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D E C I S I O N
of 8 May 2000

Case Number: T 0945/97 - 3.3.4

Application Number: 84100836.0

Publication Number: 0117440

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Language of the proceedings: EN

Title of invention:

Methods and structures employing non-radioactive chemically-labeled polynucleotide probes

Patentee:

ENZO BIOCHEM, INC.

Opponent:

Roche Diagnostics GmbH
Biotest Pharma GmbH

Headword:

Polynucleotide probes/ENZO

Relevant legal provisions:

EPC Art. 123(2)(3)

Keyword:

"Main request - claims as granted - added subject-matter (yes)"

"Auxiliary requests 1 and 3 - extension of protection conferred (yes)"

"Auxiliary requests 2 and 4 - added subject-matter (yes)"

Decisions cited:

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Catchword:

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Case Number: T 0945/97 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 8 May 2000

Appellant: ENZO BIOCHEM, INC.
(Proprietor of the patent) 325 Hudson Street
New York, N.Y. 10013 (US)

Representative: VOSSIUS & PARTNER
Postfach 86 07 67
D-81634 München (DE)

Respondent I: Roche Diagnostics GmbH
(Opponent 01) Sandhoferstr. 116
D-68305 Mannheim (DE)

Representative: Weiss, Wolfgang, Dipl.-Chem. Dr.
Patentanwälte
Weickmann & Partner
Postfach 86 08 20
D-81635 München (DE)

Respondent II: Biotest Pharma GmbH
(Opponent 02) Landsteinerstrasse 5
D-63303 Dreieich (DE)

Representative: Keller, Günther, Dr.
Lederer, Keller & Riederer
Patentanwälte
Prinzregentenstrasse 16
D-80538 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 23 June 1997
revoking European patent No. 0 117 440 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. C. Perryman

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division issued on 23 June 1997 whereby the European patent No. 0 117 440 was revoked under Article 102(1) EPC. The opposition division decided inter alia that claim 1 as granted offended against Article 123(2) EPC, and that claim 1 of the four auxiliary requests also offended either against Article 123(3) EPC or against Article 123(2) EPC. The opposition division raised also objections under Articles 54 and 83 EPC against all requests.

Claim 1 **as granted** read as follows:

"A method for detecting a polynucleotide sequence which comprises:

- fixing said polynucleotide sequence to a solid support which comprises or is contained within a transparent or translucent system, such that the polynucleotide is in a single-strand form and is capable of hybridizing to complementary nucleic acid sequences;
- forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label comprising a signalling moiety capable of generating a signal; and
- generating and detecting a signal, characterized in that the [the] transparent or translucent system is a non-porous system and the generated signal is a soluble signal."

Claim 1 of the auxiliary requests in comparison with claim 1 as granted contained the following amendments:

- In **auxiliary request 1**, the expressions "transparent or translucent" in the first item and "the [the] transparent or translucent system is a non-porous system and" in the third item were deleted.

- In **auxiliary request 2**, the expression "solid support which comprises or is contained within a transparent or translucent system" in the first item was replaced by the expression "transparent or translucent solid, non-porous support", the expression "the [the] transparent or translucent system is a non-porous system and" was deleted in the third item, and the features of granted claim 2 were introduced at the end of the claim ("wherein said detecting step comprises spectrophotometric techniques").

- In **auxiliary request 3**, the expression "support which comprises or is contained within a transparent or translucent system" was replaced in the first item by the expression "transparent or translucent support", the third item was replaced by the following "generating and detecting a signal, characterized in that the [the] transparent or translucent support is glass, plastic, polystyrene, polyethylene or polypropylene and the generated signal is a soluble signal, wherein said detecting step comprises spectrophotometric techniques".

- In **auxiliary request 4**, the same amendments as in the auxiliary request 3 were made. However, the expression "non-porous" was added before "glass, plastic...".

- II. Both respondents (opponents 01 and 02) submitted comments on the statement of grounds of appeal filed by the appellants (patentees). All parties requested oral proceedings in case their requests could not be accepted by the board.

- III. Oral proceedings were summoned to take place on 13 April 2000 and in preparation thereof the board issued a communication. Respondents I submitted a reply thereto.

- IV. On 11 April 2000, the appellants informed the board that they would not participate at the oral proceedings. These were thus cancelled in view of the fact that the respondents' requests for oral proceedings were only conditional on the board not intending to dismiss the appeal.

- V. In the appellants' view, all the features objected to by the opposition division, although not literally mentioned in the application as filed, were implicitly contained therein and thus they did not constitute added subject-matter.

- VI. The respondents fully endorsed the opposition division's decision.

- VII. The appellants requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of the

auxiliary requests 1 to 4 on file.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

The main request

1. Claim 1 as granted contains three expressions, namely "transparent or translucent system", "non-porous system" and "soluble signal", which are not found **as such** in the application as filed. The appellants admit this; however, they submit that the skilled person would derive said expressions by way of implication. For example, the features "transparent or translucent system" and "non-porous system" are, in their view, self-evident as the support or system described (eg ELISA methods) would not function would it be porous or non-transparent/non-translucent. As for the term "soluble signal", which refers to a signal which per se is soluble and can be quantitatively determined in a fluid, the skilled person would derive it unequivocally from the application as filed where such signals are described, eg those generated when applying spectrophotometric or ELISA techniques. This, in their view, excludes radioactive signals as well signals emitted from insoluble products.

