical features could be distinguished which in view of the prior art could be regarded as special technical features in the sense of Rule 13.2 PCT, the ISA was of the opinion that there was no single inventive concept underlying the plurality of claimed inventions of the application in the sense of Rule 13.1 PCT. Since the sequences and the process to detect the A6, A5, A9, and A7 groups were not linked by a common inventive concept, the claimed subject-matter for each of these groups could be regarded as a different invention and the application could be subdivided in four separate inventions:

1) process and sequences to detect HPV group A6
2) process and sequences to detect HPV group A5
3) process and sequences to detect HPV group A9
4) process and sequences to detect HPV group A7

The common concept for invention 1 was also not new in view of document (1) which disclosed a PCR process with

consensus primers for the simultaneous amplification of HPV types 53, 56, and 66, which constitute the phylogenetic group A6. Therefore, invention 1 could be further subdivided.

Finally, the ISA stated: "The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search. No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W 17/00, point 11 and W 1/97, points 11-16)."

V. The communication of 15 January 2007 also contained the results of the partial international search.

VI. On 24 January 2007, the applicant sent an e-mail to the department for international PCT affairs of the EPO,

requesting advice on a legal issue. Said department replied to the applicant's questions with e-mail of 7 February 2007.

VII. With letter dated 13 February 2007, the applicant paid twelve additional fees under protest. The protest fee was also paid.

The applicant submitted that the ISA's reasoning in the invitation to pay additional fees lacked clarity and substantiation as it was based on a complex combination of document D3 with document D2 and two assertions not supported by documentary evidence.

The paragraph at the end of the ISA's invitation stating that if the applicant paid additional fees for one or more not yet searched group(s) of invention, and the further search(es) were to reveal further prior art giving evidence of a further lack of unity a posteriori, then a search would only be carried out for the first invention thus identified, without a further invitation to pay additional fees, amounted to a substantial procedural violation. The applicant would be placed in a position where it did not know what it would get for the fees being paid, and where it would not be allowed to obtain any search for those newly-identified sub-groups which were not the first ones within each of inventions 11 to 13, amounting to a refusal to proceed to international search. This practice was in conflict with the basic principles of procedural law and deprived the applicant from its right of having a comprehensive international search.

The applicant furthermore submitted arguments why the application complied with the requirement of unity of invention.

VIII. On 10 April 2007, the ISA invited the applicant to pay a protest fee (unless such fee had already been paid) and informed the applicant that a prior review had reached the conclusion that the invitation to pay additional search fees was justified in part. As the applicant's arguments concerning the unity of invention of inventions 1 to 10 (referred to as group 1) could be followed, nine of the additional search fees paid by the applicant would be refunded. However, the non-unity objection and the additional search fees for inventions 11 to 13 were maintained.

IX. On 25 April 2007, the ISA issued the international search report for all claims.

X. With letter of 9 May 2007, the applicant confirmed that it wished to continue with the protest, and submitted further arguments.

Reasons for the Decision

Procedural issues

1. Given that the international application under consideration has an international filing date of 11 April 2006, the protest is subject to the provisions of the PCT as in force from 1 April 2006.

2. The board is competent to decide on the protest, following decision W 20/06, points 1 to 9 of the Reasons. Also, the protest fee was paid in time, and the protest is considered to have been made (Rule 40.2(e) PCT, second sentence).

3. The protest is reasoned and thus admissible.

4. As a result of its "prior review", the ISA informed the applicant that the nine additional search fees paid by the applicant for inventions 2 to 10 would be refunded. Only the non-unity objection for inventions 11 to 13 was maintained by the ISA.

Under these circumstances, the board is only concerned with the question whether or not the invitation to pay additional search fees in respect of groups 11 to 13 was justified.

Invitation to pay additional fees sufficiently reasoned

5. Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must specify the reasons why the international application is not considered to comply with the requirement of unity of invention.

6. The applicant submits in its letter dated 13 February 2007 that the invitation to pay additional fees issued by the ISA was unjustified because the reasons lacked clarity and substantiation.

7. The purpose of the provision under Rule 40.1 PCT is to enable the applicant (and the board in case of a

protest) to examine whether the invitation is justified. This requires that the invitation must be drafted in a form that is suited to fulfil this purpose, i.e. the reasoning must be comprehensible.

8. In its invitation to pay additional fees, the ISA states that in view of document (3), the technical problem solved by the application was the provision of further multiplex PCR primers for detecting HPV, and that in view of document (2) and common general knowledge, no common inventive concept linking the different alternative solutions provided in the application could be identified. Although this line of argument is somewhat unusual, inter alia because it lacks an analysis of the special technical features of each of the separate inventions, the board is convinced that the addressee of the ISA's invitation would nevertheless be able to understand the essence of the reasoning.

