

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JACK FOLEY, JOHN CHAPMAN  
and LUDWIG WOLF JR.

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Appeal No. 1999-0331  
Application No. 08/168,438

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ON BRIEF

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Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, 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 5-7, 9, 14-17, 19, 20, 25-27, and 29-38, all of the claims remaining in the application. Claims 31, 6, and 9 are representative of the claimed method and read as follows:

31. A method for treating a body fluid to at least substantially inactivate viral contaminants that may be present therein comprising the steps of:

providing a therapeutically useful body fluid;

adding to the body fluid a viral inactivating agent in an amount and under conditions effective to at least substantially inactivate any viral contaminants present in the body fluid without destroying therapeutic benefits of the body fluid to form a resultant product;

passing the resultant product through a column including macroporous polymeric beads having an affinity for the viral inactivating agent photoproducts generated by irradiating the viral inactivating agent with light; and

selectively removing all measurable viral inactivating agent and photoproducts, as determined by high pressure liquid chromatography, from the resultant product by allowing the viral inactivating agent and the photoproducts to bind to the macroporous polymeric beads, without destroying the therapeutic benefits of the body fluid to provide a treated body fluid suitable for administration to a patient.

6. The method of Claim 31 wherein the viral inactivating agent is a light activated viral inactivating agent selected from the group consisting of: porphyrin; psoralen; phthalocyanine; and hypericin; and dye.

9. The method of Claim 31 wherein the macroporous polymeric beads have the following characteristics:

polarity – non-polar to intermediate polarity;

dipole moment - 0.1 to 3.0;

bead size – 30 to 2,000;

average pore diameter – 45 to 300 angstroms; and

bead surface area – 15 to 1,600 square meters per gram dry bead.

The examiner relies on the following references:

Hodgson et al. (Hodgson)	4,190,542	Feb. 26, 1980
Sugiyama et al. (Sugiyama)	4,728,432	Mar. 1, 1988

Australian Patent Application

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Mohr et al. (Mohr)

AU-B-63391/90

Mar. 3, 1993

Bio-Rad Catalog, "Chromatographic Supports," Life Science Research Products, pp. 11-12 (1993)

Heinmets et al. (Heinmets), "Inactivation of Viruses in Plasma by Photosensitized Oxidation," Joint Report with the Naval Medical Research Institute, WRAIR -53-55, pp. 1-16 (1995)

Claims 5, 7, 9, 15, 17, 19, 20, 27, and 29-33 stand rejected under 35

U.S.C. § 102(b) as anticipated by Mohr.

Claims 5-7, 14-17, 19, 20, 25-27, and 29-38 stand rejected under 35

U.S.C. § 103 as obvious over Heinmets in combination with either Sugiyama or Hodgson.

Claim 9 stands rejected under 35 U.S.C. § 103 as obvious over Heinmets in combination with either of Sugiyama or Hodgson, and Bio-Rad.

We affirm in part and reverse in part.

#### Background

Appellants' specification discloses a method for inactivating viruses in body fluids such as blood. In the disclosed method, a photoactive virus-inactivating agent is added to the blood. Specific virus-inactivating agent mentioned in the specification are "psoralens, porphyrins, dyes, such as methylene blue, phthalocyanines, phenothiazines, hypericin, and other compounds that are activated by light." Page 7, line 30 to page 8, line 2. The blood is then irradiated to activate the virus-inactivating agent and thereby inactivate viruses in the blood. Specification, page 5. Finally, the virus-

inactivating agent and any photoproducts thereof are removed from the blood by passing the treated blood over a column of “macroporous polymeric beads,” or biobeads. See the specification, page 10, lines 4-18:

[t]he term “biobeads refers to neural [sic, neutral?] macroporous polymeric beads with a high surface area for adsorbing organics from aqueous solutions. Biobeads can vary in their hydrophilic and hydrophobic polarities. The range of believed useful properties of biobeads for the present invention is as follows: polarity (non-polar to intermediate polarity); Dipole Moment (0.1 to 3.0); bead size (30 to 2000  $\mu\text{m}$ ); average pore diameter (45 to 300 angstroms); bead surface area (150 to 1,600 sq. meters/gram dry bead). It has been found that biobeads available from Biorad Laboratories . . . under the name Macro-Prep<sup>®</sup> t-butyl HIC function satisfactorily to remove methylene blue and methylene blue photoproducts Azure A and B.

