

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte  
THOMAS A. AUGURT

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Appeal No. 1997-3805  
Application No. 08/439,602<sup>1</sup>

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ON BRIEF

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Before WILLIAM F. SMITH, ROBINSON, and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

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<sup>1</sup> Application for patent filed May 12, 1995. According to appellant, this application is a divisional of application serial no. 08/121,072, filed September 14, 1993, now U.S. Patent No. 5,447,868.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 24 through 26 and 30 through 43, all the claims remaining in the application.

Claims 24, 25 and 26 are representative of the claims on appeal and read as follows:

24. A method for detecting occult blood in a specimen comprising combining the specimen with

- (a) hydrogen peroxide or a peroxide source;
- (b) an oxidizable substrate that produces a colored product in the presence of peroxide and hemoglobin; and
- (c) an enhancer consisting of a composition selected from the group consisting of tertiary and quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen in a liquid carrier, wherein the peroxide, oxidizable substrate and enhancer are combined with the specimen in amounts effective to produce a visually detectable color change if medically significant amounts of blood are present in the specimen.

25. A composition for use as a liquid developer in a test for fecal occult blood based upon the oxidation of a substrate to a colored product comprising

- (a) hydrogen peroxide or a peroxide source;
- (b) an amount of an enhancer effective to enhance the amount of colored product produced; and
- (c) a carrier comprising water and ethanol, wherein the enhancer is selected from the group consisting of tertiary and quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen.

26. A kit for the detection of occult blood comprising, in packaged combination,

- (a) an oxidizable substrate which is converted to a colored product in the presence of peroxide and hemoglobin; and
- (b) a developer comprising a liquid carrier, hydrogen peroxide or a peroxide source, and an enhancer in an amount effective to enhance the conversion of the oxidizable substrate to the colored product, wherein the enhancer is selected from the group consisting of tertiary and quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen.

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The references relied upon by the examiner are:

Gantzer	4,556,640	Dec. 3, 1985
Eur. Pat. Spec. (Baker)	0 308 227	Jul. 22, 1992

Claims 24 through 26 stand rejected under the judicially-created doctrine of obviousness-type double patenting as unpatentable over claims 4, 10 and 16 of U.S. Patent No. 5,563,071, while claims 24 through 26 and 30 through 43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Baker and Gantzer.

We affirm the obviousness-type double patenting rejection and reverse the obviousness rejection.

### DISCUSSION

The claims on appeal are drawn to methods, compositions and kits for detecting occult blood. Each of the claims requires an enhancer in a liquid carrier, wherein the enhancer is selected from the group consisting of tertiary and quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen.

#### Obviousness-type Double Patenting

In deciding this issue, we have considered the arguments made in appellant's Brief (paper no. 11) and in the Examiner's Answer (paper no. 12). We have also considered the prosecution histories of parent application serial no. 08/121,072 (now U.S. Patent

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5,447,868); the present divisional application; and divisional application serial no. 08/439,603 (now U.S. Patent 5,563,071).

Claims 24 through 26 on appeal are directed to a method, composition and kit, respectively, each requiring an enhancer selected from the group consisting of tertiary and quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen. Patent No. 5,563,071 claims a similar method, composition and kit, but each independent claim requires an enhancer selected from the group consisting of tertiary and quaternary amines having a hydroxy alkyl or esterified hydroxy alkyl group attached to the nitrogen. Patented claims 4, 10, and 16 limit the enhancer component to phenyl diethanolamine. The examiner argues that patented claims 4, 10 and 16 are not patentably distinct from claims 24 through 26 on appeal because phenyl diethanolamine is simultaneously a tertiary amine having a phenyl group attached to the nitrogen, and a tertiary amine having a hydroxy alkyl group attached to the nitrogen. Examiner's Answer, page 5. That is, the specific enhancer of the patented claims, phenyl diethanolamine, falls within the presently claimed genus of enhancers comprising tertiary and quaternary amines having a phenyl group attached to the nitrogen, as well as the patented genus of enhancers comprising tertiary amines having a hydroxy alkyl group attached to the nitrogen. Accordingly, the claims stand rejected under the doctrine of obviousness-type double patenting.

Appellant argues that the double patenting rejection is improper because the present application and the application leading to the patent were filed in response to a

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restriction requirement in parent application serial no. 08/121,072, and the generic enhancers in the two divisional applications remain the same as they were at filing. Brief, page 4.

The examiner points out that patented claims 4, 10 and 16 were not original claims in the parent application that gave rise to the two divisional applications at issue here, but were added by amendment. Thus, the examiner argues that “these claims are not consonant with the restriction requirement made in the parent application since the claims have changed in material respects from the claims at the time the requirement was made . . . and the line of demarcation between the independent and distinct inventions identified by the examiner in the parent application does not exist.” Examiner’s Answer, page 8.