9. Hence, the ISA has fulfilled its obligation to substantiate its finding of non-unity.

Examination of the protest

10. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack unity of invention, it is empowered, under Article 17(3)(a) PCT, to invite the applicant to pay additional fees.

11. Lack of unity may be directly evident *a priori*, i.e. before the examination of the merits of the claims in comparison with the state of the art revealed by the search (cf., for example, decision W 13/87 of 9 August 1988). Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal (OJ EPO 1991, 155), the ISA may also raise an objection *a posteriori*, i.e. after having taken the prior art revealed by the search into closer consideration. The Enlarged Board of Appeal indicated that such consideration represents only a provisional opinion on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination of the application (point 8.1. of the Reasons for the decision). In point 8.2 of the Reasons, the Enlarged Board mentioned that such invitation to pay additional fees should always be made "with a view to giving the applicant fair treatment" and should only be made in clear cases.

12. The ISA has based its finding of lack of unity upon *a posteriori* considerations (see section IV above).

12.1 In the invitation to pay additional fees, the ISA did not call into question the novelty of the processes according to claim 1 over any of documents D1 to D3. The board likewise sees no reason to doubt the novelty of the processes according to claim 1 over any of these documents.

12.2 In its reasoning as to why the application lacked unity, the ISA formulated the technical problem solved by the application on the basis of document (3), and argued that in view of document (2) and common general

knowledge, no common inventive concept linking the different alternative solutions provided by the application could be identified. This line of argument thus concerned the question whether or not the claimed subject-matter involves an inventive step.

12.3 However, according to decision G 1/89 (*supra*), restraint should be exercised in the assessment of novelty and inventive step, and in borderline cases it should be refrained from considering an application as not complying with the requirement of unity of invention on the grounds of lack of novelty or inventive step.

12.4 In the present case, the board considers that the assessment of an inventive step of the claimed subject-matter over a combination of documents (3) and (2) and common general knowledge would involve complex considerations, which, in order to give the applicant fair treatment, would require a detailed discussion with the applicant. The present case is therefore not a case in which an assessment of inventive step should be made in the context of unity of invention.

13. Consequently, the application is considered to comply with the requirement of unity of invention under Rule 13.1 PCT.

Procedural violation

14. In the protest, the applicant also submitted that the general reservation of the ISA at the end of the invitation (see point VII above) constitutes a "substantial procedural violation".

15. Firstly, it is not immediately apparent from the protest what the appellant seeks to achieve by this statement. The PCT - in contrast to the EPC - does not use the notion of "substantial procedural violation", and even if the board supported this finding concerning its substance, no further legal consequences could be drawn from this, in the absence of any legal basis.

16. Secondly, it is noted that all claims were covered by the final International Search Report, so the applicant did actually receive what he expected following the payment of the additional fees, namely a comprehensive search. In that sense the applicant did not suffer any injustice on a substantive basis. The complaints thus appear to be of theoretical nature only. For these reasons alone, this objection would need no further consideration.

17. However, in order to clarify the legal framework of the search and protest procedure under the PCT, the board deems it expedient to address this issue, not the least because the objected final passage of the invitation (see last paragraph of point IV) appears to be a standard clause used by the ISA. Thus, applicants may be expected to encounter it on a regular basis, and therefore its proper interpretation appears desirable.

18. The applicant mentioned several facts which are perceived not only as apparently unjust, but directly violating its procedural rights, such as:

(a) the right to have all claims searched in the international stage ("the right to have a comprehensive international search");

(b) the right of the applicant to comment on non-unity objections;

(c) the right to know what search may be expected for the paid search fees.

19. These rights of the applicant are also perceived by the applicant as an obligation of the ISA

(a) to conduct the search procedure in a manner which allows applicants to have all claims searched under any circumstances;

(b) to refrain from raising non-unity objections on which the applicant has no opportunity to comment;

(c) to identify all non-unitary groups of inventions once for all, i.e. in the first invitation.

20. These rights vs. obligations are only perceived by the applicant. The PCT Chapter I procedure indeed seeks to provide a procedure which - in most cases - ends with all claims searched, where no further non-unity objections are raised, and if any are raised, they may all be commented on (as far as the protest procedure may be considered as a possibility to "comment", see below). However, these are merely general objectives of the search procedure, but not absolute, guaranteed rights of the applicant.

