

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 87

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte NORBERT HEIMBURGER, GERHARDT KUMPE,  
WILFRIED WORMSBACHER and HANS PREIS

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Appeal No. 1999-0959  
Application No. 08/415,166

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ON BRIEF

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Before WINTERS, ADAMS, 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 3, 5-8, and 11-22, all of the claims remaining in the application.

Claims 21 and 5 are representative and read as follows:

21. A process for the preparation of a virus-free product of blood coagulation factors II, VII, IX, and X comprising heating an aqueous solution containing these factors to a temperature ranging from 30°C to 100°C for a period ranging from 1 minute to 48 hours, in the

presence of at least one compound selected from the group consisting of an amino acid, a saccharide and a sugar-alcohol and also in the presence of calcium ions and a chelating agent, wherein the concentration of calcium ions is from 1 to about 30 mmol/l and the concentration of the chelating agent is from 1 to about 7 mmol/l.

5. The process as claimed in claim 8, wherein the solution is heated in the presence of 0.2-2 units/ml of antithrombin III, 2-20 USP units/ml of heparin, 25 to 30 mmol/l of calcium ions, 1 to 7 mmol/l of EDTA, 1-3 mol/l of at least one amino acid selected from the group consisting of glycine, alpha-alanine, beta-alanine, lysine, leucine, valine, asparagine, serine, hydroxyproline, proline and glutamine or one substance selected from the group consisting of alpha-aminobutyric acid, beta-aminobutyric acid and gamma-aminobutyric acid, and 20 to 60 g/100 g of a solution of a mono-saccharide, oligo-saccharide or sugar-alcohol.

The examiner relies on the following references:

Schwinn et al. (Schwinn '187)	4,404,187	Sept. 13, 1983
Schwinn et al. (Schwinn '603)	4,405,603	Sept. 20, 1983

Claims 3, 5-8, and 11-22 stand rejected under 35 U.S.C. § 112, first paragraph, as unsupported by an adequate written description.

Claims 3, 5-8, and 11-22 also stand rejected under 35 U.S.C. § 103 as obvious over Schwinn '187 and Schwinn '603.

We reverse both of the rejections.

#### Background

Appellants' specification discloses a method for inactivating viruses in a preparation of blood coagulation factors. The method involves heating the preparation in the presence of an amino acid, a saccharide, and/or a sugar alcohol, in the presence of calcium ions and a chelating agent. See page 4.

The instant application claims benefit under 35 U.S.C. § 120 to a series of earlier applications dating back to October 5, 1984. One of these earlier applications (serial number 07/127,561) was the subject of a previous appeal to this board (appeal number 90-2287, decided June 18, 1991). In that case, the claims were rejected under 35 U.S.C. § 103 as obvious over the same Schwinn '187 and Schwinn '603 patents that form the basis of the § 103 rejection now on appeal. The Schwinn patents disclose processes similar to the one now claimed, but the Schwinn '187 process does not use calcium and the Schwinn '603 process does not use a chelating agent. The rejection was affirmed on the basis that a person of ordinary skill in the art would have been led to combine the reagents used in the two processes, with a reasonable expectation of success, to heat-stabilize a solution containing clotting factors II, VII, IX and X.

Appellants amended the claims to add the limitations that the calcium ions and chelating agent are present at concentrations of 1-30 mM and 1-7 mM, respectively. The examiner maintained the § 103 rejection and imposed an additional rejection based on lack of an adequate written description. This appeal followed.

### Discussion

#### 1. The written description rejection

The claims are directed to a method of inactivating viruses in a preparation of blood coagulation factors, comprising heating the preparation in the presence of, inter alia, 1-30 mM calcium ions and 1-7 mM chelating agent.

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The examiner rejected all of the claims on the basis that the specification does not adequately describe the concentration ranges recited in the claims:

Claim 5 at line 3 recites “25-30 mmol/l”. There is no support in the specification for such a limitation. The specification shows support . . . for only the range 25-50 mmol/l. The new range could not be found in the specification as filed. . . .

Similarly in claim 5, line 3, “1-7 mmol/l” of EDTA could not be found in the specification. Page 5, lines 18-19, for instance does not show 7 mmol/l, it shows 1-20, preferably 5[ ]mmol/l. Examples show 5 mmol/l.

Claim 21 also recites “30 mmol/l” of calcium ions and “7 mmol/l” of chelating agent. And, as discussed above for claims 5 and 21 [sic], there is no support for these numbers in the specification.

Examiner’s Answer, pages 3-4.

Appellants argue that the specification discloses that calcium ions and chelating agents may be used at concentrations of 1 -50 mM and 1-10 mM, respectively. Appellants argue that these disclosures provide an adequate description of the claimed process because the broader concentration ranges recited in the specification show possession of the narrower ranges recited in the claims. Appellants cite several cases in support of their position, including In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), and In re Blaser, 556 F.2d 534, 194 USPQ 122 (CCPA 1977).

We agree with Appellants that the examiner’s position conflicts with Wertheim and Blaser. The Wertheim court stated that the issue in a case like this is

whether the invention appellants seek to protect by their claims is part of the invention that appellants have described as theirs in the

specification. That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

Wertheim, 541 F.2d at 263, 191 USPQ at 97 (emphasis in original).

In Wertheim, the relevant claim limitation recited “between 35% to 60%” by weight of coffee solids. Id. at 262, 191 USPQ at 96. The specification recited a range of 25% to 60% and exemplified processes using 36% and 50% solids.

See id. The court concluded that

[i]]n the context of this invention, in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants’ invention. . . . The PTO has done nothing more than argue lack of literal support, which is not enough.