Nevertheless, appellant argues “to claim the specific compound, Applicant could and did place it in one (and only one) of the two applications” and “should not be penalized or limited in the scope of his rights because the Examiner failed to appreciate that the groups were not fully distinct at the time the restriction requirement was made.” Brief, page 4. We note that appellant, despite being aware of the same facts as the examiner, did not traverse the restriction requirement. Instead, appellant chose to place a claim in one of the divisional applications that is simultaneously a species of the genres claimed in the two divisional applications. Be that as it may, we do not find that the confusion surrounding the original restriction requirement, in and of itself, justifies an extension of the

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patent term for the presently claimed genus, which is not, in fact, separate and distinct from the patented genus.

There is no dispute between appellant and the examiner that the presently claimed genus is obvious over the patented species, but the patented species is not obvious over the claimed genus. Examiner's Answer, page 9. Thus, in our view, the dispositive issue is whether one-way obviousness is sufficient basis for the examiner's rejection of claims 24 through 26 under the doctrine of obviousness-type double patenting.

According to appellant, the examiner must apply the two-way obviousness analysis described in In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir.1991) because the two divisional applications were filed concurrently. Inasmuch as the patented claims are directed to a species which falls within the scope of the generic claims of this application, appellant argues that, in keeping with Braat, the examiner must determine not only whether the genus is an obvious modification of the species, but whether the species is also an obvious and trivial modification of the genus, and "submits that such a showing could not be made." Brief, pages 4 and 5.

Nevertheless, the examiner does not concede that a two-way test of obviousness is required under the circumstances. In our judgment, the examiner is correct in applying the one-way test.

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In In re Berg, 140 F.3d 1428, 1432, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998), the court discussed circumstances under which a two-way test of obviousness would be appropriate:

Generally, a “one-way” test has been applied to determine obviousness-type double patenting. Under that test, the examiner asks whether the application claims are obvious over the patent claims. In a recent case, with unusual circumstances, however, this court instead applied a “two-way” test. See Braat, 937 F.2d at 592, 19 USPQ2d at 1291-92. Under the two-way test, the examiner also asks whether the patent claims are obvious over the application claims. If not, the application claims later may be allowed. Thus, when the two-way test applies, some claims may be allowed that would have been rejected under the one-way test. . . . The essential concern was to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing.  
\* \* \*

. . . Since Braat, many patent applicants facing an obviousness-type double patenting rejection under the one-way test have argued that they actually are entitled to the two-way test. The two-way test, however, is a narrow exception to the general rule of the one-way test. . . . Nevertheless, the notion survives that in certain unusual circumstances, the applicant should receive the benefit of the two-way test. The question then is: when?

According to the court, Id., 140 F.3d at 1435, 46 USPQ2d at 1232,

The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application.

Assuming, for the sake of argument, that the first prong of the test has been satisfied (since the separation of the “phenyl” genus and the “hydroxy alkyl” genus of enhancer into two divisional applications was the direct result of a restriction requirement

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in the parent application), the dispositive question is whether or not the second prong of the test has been satisfied; that is, whether or not the PTO controlled the rate of prosecution to cause the species claims to issue before the genus claims.

The actions taken by the PTO and by appellant are set forth in chronological order in the following table and distinguished by different type fonts and columns:

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September 14, 1993	Parent application 08/121,072 filed	
January 26, 1994	Restriction requirement made in '072, separating "phenyl" genus (P) and "hydroxy alkyl" genus (HA)	
May 12, 1995	P divisional filed (08/439,602)	<i>HA divisional filed (08/439,603) Concurrent preliminary amendment adds phenyl diethanolamine species (PHA) claims</i>
September 20, 1995	PTO rejects on several grounds, including provisional obvious-type double patenting rejection over PHA claims	<i>PTO rejects</i>
November 6, 1995		<i>Applicant responds (about 1.5 months after rejection)</i>
January 5, 1996	Applicant responds (about 3.5 months after rejection)	
February 1, 1996		<i>PTO finally rejects (about 3 months after response)</i>
April 5, 1996	PTO finally rejects (about 3 months after response)	
April 29, 1996		<i>Applicant responds (about 3 months after final rejection)</i>
May 14, 1996		<i>PTO allows</i>
September 27, 1996	Applicant responds (about 5 months after final rejection)	
October 8, 1996		<i>PTO issues patent</i>
October 9, 1996	Applicant files notice of appeal	
October 16, 1996	PTO sends advisory action	
April 4, 1997	Applicant files appeal brief	

