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D E C I S I O N
of 25 April 2006

Case Number: T 0248/05 - 3.3.08

Application Number: 93108764.7

Publication Number: 0560411

IPC: G01N 33/52

Language of the proceedings: EN

Title of invention:
Specific binding assays

Patentee:
Inverness Medical Switzerland GmbH

Opponents/Interveners:
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2. VEDA LAB
3. Cardimac Gesellschaft für Diagnostische Schnellteste mbH
4. Opfermann Arzneimittel GmbH
5. Adexpert GmbH
6. Acon Laboratories
7. Biomar Diagnostic Systems GmbH
8. Quidel Deutschland GmbH
9. QUIDEL CORPORATION
10. Progen Biotechnik

Headword:
Particulate direct label/INVERNESS

Relevant legal provisions:
EPC Art. 123(2), 104(1)

Keyword:
"Main request - added subject-matter (no)"
"Apportionment of costs (no)"
"Remittal to the first instance (yes)"

Decisions cited:
G 0001/03

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0248/05 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 25 April 2006

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 5 January 2005 revoking European patent No. 0560411 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
B. Günzel

Summary of Facts and Submissions

I. European patent No. 0 560 411 was granted on the basis of European patent application No. 93 108 764.7, which was a divisional patent application of the earlier European patent application No. 88 303 744.2 published and granted as European patent 0 291 194. The patent was opposed by two opponents (opponents 01 and 02) and nine interveners under Article 105 EPC (opponents 03 to 11) on the grounds of Articles 100(a), (b) and (c) EPC. The patent was revoked because the sole request before the opposition division (claims as granted) was considered to contain subject-matter which extended beyond the content of the application as filed (Articles 100(c), 123(2) and 76(1) EPC). The intervention by intervener 11 was not considered admissible for being late filed.

II. The patentee (appellant) lodged an appeal against this decision and, with the statement of grounds of appeal, filed auxiliary requests 1 to 12.

III. The opponent 02 (respondent II) and interveners/opponents 04, 05 and 06 (respondents IV, V and VI) replied to the appellant's statement of grounds of appeal.

IV. With the summons to the oral proceedings, a communication under Article 11(1) of the Rules of Procedure of the Boards of Appeal (OJ EPO, 2003, 89) was sent to the parties. The Board indicated therein its preliminary opinion and informed the parties of its intention to remit the case to the first instance

(Article 111(1) EPC), if the issues on Articles 123(2) and 76(1) EPC were decided in favour of the appellant.

V. The appellant replied to the board's communication and requested the board to address the whole case at the oral proceedings.

VI. The respondents II and IV (opponent 02 and intervener/opponent 04) replied to the board's communication, the latter respondent requesting the board not to address the whole case at the oral proceedings.

VII. With letter dated 21 April 2006, the intervener/opponent 06 withdrew its intervention and opposition.

VIII. The respondent V (intervener/opponent 05) and the respondents VIII to X (interveners/opponents 08, 09 and 10) announced their intention not to attend the oral proceedings

IX. Respondent I (opponent 01) and respondent III (intervener/opponent 03) did not reply to the board's communication.

X. Oral proceedings, which took place on 25 April 2006, were attended by the appellant, respondents II and IV (opponent 02 and intervener/opponent 04), and the respondent VII (intervener/opponent 07).

XI. Claim 1 as granted read as follows:

"A specific binding assay involving the use of a labelled reagent specific for an analyte which labelled reagent is free to migrate through a porous carrier (206) moistened by the application thereto of an aqueous sample suspected of containing the analyte, there being a detection zone (209) on the porous carrier, in which detection zone an unlabelled specific binding agent for the analyte is permanently immobilised and is therefore not mobile in the moist state, which unlabelled specific binding agent can participate in a sandwich-format reaction with the analyte and the labelled reagent, the porous carrier comprising part of an analytical test device, characterized in that

a) the label is a particulate direct label;

b) there is a control zone (210) on the porous carrier downstream from the detection zone, which control zone contains immobilised antibody that can bind to the labelled reagent or immobilised analyte that can bind to the labelled reagent; and

c) the labelled reagent is picked up from the dry state within the analytical test device by the aqueous sample and migrates therewith through the detection zone and the control zone, whereby a positive assay result is revealed by visible binding of the same labelled reagent in both the detection zone and the control zone, and a negative assay result is revealed by visible binding of the labelled reagent in the control zone only."

