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To the

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Appeal Case T 0945/97 - 3.3.4.
ENZO BIOCHEM, INC.
Our Ref.: S 808 EP

November 3, 1997
Uex/Ba/ALR/ne

In the following we submit the grounds in support of the formal appeal dated September 3, 1997.

In its Decision the Opposition Division has revoked the patent alleging that neither the subject matter of the claims according to the main request nor to the auxiliary requests is allowable under Art. 123(2) EPC, is sufficiently disclosed (Art. 100(b) and Art. 83 EPC), and is novel (Art. 100(a) and Art. 54 EPC).

We cannot agree thereto for the following reasons:

1. THE SUBJECT MATTER OF THE PATENT

The subject matter of the patent provides a method and an arrangement for the detection of polynucleotide sequences whereby detection is effected by fixing a single-stranded polynucleotide to a solid support which is or is contained within a system, forming an entity with a labelled polynucleotide probe

and generating and detecting the signal originating from the label, whereby the system is transparent or translucent and non-porous and the signal is a soluble signal.

2. THE SUBJECT MATTER OF THE CLAIMS SET DOES NOT GO BEYOND THE DESCRIPTION AS ORIGINALLY FILED (ART. 123(2) EPC)

2.1 The terms "transparent/translucent system" and "non-porous substrate or system"

We are of the opinion that the terms "transparent/translucent system" and "non-porous substrate or system" are disclosed in the specification as originally filed. In order to avoid unnecessary repetitions we want to refer the Board of Appeal to our reply of February 12, 1996 to the Communication pursuant to Art. 101(2) and Rule 58(1) to (4) EPC dated August 2, 1995, where we extensively discussed why, according to our opinion, the features "non-porous substrate or system" and "translucent or transparent system" are unambiguously derivable from the specification or contained within the specification as self-evident features, even if these features are not literally mentioned in the specification as originally filed.

In this context we gave a short summary of the prior art (see item 2.1.1) thereby providing a series of documents partly incorporated within the description demonstrating that the objected to features of claim 1 are self-evident features implicitly contained within the disclosure as originally filed. We further referred in item 2.1.2 the Opposition Division to the specific disclosure in the description (see pages 50-58) from which the features "non-porous substrate or system" and "transparent/translucent system" are clearly derivable as the support or the system described would not function would it be porous or non-transparent/non-translucent. It is furthermore stated that the embodiments specifically described in the application (see the reference to pages 50 to 58) referring to the later and more difficult embodiments of ELISA as they have been

developed in the prior art for e.g. antigen/antibody reactions, certainly communicate the older and better known established ELISA detection utilizing beads and other solid supports within a distinct and separate system (see the paragraph bridging pages 10 and 11).

In summary, our comments provided in the reply to the EPO demonstrate that the embodiments of claim 1 wherein the support is the system or the support is contained within a system, the system thereby being transparent or translucent and non-porous are self-evident and comprised by or derivable from the description as originally filed.

2.2 The terms "soluble signal", "non-porous system or support" and "transparent or translucent system" as objected to in the Decision Revoking the European Patent

In the following we want to specifically refer to the statements of the Opposition Division in the Decision revoking the European Patent whereby we will demonstrate that the decision and the grounds for the decision are not justified in view of the disclosure of the application as originally filed.

2.2.1 Soluble Signal

2.2.1.1 The Opposition Division first discussed a meaningful interpretation of the term "soluble signal" as this expression was seen as being unclear (which is, however, not a ground for opposition). In view of the proprietor's submission of December 28, 1994 it thereby referred to spectrophotometric and ELISA techniques involving enzyme-linked reagents which produce a color change in a substrate or precipitate and to Table II disclosing chromogens which produce an insoluble product. In view of this the feature "soluble signal" was interpreted in a broader sense as "a signal that can be detected in solution".

However, in view of the fact that radioactive signals which are detectable in solution are excluded from the disclosure of the

application as filed, the Opposition Division came to the conclusion that the expression "soluble signal" describes a novel class of signals which were not disclosed in the application as filed. Thus, the use of such an expression allegedly violates Art. 123(2) EPC.

2.2.1.2 The term "soluble signal" per se, in the context of claim 1 and in view of the description unambiguously implicates to the skilled person that a soluble signal per se is soluble in a fluid in contrast to the Opposition Division's interpretation that insoluble precipitates or fixed signalling agents generate a "soluble signal".

There are numerous locations throughout the specification indicating the generation of soluble signals being measured while being dissolved in a fluid. We want to refer the Board of Appeal to representative disclosure in the specification as e.g. on page 21, lines 9 to 26, already referred to in the statement of December 28, 1994, item 3.3.1.2, relating to spectrophotometric and ELISA techniques. The reference to spectrophotometric techniques including the passage of lines 13 to 21 referring to the measurement of an enzymatically generated product for quantitative determination and the passage on page 53, lines 1-3 mentioned in the above statement referring to an enzymatically generated product measured by spectrophotometry clearly show that by the term "soluble signal" the measurement of a signal in a solution is comprised.

We cannot share the Opposition Division's opinion that the term "soluble signal" comprises signals generated by the chromogen products of Tables I and II and also radioactive signals detectable e.g. by a scintillation counter. Tables I and II substantially relate to insoluble products which are visually evaluated while being bound to a support usually not allowing a quantitative determination as is e.g. a significant property of the soluble signals. Such precipitates do not need the detection in solution although detection is possible by e.g. submersing the support into a clear fluid. This, however, cannot be equalled to a soluble signal measured in the fluid whereas a precipitate remains an

insoluble signal. Also the arguments of the Opposition Division relating to radioactive labels cannot hold. The radioactively labelled oligo- or polynucleotide is fixed to the membrane and represents therefore an insoluble signal not comparable to signals being soluble in a fluid.

2.2.1.3 Thus, according to our opinion, the term "soluble signal" is not only unequivocally derivable from the description but is furthermore clearly delimited from other kinds of signals mentioned in the description, as these signals are insolubly precipitated or fixed signals. Such kinds of signals do not fulfil the requirements of a soluble signal. Therefore, no novel class of soluble signals is described, but the signals comprised by the term "soluble signal" are clearly derivable from the description.

2.2.2 Non-Porous System or Support

2.2.2.1 The Opposition Division is of the opinion that the term "non-porous" cannot be derived from the application as filed neither in connection with the term "support" nor with the term "system". The Opposition Division argues that despite the presence of the word "system" in items 71 and 101-108 and original claims 34 to 37 no meaningful information in connection with the term "non-porous" could be derived. Also the use of a soluble signal does not imply the use of a non-porous system in view of the different embodiments which can be represented by a system.

With respect to the term "non-porous support", the Opposition Division has acknowledged that "non-porous supports" are disclosed in the specification. However, it emphasizes that since the specification as filed does not attach any importance to this feature, a generalization as in claim 1 seems to be unjustified.

2.2.2.2 We cannot agree to the Opposition Division's arguments. The term "non-porous" is not literally mentioned in the specification. Such literal disclosure is, however, not required. We are of the opinion that the specification discloses embodiments of claim 1 which allow the conclusion that the feature "non-porous" in

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