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As shown in the table, the two divisional applications were filed on the same day. Likewise, the PTO initiated prosecution of the two applications on the same day, imposing the double patenting rejection from the start. On the other hand, appellant's initial response in the phenyl "genus" divisional was submitted approximately two months later than the initial response in the phenyl diethanolamine "species" divisional, and this pattern continued throughout prosecution of the two applications. Given this prosecution history, we see no evidence that the PTO controlled the rate of prosecution in such a way as to cause the phenyl diethanolamine species claims to issue before the phenyl genus claims. Thus, we conclude that the second prong of the test has not been satisfied, and a two-way obviousness analysis is not required in this instance. Inasmuch as there is no dispute that one-way obviousness exists between the genus and species claims, the rejection of the claims under the doctrine of obviousness-type double patenting, based on a one-way analysis, is affirmed.

#### Obviousness

Claims 24 through 26 and 30 through 43 stand rejected under 35 U.S.C. § 103 as unpatentable over Baker and Gantzer.

Baker describes a method, composition, and kit for determining occult blood in a fecal sample. The sample is combined with an oxidizable substrate (guaiac) and a developer solution comprising ethanol, water, a peroxide, and an enhancer. Hemoglobin in the sample has peroxidative activity and catalyzes the oxidation of guaiac, resulting in a

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blue color. Baker's enhancer, which provides better color production, is phenol or a "phenolic type compound[]" (page 2), rather than a tertiary or quaternary amine with a phenyl or substituted phenyl group attached to the nitrogen, as required by the claims on appeal.

Gantzer describes a method for determining substances, particularly occult blood, in a test sample, comprising the steps of combining the test specimen with a peroxide source, an oxidizable indicator, and a stabilizer, for example, an aniline compound that serves to stabilize the reagents and enhance the overall sensitivity of the test. Aniline compounds are tertiary or quaternary amines having a phenyl or substituted phenyl group attached to the nitrogen. The reference also describes a composition, preferably applied to a matrix strip as two separate solutions and then dried, wherein the first solution comprises an enhancer such as aniline, and the second solution contains a peroxide and an oxidizable indicator compound.

According to the examiner (Examiner's Answer, pages 7 and 8),

Gantzer renders obvious the composition recited in [the instant claims] since at the point at which both the first and second solutions are applied to the dry-matrix test strip, all components of the composition are mixed together including the enhancer, the peroxide, the indicator substrate and the water and ethanol.

Thus,

[I]t would have been obvious to one of ordinary skill in the art . . . to substitute the aniline compounds taught by Gantzer for the phenol compounds as the enhancer in the method, composition and kit of [Baker] since Gantzer teaches that aniline compounds enhance the stability of the reaction thus

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enabling the method to be more sensitive to the presence of occult blood. Therefore, one . . . would have found the aniline compounds taught by Gantzer to work equally as well as the phenol compounds in the method, composition and kit taught by [Baker] as enhancers for detecting occult blood.

We have no doubt that the prior art could be modified in a manner consistent with appellant's specification and claims. The fact that the prior art could be so modified, however, would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Here we find no reason stemming from the prior art which would have led a person having ordinary skill to the claimed method.

In addition to producing "a more intense and readable blue color end point," Baker's phenolic enhancer "degrades and inhibits the more labile peroxidases" which often contaminate fecal samples and interfere with test results by causing false positive reactions. Page 2.

Gantzer, on the other hand, is narrowly focused on improving the shelf-life of solid phase "dip-and-read" devices impregnated with peroxidatively active substances. The aniline stabilizer is dried onto the device along with, or in addition to, the a peroxide source and a colorimetric indicator. According to Gantzer, the "anilines are believed to function not only as inhibitors of chain decomposition of the organic hydroperoxides commonly used in solid phase assays, but also are advantageous for diminishing or preventing deleterious interactions between reagents." Column 4, lines 55-58.

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In our view, the mere fact that both references are directed to test systems for detecting occult blood would not have led one skilled in the art to substitute the aniline stabilizer from Gantzer's solid phase system for the phenolic enhancer/developer in Baker's liquid phase system, when the stated functions of those reagents in their respective systems are different.

In our judgment, the only reason or suggestion to combine the references in the manner proposed by the examiner comes from appellant's specification. Accordingly, the rejection of claims 24 through 26 and 30 through 43 as unpatentable over Baker and Gantzer is reversed.

#### CONCLUSION

For the reasons set forth in the body of this opinion, we have affirmed the rejection of claims 24 through 26 under the doctrine of obviousness-type double patenting, and reversed the rejection of claims 24 through 26 and 30 through 43 under 35 U.S.C. § 103. As a result of the action taken today, claims 30 through 43 are free of rejection.

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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

William F. Smith	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Douglas W. Robinson	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Toni R. Scheiner	)	
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