

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte SHARON M. DEVEREAUX

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Appeal No. 1997-4132  
Application No. 08/263,500<sup>1</sup>

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ON BRIEF

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Before ROBINSON, SPIEGEL, and MILLS, Administrative Patent Judges.  
SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 4 through 10, 12 and 14 through 20, which are all of the claims pending in this application.<sup>2</sup> Claim 1 is illustrative:

1. An article comprising a unit-of-use reagent composition for a specific binding assay, said article comprising:

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<sup>1</sup> Application for patent filed June 21, 1994. According to appellant, this application is a continuation of application no. 07/776,518 filed October 11, 1991, now abandoned.

<sup>2</sup> We note that application no. 07/776,518 was filed without an original claim 11 and that original claims 12-20 were never renumbered per 37 CFR 1.126. This clerical error was carried over into the present application. Consequently, the record does not reflect a cancellation of claim 11 because neither an originally numbered or a renumbered claim 11 ever existed.

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- a) a porous material;
- b) a mixture of an assay reagent and a carrier matrix, said mixture comprising gelatin, said assay reagent encapsulated by said carrier matrix, said mixture being coated on said porous material, wherein said assay reagent is a specific binding member in an amount sufficient to perform a single binding assay; and wherein said carrier matrix is lyophilizable, and wherein said carrier matrix can be rehydrated upon contact with a solvent to expose or release said assay reagent from said porous material for a specific binding reaction.

The reference relied on by the examiner is:

Ito et al. (Ito)	4,966,856	Oct. 30, 1990
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Claims 1, 2, 4-10, 12 and 14-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ito. We REVERSE.

In reaching our decision in this appeal we have given careful consideration to the appellant's specification and claims and to the respective positions articulated by the appellant and the examiner. We make reference to the examiner's answer (Paper No. 23, mailed May 28, 1997) for the examiner's reasoning in support of the rejection and to the appellant's brief (Paper No. 22, filed March 4, 1997) for the appellant's arguments thereagainst.

According to appellant, "[t]he appeal claims stand or fall together" (brief, p. 3). We therefore limit our discussion to claim 1. 37 CFR § 1.192(c)(5)(1994).

### THE INVENTION

According to appellant,

[t]he invention is directed to an article comprising a unit-of-use reagent composition for a single specific binding assay. The claimed article contains a porous material. A carrier matrix made up of gelatin encapsulates an assay reagent which is a specific binding member. The resultant mixture coats the porous material (page 12, lines 3-5 and 24-28).

The carrier matrix is lyophilizable, and may be rehydrated upon contact with a solvent to expose or release the assay reagent from the porous material for a specific binding reaction (page 12, lines 5-6 and page 13, lines 30-33). [Brief, p. 2, § 5.]

### OPINION

According to the examiner,

Ito ... teach[es] the use of multilayer assay devices in several configurations. Ito ... teach[es] that the specific binding pair member, gelatin, and trehalose (column 12, lines 16-20; column 16, line 50 to column 17, line 20) are cast or molded in a porous reaction layer (Fig. 2, layer 1; column 15, lines 11-15). Ito ... teach[es] that in order to maintain the activities of the material capable of specifically combining [sic, combining] with the immobilized specific component, signal modulation material and labeled material, preservation materials such as gelatin and non-reducing sugars may be incorporated in the element (column 16, line 50 [sic, line 50] - column 17, line 3). This reference fails to specifically exemplify a device in which the assay reagent, i.e., the specific binding member [sic, member], is "encapsulated" in the carrier matrix, i.e., the gelatin, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add gelatin to the assay reagent layer because Ito ... specifically teach[es] that in order to maintain the activities of the material capable of specifically combining [sic, combining] with the immobilized specific

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component, signal modulation material and labeled material, preservation materials such as gelatin and non-reducing sugars may be incorporated in the element. [Answer, para. bridging pp. 4-5.]

The examiner expressly relies on "Ito's use of gelatin as a preservative..., not its use as another porous layer" (answer, p. 6, para. 3). More specifically, in view of Ito's statement that "[t]hese preservatives are desirable to be present in the proximity of the immobilized materials and labeled materials" (c. 17, ll. 1-3), it is the examiner's position that "it is unclear how one could interpret a preservative as not being in contact with the material being preserved" (answer, p. 8, ll. 3-4).

However, we agree with appellant that " 'encapsulation' and 'in the proximity of' are simply not the same" (brief, p. 4, para 3). For example, assay reagent might be diffusively or non-diffusively attached to an application pad or zone of an analytical device, followed by overcoating all or a part of the application pad or zone with gelatin. See e.g., U.S. Patent 5,075,078 issued December 24, 1991 to Osikowicz et al. at c. 13, ll. 35-47 and c. 13, l. 58 - c. 14, l. 6 (copy attached). Since the examiner has failed to establish a factual basis for concluding that the gelatin preservative of Ito necessarily encapsulates the immobilized specific binding materials and/or labeled materials, the examiner's stated obviousness rejection cannot be sustained.

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CONCLUSION

The decision of the examiner to reject claims 1, 2, 4-10, 12 and 14-20 under 35 U.S.C. § 103(a) as being unpatentable over Ito is reversed.

REVERSED

DOUGLAS W. ROBINSON	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
CAROL A. SPIEGEL	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
	)	
	)	
DEMETRA J. MILLS	)	
Administrative Patent Judge	)	

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APPLICATION NO. 08/263,500

APJ SPIEGEL

APJ ROBINSON

APJ MILLS

DECISION: **REVERSED**

Prepared By:

**DRAFT TYPED:** 24 Aug 01

**FINAL TYPED:**