Id. at 265, 191 USPQ at 98 (emphasis in original).

Similarly, in Blaser the claims recited “heating the reaction blend . . . obtained[] after completing of said mixing to 80° C to 200° C.” Blaser, 556 F.2d at 536, 194 USPQ at 125. The specification disclosed initially mixing the starting materials (at temperatures of up to 80° C) and then heating the reaction blend to temperatures between 60° C and 200° C. See id. The court framed the issue as “whether the disclosed range of 60° C to 200° C in [the specification] supports the recitation of 80° C to 200° C in the claims on appeal,” id., and concluded that it did:

Appellants rely on the rationale of In re Wertheim, supra, as “clearly applicable here.” Appellants urge that if a disclosure of 25-60% solids content taught those skilled in the art that 35-60% was part of the invention in Wertheim, although the latter range was not expressly mentioned therein, then appellants’ disclosure of 60° C to 200° C in [the specification] would likewise teach 80° C to 200° C as part of appellants’ invention. We agree with appellants that Wertheim is controlling on this point.

Id.

In the present case, the specification discloses use of calcium ions at a concentration of 1 -50 mM and use of chelating agents at a concentration of 1-10 mM. See page 4, lines 28-29, and page 5, lines 17-19. The combination of 25 mM calcium and 5 mM EDTA (chelating agent) is disclosed to be “particularly suitable.” Page 5, lines 20-21. The claims recite calcium at 1-30 mM (claims 3, 6-8, 11-18, and 21) or 25-30 mM (claim 5), and a chelating agent at 1-7 mM (all but claims 20 and 22<sup>1</sup>).

Thus, as in Wertheim, the specification discloses a broader range that encompasses the claimed range and expresses a preference for one or more specific values within the claimed range. Under the rationale of Wertheim and Blaser, the instant specification adequately describes the ranges recited in the claims on appeal. That is, the specification reasonably conveys to the skilled artisan that Appellants had possession, at the time the application was filed, of the invention now claimed. Such a disclosure satisfies the written description

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<sup>1</sup> Claim 22 is limited to 25 mM calcium and 5 mM chelating agent, both of which the examiner has conceded to be adequately supported by the specification. See the Examiner’s Answer, page 3 (“Examples show support for 25 mmol/l calcium ions.”) and page 4 (“[T]he specification . . . shows 1-20, preferably 5[ ]mmol/l” of EDTA.”). Claim 22 therefore should not have been included in this rejection.

requirement. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

## 2. The obviousness rejection

The examiner rejected all of the claims as obvious over Schwinn '187 and Schwinn '603. The examiner appears to acknowledge that neither of the Schwinn references teaches or suggests using calcium ions or a chelating agent at the concentrations recited in the claims,<sup>2</sup> but argues that

[i]t would have been within the realm of the artisan to adjust the amounts of calcium and chelating agent at the time of combining such teachings from amounts taught by each patent for individual use, as such adjustment would be routine when combining the teachings of two references.

Examiner's Answer, page 7. As we understand it, the examiner's position is that the claims are prima facie obvious because it would have required only routine skill to adjust the concentrations of calcium and chelating agent in order to obtain a concentration within the range recited in the claims.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "Under

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<sup>2</sup> The examiner states that "[w]hile the 2 patents do not teach the amounts of chelating agent and calcium ions as claimed, they are either within or about the ranges claimed." Examiner's Answer, page 7. This statement is self-contradictory. Either the references "do not teach the amounts of chelating agent and calcium ions as claimed," or they teach amounts that are "within . . . the ranges claimed;" they cannot do both. We note that Schwinn '187 discloses use of chelating agent at a concentration of "0.01 to 0.3 mole/l" (col. 2, line 23), i.e., 10 to 300 mM, and Schwinn '603 teaches use of calcium at "0.05 to 2.0 moles/l (col. 2, line 7), i.e., 50 to 2000 mM. The examiner therefore had it right when she stated that "the 2 patents do not teach the amounts of chelating agent and calcium ions as claimed."

section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.’ Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious ‘modification’ of the prior art.” Id. at 1266, 23 USPQ2d at 1783 (citations omitted, emphasis in original).

The examiner asserts that those skilled in the art would have found it obvious in view of the Schwinn patents to practice the claimed method employing calcium ions at 1-30 mM and a chelating agent at 1-7 mM. However, the prior art teaches use of these reagents at concentrations significantly higher than those recited in the claims, i.e., calcium at 50-2000 mM and chelating agent at 10-300 mM. The examiner points to nothing in the references that would have led a person of ordinary skill in the art to modify the disclosed methods by using calcium and chelating agent at the concentrations recited in the claims. Nor does the examiner provide other evidence or reasoning that would have led those skilled in the art to modify the method disclosed by the Schwinn patents by reducing the concentrations of calcium and chelating agent.

“The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” In re Fritch, 972 F.2d at 1266, 23 USPQ2d at 1783. Since the relied-on references do not provide motivation to modify a known process as required by the claims, they do not support a prima facie case of obviousness. The rejection is reversed.

Summary

We reverse the written description rejection because the examiner's position is not supported by the relevant case law. We reverse the obviousness rejection because the cited references do not provide the requisite motivation to modify their teachings in order to meet the limitations of the instant claims.

REVERSED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
DONALD E. ADAMS	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
ERIC GRIMES	)	
Administrative Patent Judge	)	

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FINNEGAN HENDERSON FARABOW  
GARRETT & DUNNER  
1300 I STREET NW  
WASHINGTON, DC 20006-3315

EG/jlb