#### Discussion

##### 1. The rejection under 35 U.S.C. § 102(b).

The examiner rejected claims 5, 7, 9, 15, 17, 19, 20, 27, and 29-33 as anticipated by Mohr. Appellants have not presented separate arguments with respect to these claims, so the claims stand or fall together.<sup>1</sup> See In re Kaslow, 707 F.2d 1366, 1376, 217 USPQ 1089, 1096 (Fed. Cir. 1983) (“Since the claims are not separately argued, they all stand or fall together.”). Therefore, we will limit our consideration to claim 31.

Claim 31 is directed to a process of treating a body fluid, such as a blood product, comprising adding a “viral inactivating agent” to the fluid, then passing the mixture through a column containing “macroporous polymeric beads” to

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<sup>1</sup> Appellants do present a separate argument with respect to claims 16 and 26, see the Appeal Brief, page 13, but these claims are not rejected under § 102(b).

remove the viral inactivating agent and photoproducts thereof from the body fluid.

The specification states that methylene blue dye is an example of a “viral inactivating agent.” See page 7, line 30 to page 8, line 2. The specification also states that “macroporous polymeric beads” are also known as “biobeads” and are available, for example, from Bio-Rad Laboratories. See page 10, lines 4-18.

Finally, the specification states that “column refers broadly to a chamber or device that includes material that will remove specific compounds.” Page 8, lines 30-31. Thus, an exemplary process within the scope of claim 31 would comprise adding methylene blue to a blood product and passing the resulting mixture through a device containing biobeads from Bio-Rad Laboratories, in order to remove the methylene blue and any photoproducts thereof.

Mohr teaches a process for inactivating viruses in blood or blood products. The disclosed process comprises adding a phenothiazine dye, such as methylene blue (page 2, line 2), to the blood product, irradiating the mixture, and passing the treated blood product over an adsorbing agent to remove the dye. See page 1, lines 7-14. Mohr discloses that biobeads, obtained from Bio-Rad, may be used to remove methylene blue and other phenothiazine dyes from treated blood products. See pages 15-17. Mohr also discloses passing the treated blood product through a column containing biobeads to remove the methylene blue dye. See claims 6 and 7. The process disclosed by Mohr and the process of instant claim 31 involve the same products and the same method steps in the same order. Thus, Mohr supports a prima facie case of anticipation.

Appellants argue that Mohr “fails to recognize or teach the removal of photoproducts generated by irradiating the viral inactivating agent. . . . Appellants were the first to discover the advantageous removal of these products.” Appeal Brief, page 14.

It is true that Mohr does not discuss removal of methylene blue photoproducts using biobeads. However, the instant specification does not disclose that any special treatment of biobeads is required to enable the biobeads to adsorb methylene blue photoproducts. Thus, it reasonably appears that such adsorption is an inherent property of biobeads. In addition, we note that the instant specification characterizes biobeads as useful for “adsorbing organics” (page 10, line 6), indicating that their affinity is not specific to methylene blue. Also, Mohr states that biobeads are useful for removing methylene blue “and other phenothiazine dyes,” again indicating that their affinity is not limited to methylene blue. Thus, those skilled in the art would reasonably expect that the process disclosed by Mohr inherently removed photoproducts of methylene blue from a treated blood product.

Discovery of a property inherent to a prior art process does not render that process patentable, even if the prior art did not appreciate the property. See Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 630, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). See also In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) (“It is a general rule that merely discovering and

claiming a new benefit of an old process cannot render the process again patentable.”).

Since the cited reference provides a reasonable basis for concluding that the disclosed process inherently possessed all of the properties of the claimed process, the burden shifts to Appellants to provide evidence that their process differs from that of the prior art. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”). Appellants have provided only argument, not evidence, to support their position. Attorney’s argument cannot take the place of evidence. See In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974). The rejection under 35 U.S.C. § 102(b) is affirmed.