Claims 2 to 7 concerned further embodiments of claim 1.

XII. The appellant's arguments in writing and at oral proceedings which are relevant to the present decision may be summarized as follows:

Added subject-matter (Article 100(c) EPC)
The feature "particulate direct label"

Although this feature had no explicit basis in the application as filed, it was directly derivable therefrom. As preferred embodiments, the application referred to direct labels, which were first defined by a practical feature (production of an instant analytical result without needing further reagents for developing a detectable signal) and then, in more detail, by their specific nature (readily visible either to the naked eye or with the aid of an optical filter and/or applied stimulation). These definitions were consistent with each other and in line with the examples, such as the "very suitable" minute coloured particles: dye sols, metallic (e.g. gold) sols, and coloured latex particles. This enumeration was exhaustive and it could not include any other particles. All direct labels disclosed in the application were of a particulate nature, including the specific ones of Section 2 ("Preparation of Labels") of the description.

In the context of the application as a whole, the term "minute coloured particles" was synonymous with the term "particulate direct label". The former term contained two essential elements defining the "particles". The first element ("minute") indicated

that the particles had to be small enough so as to travel through the porous material towards the detection zone. The second element ("coloured") indicated only that these particles had to be able to concentrate into a small zone of the porous material so as to give rise to a readily detectable signal (allowing the identification of the label against the background formed by the porous material). In the context of the application as a whole, such a generic "colour" (detectable signal) actually corresponded to the definition of a direct label. In fact, the term "minute coloured particles" was an abstract term that covered all the specific examples of direct labels disclosed in the application. In the combined feature "direct label ... (in the form of) minute coloured particles", the term "coloured" contained implicitly the feature "direct label". Since the term was redundant, it could be ignored and direct labels were clearly defined as being "in the form of minute particles". This was not an intermediate generalization derived from the specific examples but a mere transformation of a combined technical term ("direct label in form of minute coloured particles") into a synonymous term ("particulate direct label") made in accordance with its function. The introduced feature did not add any additional information and if it was considered as an intermediate generalization, then this generalization was already covered by the term "minute coloured particles".

Similarly, since dyes were understood to be coloured materials and readily visible to the naked eye, they were "direct labels". Thus, in the context of the

application as a whole, the term "particulate dyes" was also synonymous with "particulate direct labels".

Moreover, the application as filed referred to the selection of a carrier material with appropriate pore size. For the average skilled person, it was evident - as it was suggested in the application - that the pore size was directly related to the size of the particles of the labelled reagent (direct label) used in the specific binding assay.

In accordance with the established case law of the Boards of Appeal, broader claims and generalizations were allowed if they were directly and unambiguously derived from the application as filed. This was the case for the feature "particulate direct label", for which no generalization had to be made since it was directly and unambiguously derivable from the application as filed.

The feature "test strip device without a hollow casing and with a control zone"

At the beginning of the application as filed (page 2), the two embodiments (test devices) of the invention were explicitly described, namely a device with a hollow casing and a device without a hollow casing. From this reference alone, it was evident that the presence of a hollow casing was not an essential feature of the invention. The application further described the preferred carrier material and the direct labels for use in both embodiments. When describing the porous receiving member, it was mentioned that an aperture in the hollow casing had to be provided if a

control zone was present. However, when the control zone itself was described in more detail, no reference was made to a hollow casing. Specific examples of the two embodiments were described. "Embodiment 1" (Figures 1 and 2) corresponded to a test device without a hollow casing and "Embodiments 2 to 5" (Figures 6 to 14) related to test devices with a hollow casing. The application as filed further described the preferred materials and reagents for use in these two embodiments. The "liquid conductive material" and the "labels" described in this part of the description were for use in the two embodiments. And so it was the preparation of the reagent strip referred to immediately afterwards, which contemplated the optional presence of "various control zone options" without any reference to a hollow casing.