2. As regards the expression "transparent or translucent system", the opposition division observes in the decision under appeal that, while in the application as filed the qualifier "transparent or translucent" is found attached to the terms "support" or "substrate" (cf eg items 30,

53, 80, 101), it is never found attached to the term "system". It is also observed that the latter term, for which no explicit definition is given, is mentioned in items 71, 101 to 108, in the originally filed claims 34 to 37 and in the section preceding Table I either to mean an apparatus (eg a photospectrometer) or a substrate/product combination (eg the avidin/streptavidin system). Thus, it is concluded that the attachment of the qualifier in question to the term system finds no basis whatsoever in the application as filed.

The board fully agrees with this reasoning and conclusion. As a matter of fact, since "system" in the context of the application is not the same as "support" or "substrate", the feature "transparent or translucent system" (whatever it means) refers to a system which is not at all described in the application as filed. The argument put forward by the appellants that ELISA methods as described function only in a transparent or translucent system, regardless of any possible merit, is irrelevant as claim 1 is generally formulated and is not limited to such methods. No basis is found in the application as filed for its subject-matter.

3. As for "non-porous system", the opposition division observes in the decision under appeal that the term "non-porous" does not occur at all in the application as filed and that, although "substrates" (**not** systems) of porous and non-porous nature are referred to (cf item 82), neither explicit nor implicit emphasis is given to this property. Thus, the said expression constitutes new specific information with no basis in the application as filed. Also in respect of this, the board fully agrees

with the reasoning and the conclusion of the opposition division. Nowhere in the application as filed is a "non-porous **system**" (whatever meaning is attributed to the term "system") described or implied. The appellants' argument that ELISA methods require a non-porous support or system, regardless of any possible merit, is irrelevant as claim 1 is not limited to such methods.

4. As regards "soluble signal", the opposition division, after observing that it is an unclear expression, considers that it has to be interpreted as "a signal that can be detected in solution" which is not to be equated with "a signal produced by a soluble product". It is thus observed that the expression as such embraces not only signals generated by the insoluble chromogens of Tables I and II, but also signals such as radioactive signals which are detected in solution eg in a scintillation counter, these signals not being disclosed in the application as filed, as they are in fact expressly excluded therefrom (cf eg page 20, first sentence of second paragraph).

The board notes that, although Article 84 EPC is not as such a basis for an objection under the term of Article 100 EPC, questions of clarity may affect the decision on issues under Article 100 EPC, when - as in the present case - failing a definition of a given expression, it is necessary to interpret it having regard to the whole contents of the application as filed. In this respect, the board finds that the interpretation given by the opposition division is logical, while that provided by the appellants in their submissions (cf point 1 supra) is still ambiguous and does not explain why

radioactive signals are excluded. Claim 1 is not limited to signals detected only within the framework of spectrophotometric or ELISA techniques. For these reasons, the board fully agrees with the reasoning and conclusion of the opposition division that the expression "soluble signal" extends beyond the content of the application as filed.

5. In sum, in agreement with the position of the opposition division, the board finds that claim 1 of this request offends against the provisions of Article 123(2) EPC.

Auxiliary request 1

6. As correctly decided by the opposition division, the deletion in claim 1 of this request of the features "transparent or translucent" and "non-porous" results in an extension of the protection conferred in comparison with claim 1 as granted, and thus in a manifest offence against Article 123(3) EPC.

Auxiliary request 2

7. Claim 1 of this request was considered by the opposition division to offend against Article 123(2) EPC because of the feature "non-porous support" which - for the same reasons given in respect of the claims as granted - cannot be considered to be disclosed in the application as filed.

The board agrees with this view. As stated above (cf point 3 supra), although the application as filed refers to specific substrates (cf eg item 82) which can be

either porous or non-porous, the general teaching of using a "transparent or translucent, solid, **non-porous** support" (emphasis added) is derivable neither directly nor by way of implication from the application as filed.

Auxiliary request 3

8. In claim 1 of this request the qualifier "non-porous" for the solid, transparent or translucent support is deleted, and the said substrate is specified to be either glass, plastic, polystyrene, polyethylene or polypropylene, the latter being the features of claim 5 as granted. The opposition division correctly decided that, since claim 1 as granted from which granted claim 5 depends, refers to the "non-porous" nature of the support, the deletion of the qualifier "non-porous" results in an extension of the protection conferred in comparison with claim 1 as granted. The board fully agrees with this. Thus, claim 1 of this request offends against the provisions of Article 123(3) EPC.

Auxiliary request 4

9. Claim 1 of this request differs from claim 1 of the auxiliary request 3 in that the qualifier "non-porous" is added before "glass, plastic...". As correctly noted by the opposition division, although this amendment remedies the offence against the provisions of Article 123(3) EPC, it results in subject-matter which extends beyond the content of the application as filed because nothing therein points to eg non-porous glass or plastic. As these materials can exist both in the non-porous or porous form, the skilled person is presented here with

new information which is not unambiguously derivable from the application as filed. Consequently claim 1 of this request offends against Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairperson:

D. Spigarelli

U. Kinkeldey