21. The international search procedure pursuant to Article 17 PCT is primarily governed by the tight time frame available for the search, said time frame being

dictated by the legislative intention to publish the search report together with the application and to complete the search until entry into the national phase at the end of the PCT Chapter I procedure, which was originally 20 months after the priority date. Adding up the time limits available to the International Bureau and the ISA (13 months (Rule 22.1 (a) PCT) + 3 months (Rule 42.1 PCT) + 1 month (Rule 40.1 (ii) PCT) + 3 months (Rule 42.1 PCT), it becomes evident why neither further rounds of invitations nor searches are foreseen by the PCT (see also W 0001/97, OJ EPO 1999, 33, Headnote and points 11 and 12 of the reasons and W 0017/00 of 21 May 2001, point 11 of the reasons).

22. Since a "third" round of search is thus not provided for in the PCT, there is also no need for an **invitation** to pay further fees, hence no need either for a further protest procedure for "commenting" on the finding of non-unity which might arise from the results of the second round of search. In that respect, no rights of the applicant are violated. Further, as explained below, the protest procedure is not "an opportunity to comment" on the **finding** of non-unity, but a procedural possibility to reclaim search fees paid unnecessarily.

23. On the other hand, neither the Articles nor the Rules of the PCT imply that the second round of search(es) performed by the ISA (i.e. the searches performed for the additional search fees pursuant to Rule 40 PCT) should be performed by a methodology significantly different from that used when performing the first round of search. This methodology expressly foresees that the examiner addresses the issue of non-unity, both on an "*a priori*" and "*a posteriori*" basis. The

possibility of raising a non-unity objection "*a posteriori*" is a long recognised principle of the search procedure under the PCT. It may not be directly mentioned in the Articles, but nevertheless it is explained at length, both in the Guidelines and in the Administrative Instructions. This issue was specifically addressed by the Enlarged Board of Appeal in decision G 1/89 (*supra*).

24. Thus, there is no provision in the PCT which would forbid the ISA to raise any non-unity objection when the second round of search is performed. Such finding indeed serves the interest of the applicant in view of the later procedure before the national offices, while at the same time seeks to strike an equitable balance between the interest of the applicant and that of the office, which latter can only be expected to search one invention for one search fee.

25. Given the generally recognized methodology of establishing non-unity (see point 23 above) and considering it in the light of the applicant's argumentation (see points 18 and 19 above), it would seem absurd if the examiner would be required to establish a finding of unity for claims which were not yet searched. However, it is clear that no "*a priori*" unity objections can be raised in a second finding of non-unity. It appears equally absurd to require of an examiner to predict with an absolute certainty which groups of inventions will remain unitary even after a search. It is of course expected from him to identify those groups which are **likely** to remain unitary, while also corresponding to the presumed intentions of the applicant, but guarantees can not be given. The passage

of the invitation objected to by the applicant simply expresses this fact, and it is regarded by the board as an appropriate warning to the applicant. Given that the present application contains a large number of gene sequences, such a warning appears justified, and need not give rise to the fears voiced by the applicant.

26. From the above it follows that the PCT does not provide any legal guarantees that all claims of an international application are going to be searched in the international phase even beyond the scope of Article 17(2)(a) and Rule 39 PCT. It may happen, albeit rarely, that some claims can only be searched in full during the national phase. It might have been helpful if the warning of the ISA had an express reference to this latter possibility, thus making it clear that the applicant is in fact not deprived from the "right" to have all claims searched, though possibly at a later stage of the grant proceedings.

27. Contrary to the position of the applicant, it is clear from the invitation what the applicant may expect for the paid further search fees: The search of those inventions that the examiner has unilaterally defined, to the extent that these (groups of) inventions are reflected in the features of those claims which were assigned by the examiner to the established (groups of) inventions, unless it turned out that these inventions again lack unity.

28. The possibility of establishing the (groups of) inventions unilaterally may appear unjust to the applicant, but this is, how it is foreseen by the PCT. Not even the protest procedure provides the applicant

with the procedural right to interfere with the choice of the examiner, in the sense that the applicant is entitled to suggest different (groups of) inventions, though this is not excluded (see W 0001/97, *supra*, point 16 of the reasons). There is no requirement for the applicant to be heard in the strict sense of Article 113(1) EPC, because no rights can be lost in the PCT procedure, once such rights have been established. Due to the strictly limited time frame, it is **not** foreseen that the applicant enters into a dialogue with the examiner about unity of invention in the light of the available prior art. The purpose of the protest procedure is only to compensate the applicant for any financial loss, in case the non-unity objection of ISA - later - turns out to be unfounded.

29. In light of the above, the position of the applicant of a "substantial procedural violation" is unfounded.

Order

For these reasons it is decided that:

1. Refund of the three additional search fees paid by the applicant is ordered.

2. The protest fee shall be refunded.

The Registrar: The Chair:

P. Cremona U. Kinkeldey