In fact, the general part of the application as filed concerned only features that were of importance in connection with the test strip. The function of these features applied solely to the test strip and no connection to a hollow casing was shown here. Rather the function of the control zone was clearly presented: the control zone in the test strip had to be downstream from the second zone and it was an indicator on the test strip that showed that the sample had passed through the test strip. All the statements about the function of the control zone were made in close relation to the test strip. Nowhere could an indication be found that there was a necessary functional connection with the casing - apart from the fact that if a control zone was present, an aperture in the hollow casing was required. Thus, the statements about the control zone were solely in connection with the

test strip according to their function and irrespective of the question whether or not the test strip was in a casing. The combined feature *"test strip device without a hollow casing and with a control zone"* was directly and unambiguously derivable from the application as filed.

Apportionment of costs

None of the requirements established by the case law of the Boards of Appeal for allowing an apportionment of costs were fulfilled in the present case.

XIII. The arguments of the respondents in writing and at oral proceedings which are relevant to the present decision may be summarized as follows:

Admissibility of the appeal

Respondent V (intervener/opponent 05) argued that for an appeal to be admissible, it had to be clear and coherently substantiated. Although claim 1 related to "a specific binding assay", it contained only features of a device. Since the appellant did not make clear whether claim 1 was directed to a method or to a device, the appeal was unclear and thus, inadmissible.

Apportionment of costs

Respondent V (intervener/opponent 05) submitted that, if claim 1 was understood as being directed to a method, then further research of relevant prior art was required and the case should be remitted to the first instance so as to take a decision on the substance of

the claim as understood by the board. Since this reinterpretation of claim 1 was made only in appeal proceedings and it made necessary a further research and additional proceedings before the opposition division, a request for an apportionment of the costs of the appeal was justified.

Added subject-matter (Article 100(c) EPC)
The feature "particulate direct label"

According to the established case law of the Boards of Appeal, a strict approach had to be followed when assessing added subject-matter under Article 123(2) EPC. This approach was justified in the light of the important consequences of added subject-matter when assessing the scope of the claims and the extent of protection conferred. Article 123(2) EPC prevented the introduction of features that were not disclosed in the original application and which gave an unwarranted advantage to an applicant or to a patentee, damaging the legal security of third parties. If an added feature, although limiting the scope of protection conferred by a patent, provided a technical contribution to the claimed subject-matter, then it also provided an unwarranted advantage and contravened Article 123(2) EPC (cf. G 1/03, OJ EPO 1994, 541, points 9 and 16 of the Reasons). This was the present situation, where the generic feature "particulate direct label" was a technical contribution relevant in the assessment of inventive step. However, there was no explicit basis in the application as filed for this generic feature.

It was established case law of the Boards of Appeal, that an undisclosed generalization was allowable in very exceptional cases and only if certain conditions were fulfilled, in particular when it was directly and unambiguously derivable from a basic teaching or concept conveyed by the application as filed. It was not a question of obviousness but of assessing whether the added generic feature or intermediate generalization could be directly and unambiguously derived from the application as filed.

In the present case, the application as filed referred to direct labels in general and to specific examples thereof, such as minute coloured particles (dye sols, metallic sols (e.g. gold) and coloured latex particles). However, it failed to disclose a common basic concept linking the non-exhaustive, limited list of specific direct labels disclosed. Examples of non-particulate direct labels were also referred to in the application as filed, such as the (normally non-particulate) fluorescent dyes. Nowhere it was suggested that a common basic and essential feature that had to be shared by all direct labels was their "particulate" nature. Nor was this property or attribute highlighted over other properties of the disclosed direct labels. This feature singled out a new property and thereby defined a new, undisclosed class of direct labels. Thus, it provided a new technical teaching that was not conveyed to the skilled person by the application as filed and it gave to the appellant an unwarranted advantage.

In fact, the feature *"particulate direct label"* represented an intermediate generalization between the generic "direct labels" and the specific examples of direct labels disclosed in the application as filed. However, this intermediate generalization was not the only possible generalization directly derivable from the examples nor were the disclosed examples an exhaustive list or enumeration of all possible direct labels falling under this generalization. Other direct labels well-known from the prior art were comprised in this generalization, such as radioactive labels. These direct labels were not disclosed in the application as filed nor could they be directly derived therefrom.