2. The rejections under 35 U.S.C. § 103.

The examiner rejected all of the claims as obvious in view of the combined teachings of Heinmets, either of Sugiyama or Hodgson, and Biorad.<sup>2</sup> Heinmets teaches a process for inactivating viruses in plasma by adding one of several dyes (such as methylene blue) to the plasma, irradiating the mixture, and removing the dye using an ion exchange column. Heinmets, however, does not teach removing dye from treated plasma using “macroporous polymeric beads,”

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<sup>2</sup> Biorad was relied on only with respect to claim 9.

as required by the claims. The examiner relies on either of Sugiyama or Hodgson to remedy this deficiency. The examiner reasons as follows:

Sugiyama . . . teaches in the claims a method for removing soluble poisonous substances from blood by bringing the blood into contact with an absorbent which in claim 4 is activated carbon. In column 2 lines 40-48, the adsorbents may be porous resins, porous alumina, porous glass or ion exchange resins, selected depending upon the substances which are to be removed from blood by absorption.

Hodgson . . . teaches a column for purifying blood, in column 2 lines 35-42, the column may be filled with granules having activated carbon or polystyrene granules. In column 2 lines 55-60, other polymers are shown. In column 4 line 6, any known particulate absorbent may be used.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the macroporous polymeric beads of either Sugiyama or Hodgson in the method of Heinmets to remove selected substances from blood because Sugiyama and Hodgson show such porous polymers are compatible with blood and effectively remove selected substances.

Examiner's Answer, pages 6-7.

"The PTO has the burden under section 103 to establish a prima facie case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (citations omitted). "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the

suggestion and expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (citations omitted).

The references relied on by the examiner in this case do not provide the required motivation to combine their teachings. Heinmets does not suggest using chromatographic media other than an ion exchange resin to remove methylene blue from treated plasma. Sugiyama and Hodgson, while they teach removing substances from blood using macroporous polymeric beads, do not discuss adsorption of methylene blue dye.

Sugiyama states that the object of his invention was "to remove soluble poison substances" from blood (column 2, line 13), which are defined as substances resulting from renal failure or liver failure, such as creatinine, uric acid, and urea. Column 1, lines 16-20. Sugiyama also teaches that the particular chromatographic medium used will depend on what substances are to be removed from the blood. Sugiyama does not discuss what media would be effective for removing methylene blue dye from blood.

Hodgson is directed to a method for removing "for instance, barbiturates or other poisons" from blood. Similar to Sugiyama, Hodgson provides no reason, suggestion, or motivation for using the disclosed process to remove methylene blue dye from treated plasma. There is simply no adequate connection made in the cited references between the methylene blue-containing blood taught by Heinmets and the chromatographic media taught by Sugiyama and Hodgson.

Since the prior art provides insufficient motivation to modify the process taught by Heinmets by substituting macroporous polymeric beads for the ion exchange resin used by Heinmets, the prior art does not support a prima facie case of obviousness. We therefore reverse the rejection under 35 U.S.C. § 103.<sup>3</sup>

#### Other Issues

The examiner did not reject claims 35-37 for anticipation. Claims 35-37 depend from claims 31-33, respectively, and add the limitation that the photoproduct removed from the body fluid is selected from Azure A and Azure B. Azure A and Azure B are photoproducts of methylene blue. Specification, page 3. We have concluded that Mohr anticipates claims 31-33 and that the process disclosed by Mohr reasonably appears to inherently remove photoproducts of methylene blue from a treated blood product. See pages 6 to 7, supra. Thus, claims 35-37 would also appear to be anticipated by Mohr. Upon return of this application, the examiner should consider whether claims 35-37 should be rejected under 35 U.S.C. § 102(b) as anticipated by Mohr.

#### Summary

We affirm the rejection for anticipation because the prior art process reasonably appears to be identical to the process of claim 31 and Appellants have provided no evidence in rebuttal. However, we reverse the rejections for obviousness because the cited references do not provide the requisite motivation

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<sup>3</sup> We also note that none of the references relied on by the examiner disclose the specific virus inactivating agents recited in claims 6, 14, 16, 25, and 26. These deficiencies would require reversal of the rejection with respect to these claims even if the rejection was affirmed with respect to the broader claims.

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to combine their respective teachings. Thus, claims 6, 14, 16, 25, 26, and 34-38 are not subject to any outstanding rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED IN PART

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
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	)	BOARD OF PATENT
DEMETRA J. MILLS	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
ERIC GRIMES	)	
Administrative Patent Judge	)	

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