The properties that characterized a direct label were ambiguously defined in the application as filed, which referred to these labels either as being capable of producing a detectable signal without requiring the addition of a further reagent or else as being capable of producing a readily visible signal. None of these definitions, however, allowed to replace the term "coloured" by the term "direct label" in "minute coloured particles". Direct labels were not limited to coloured labels and similarly, the term "particulate dyes" could not be directly equated to "particulate direct labels". In fact, both "minute coloured particles" and "particulate dyes" were described only as preferred direct labels. The disclosure of single, very specific examples could not be a valid basis for an intermediate generalization. Moreover, since the definition of a direct label was ambiguous, it was not in the interest of the legal security of third parties to introduce a further feature that only added more ambiguity to the patent.

References to "particles" were always linked to their specific properties (such as their size) in the application as filed. There was no basis for disconnecting these "particles" from those properties. This was also the case of the "porous carrier material" for which the specific pore size was always defined or selected so as to allow the flow of the specific label used. However, no direct link could be made between the nature and properties of this porous material (pore size) and the ones of the direct label used. It was not allowable to transfer essential features of the porous material to the direct label nor to generalize from a very specific example without any indication thereto. Thus, the references in the application as filed to the pore size of the porous carrier material were of no relevance for the nature and properties of the direct label.

The feature "test strip device without a hollow casing and with a control zone"

The first reference to a control zone in the application as filed was found in combination with a hollow casing and nowhere was it stated that this feature was only optional. The presence of a control zone was shown only in those figures which had a hollow casing but not in figures which did not have a hollow casing. According to the application as filed, Figures 1 and 2 of "Embodiment 1" did not illustrate any practical embodiment (concrete mode of realisation) of the invention but only the general principle underlying the invention. No mention was made in "Embodiment 1" - the only one without a hollow casing -

of a control zone. Although there was a reference to multiple lines dispensed in discrete zones, these zones were used to detect the presence of other analytes and none of them was a control zone. Three different practical embodiments were contemplated in the application. A first embodiment illustrated in Figures 6 and 7 and a second and a third one in Figures 8 to 10 and 11 to 12, respectively. These three embodiments shared a common essential feature - a hollow casing - that was part of the analytic testing device containing in its interior a porous carrier. The hollow casing had two apertures (windows) for viewing the detecting and the control zone, respectively. There was no indication suggesting that the testing device could be used without a hollow casing. On the contrary, the hollow casing was an essential part of this device since it isolated the porous material (with all its reagents) from the external medium so as to avoid any possible alteration of its properties (by possible contaminants) and to prevent any contact of the analyte (in solution) with the detection zone and/or the control zone.

The claims of the application as filed, in particular the ones concerned with the embodiment without a hollow casing, did not provide a formal basis for the added feature. Claim 14 related to a dry porous carrier with a strip of a very specific pore size but there was no reference to a control zone. Nor was this reference found in any of the other dependent claims 15 to 18 or in claim 19.

Thus, the feature "test strip device without a hollow casing and with a control zone" provided an additional technical information that was not present in the application as filed and which was not directly derivable therefrom. In order to arrive at this feature, it was necessary to put together in a mosaic way unrelated parts of the information disclosed in the original description. Such an arbitrary combination of different parts of the description contravened the requirements of Article 123(2) EPC.

Requests of the parties

XIV. As main request the appellant (patentee) requested that the decision under appeal be set aside and the patent be maintained as granted. As the first to the twelfth auxiliary requests, the appellant requested that the patent be maintained on the basis of any of these requests to be taken in their numerical order. The appellant also requested that the request of respondent V for apportionment of its appeal costs be rejected.

XV. The respondents (opponents) requested that the appeal be dismissed. Respondent V (opponent/intervener 05) requested the apportionment of its appeal costs by the appellant.

Reasons for the Decision

Admissibility of the appeal

1. Respondent V (intervener/opponent 05) argued that for an appeal to be admissible, it had to be clear and coherently substantiated. In its view, since the appellant did not make clear whether the subject-matter of its requests was directed to a method or to a device, the appeal was unclear and thus, inadmissible (cf. Section XIII *supra*).

2. An appeal is sufficiently substantiated within the meaning of Article 108, third sentence, EPC, if the appellant sets out in an understandable way why, in its view, the impugned decision is incorrect.

3. The opposition division based its decision to revoke the patent-in-suit solely on the grounds that two features of the claims as granted had basis neither in the application as filed nor in the parent application and therefore the claims as granted did not meet the requirements of Articles 123(2) and 76(1) EPC. As a consequence, a statement of grounds setting out the appellant's view why these findings of the opposition division were incorrect is sufficient to make the appeal admissible. It is irrelevant whether or not the appeal contains further statements or reasoning related to other aspects of the case which might be regarded as unclear.

4. In its statement setting out the grounds of appeal the appellant has extensively dealt with the question why the two features objected to by the opposition division

are to be regarded as disclosed in the application as filed and in the parent application. These submissions are perfectly understandable and address the reasons put forward by the opposition division.

5. Therefore, the appeal is admissible.

Admissibility of oppositions/interventions

6. Point 1 of the decision under appeal refers to the admissibility of the intervention under Article 105 EPC by interveners 05 and 11.

7. As regards the intervention filed on 4 February 2004 by respondent V (intervener/opponent 05), the opposition division has acknowledged its admissibility on the grounds that Mr Bernd Faust, having been the "Geschäftsführer" of opponent 05 and, thus, a person legally representing opponent 05, was rightly served the "Klageschrift" on 4 November 2003 for respondent V (intervener/opponent 05). The board agrees with this finding.

8. The decision taken by the opposition division that the intervention under Article 105 EPC by intervener 11 was inadmissible has not been appealed and has thus become final.

Articles 123(2) and 76(1) EPC

9. The opposition division identifies two features for which no formal basis is found in the application as filed or in the parental application, both documents having an identical description. These features are: i) "a particulate direct label", and ii) the presence of "a control zone" in the absence of "a hollow casing or housing". In the appellant's statement setting out the grounds of appeal and in the respondents' replies thereto, only these two features are addressed (cf. Sections XII and XIII *supra*). No other issues have been raised in relation to compliance with Articles 123(2) and 76(1) EPC.

The feature "a particulate direct label"

10. Admittedly, there is no explicit basis or support for this feature in the application (or earlier application) as filed. Thus, in accordance with the established case law of the Boards of Appeal, it has to be assessed whether this feature is directly and unambiguously derivable from the application as filed (cf. "Case Law of the Boards of Appeal of the EPO", 4th edition 2001, III.A.3.3, 218).

11. The application as filed refers to "labels" in general, including both "indirect labels" and the preferred "direct labels" (cf. page 4, lines 39 to 52 of the published application). Whereas for the former labels only few examples are mentioned in a single paragraph of the application, examples of "direct labels" are found throughout the whole application. They are found in the general description of the invention, where at

the beginning reference is made to preferred direct labels "such as gold sols and dye sols" (cf. page 3, lines 18 to 20), both defined as "minute coloured particles" which, together with the most preferred "coloured latex particles", are explicitly acknowledged to be "very suitable" direct labels (cf. page 4, line 41 to 43). They are then found in the description of the specific embodiments of the invention, particularly in "Embodiment 1", wherein it is stated that "the label can be a particulate dye, a gold sol or coloured latex particles" (cf. page 6, lines 34 to 35 and line 49). And further they are found in the last part of the description, wherein the preferred reagents and methods for their production are described in more detail, cf. item 2 - "Labels" and "Preparation of Labels" - which discloses only and exclusively direct labels of a particulate nature, namely gold sold, dye sol, coloured (latex) particles, antibody-dye sol and hormone-dye sol (cf. page 11, line 38 to page 13, line 5). The same type of particulate direct labels are also mentioned when describing, at the very end of the description, the sandwich and the competitive assays used (cf. page 13, lines 50 to 51 and page 14, lines 33 to 48).

12. From this disclosure, it can readily be seen that not only the very specific direct labels disclosed in the examples of the application as filed (gold sol, Foron Blue SRP or Resolin Blue, cf. page 12, lines 12 to 13) but also much broader classes of direct labels (yet narrower than the general class of direct labels itself) referred to therein, such as minute coloured particles and particulate dyes, are all of a particulate nature. In other words, the teaching which can be derived from

the whole of the application as filed is that it does not matter what type of direct label is used as long as it is of a particulate nature and readily visible (which in the context of the application might be understood as developing an instant detectable signal without requiring to add any further reagent, and detectable or visible either to the naked eye or with the aid of a filter or stimulation) (cf. page 3, lines 20 to 21 and page 4, lines 39 to 41).

13. It is also taught in the application as filed that this latter property or attribute is of relevance for selecting a suitable pore size of the carrier material. On page 3, lines 31 to 36, the pore size (greater than about 20 microns) of the preferred carrier material (nitrocellulose) is presented side by side with the size (not greater than about 0.5 micron) of the preferred direct label (coloured latex particles). This connection is also directly outlined in item 1 of the last part of the description ("Selection of Liquid Conductive material"), wherein the preferred reagents and methods are described. There it is explicitly stated that "*(e)ssential features of the material are ... its ability to allow the passage of labelled antibodies along the strip. If this is a* ***direct label****, it may be desirable for the material to allow flow of* ***particles*** *of size up to few microns (usually less than 0.5μ)*" (cf. page 11, lines 4 to 7) (in bold by the board). Thus, if the antibody is labelled with a direct label, then this label is implicitly assumed to be of a particulate nature with a specific size (usually less than 0.5 micron) and the carrier material - the size of its pores - must be selected accordingly so that the

(direct) labelled antibody can flow or migrate freely through its pores.

14. A further point to consider is the fact that there is no disclosure of any non-particulate direct label in the application as filed. The reference to the possible use of fluorescent dyes is found only in the context of the type of stimulation to be applied (so as to detect the instant visible signal) but there is no reference to the actual nature of the fluorescent dyes, i.e. whether or not they are of a particulate nature (cf. page 4, lines 41). The application as filed is also completely silent on the possible use of any - particulate or non-particulate - radioactive material. Although the feature "particulate direct label" might embrace more compounds than the specific ones disclosed in the application as filed or the broader classes of direct labels referred to therein (particulate dyes and minute coloured particles), the critical question under Articles 123(2) and 76(1) EPC is not whether this feature is broad but whether or not it is directly and unambiguously derivable from the application as filed (cf. point 10 *supra*).

15. In the light of the above considerations, in particular, the sheer number of explicit references to particulate direct labels and the connection made between the size of the porous carrier material and the size of the particles of the direct labels as well as the absence of any reference to a non-particulate direct label, the board considers that in the present case the above question must be answered in the affirmative.

16. No contradiction is seen between this conclusion and the established case law of the Boards of Appeal, which allows the introduction of broader terms and of (intermediate) generalizations as far as they are directly and unambiguously derivable from the application as filed (cf. "Case Law", *supra*, III.A.3.3, 218).

The presence of the feature "a control zone" in the absence of the feature "a hollow casing or housing"

17. The application as filed discloses two embodiments, namely (1) a "*test device comprising a hollow casing ... containing a dry porous carrier*" (cf. page 2, lines 27 to 36) and (2) "*a device ... incorporating a porous solid phase material*" (cf. page 2, lines 37 to 45). These two embodiments are further described in more detail in "Embodiments 1 to 5" (cf. page 6, line 22 to page 10, line 53). In "Embodiment 1", which corresponds to the first embodiment (a device without hollow casing), reference is made to Figures 1 and 2 that "*illustrate the underlying principle upon which the invention operates*", i.e. for both the first and the second embodiment of the invention (cf. page 6, lines 24 to 25). Whereas "Embodiments 2 to 5" explicitly refer to a "*hollow*" construction, body or device (cf. page 8, lines 19, 25 and 54 for embodiments 2 and 3 respectively, page 10, lines 18 and 39 for embodiments 4 and 5, respectively), "Embodiment 1" refers only to a "*body*" without any further indication (cf. page 7, line 50 to page 8, line 8). These two embodiments are also reflected in the claims as filed. Whereas claims 1 to 13 thereof relate to a test device

with a hollow casing, there is no reference to a hollow casing in claims 14 to 19 as filed.

18. The application as filed further describes materials, reagents and methods shared by both embodiments. In particular, a "*dry porous carrier*" or "*porous solid phase material*", such as a test strip, is an essential element common to the first and the second embodiment. The preparation of this element is disclosed in more detail in item 3 of the last part of the description ("Preparation of Reagent Strip"), wherein the preferred reagents and methods are described (cf. page 13, lines 7 to 45). Here it is explicitly stated that "*(i)n addition to the test zone various control zones options can be operated*" and, as an example, "*a zone of anti-species IgG*" is indicated (cf. page 13, lines 44 to 45). There is here no limitation to any particular embodiment nor any reference to the presence of a hollow casing in the preparation of this reagent strip.

19. In "Embodiment 1" itself the presence in the test strip of "*(m)ultiple lines ... dispensed in spatially discrete zones*" is also explicitly contemplated, wherein these zones might be used to detect multiple analytes (cf. page 7, lines 31 to 45). There is, however, no limitation as regards the nature of the appropriate specific binding reagents present in those discrete zones, which may include "*immunochemically reactive component(s) capable of binding the analyte of interest*" (cf. page 7, line 39), nor any restriction in the character of the analyte to determine, which may include "*immunoglobulins*" as well (cf. page 6, lines 53 to 58). And thus, these multiple lines may also

comprise the "*control zones*" (anti-species IgG) referred to in point 18 above.

20. In fact, the test strip used in "Embodiment 2", which comprises a hollow casing and a control zone, is said to be of "*similar construction to those described under Embodiment 1*" (cf. page 8, lines 20 to 21). No particular difference is made between the (common) test strip used in these two particular embodiments. Nor can any reason be derived from the application as filed that could justify the presence of such a difference.

21. Thus, the presence of a control zone in a device without a hollow casing is directly and unambiguously derivable from the application as filed.

Conclusion

22. Since both contested features are directly and unambiguously derivable form the application as filed, which has the same description as the earlier parent application, the requirements of both Articles 123(2) and 76(1) EPC are satisfied.

Apportionment of costs

23. The request for apportionment of costs made by the respondent V (intervener/opponent 05) was mainly based on the alleged lack of clarity of the category of claim 1 as granted and the vagueness in this respect of the appellant's submissions in the statement setting out the grounds of appeal (cf. Section XIII *supra*).

24. Article 104(1) EPC states that each party to the proceedings shall meet its own costs unless an opposition division or a board of appeal decides, for reasons of equity, and in accordance with the Implementing Regulations (Rule 63 EPC), a different apportionment of costs incurred during taking of evidence or in oral proceedings.

25. In the jurisprudence of the boards of appeal, several scenarios have been developed possibly justifying an apportionment of costs under certain circumstances, such as a late submission of documents or requests, a request for oral proceedings withdrawn or postponement requested, an appeal or opposition withdrawn, a party not appearing at the oral proceedings and an alleged abuse of procedure. In these cases, an apportionment of costs may be justified if the conduct of one party is not in keeping with the procedural care required, in particular if costs arise from culpable actions of an irresponsible or even malicious nature (see "Case Law", *supra*, VII.C.12.3, 492).

26. In the present case, none of such particular scenarios has been referred to by respondent V. The alleged lack of clarity of the category of the claimed subject-matter and the possible associated additional costs which could be incurred by a clarification of this subject-matter - said costs having, however, not been substantiated at all - would not justify an apportionment of the respondent V's costs on the appellant. Firstly, the criticised elements of claim 1 and the alleged vagueness of the statement setting out the grounds of appeal are entirely irrelevant for the subject-matter of the present appeal, i.e. the findings

of the opposition division on added subject-matter, as can be derived from the above. Secondly, unclarity of a claim or of a submission can hardly be regarded as an abuse of procedure unless that would be intentional. The board therefore sees no legal basis for any apportionment of costs.

General procedural matters

27. The decision under appeal dealt only with the issues of Articles 76(1) and 123(2) EPC for the sole request which was before the opposition division, namely the claims as granted. No other issues were treated by the opposition division. Although the board is well aware of the filing date of the earlier parent application (26 April 1988) and of the present divisional application (1 June 1993), in the present case it is considered to be pertinent to allow a discussion of all the other requirements of the EPC before the department of the first instance. Therefore, the board exercises its discretion under Article 111(1) EPC to remit the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The intervention of intervener 05, Adexpert GmbH, is admissible.

2. The decision under appeal is set aside.

3. The case is remitted to the opposition division for further prosecution on the basis of the appellant's main request (claims as granted) submitted with the statement setting out the grounds of appeal dated 12 May 2005.

4. The request for appointment of its appeal costs filed by intervener 05, Adexpert GmbH, is rejected.

The Registrar: The Chairman:

A. Wolinksi L. Galligani