

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 48

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte MAKOTO NAKAMURA,  
TOYOHIRO TAMAI and RYOUHEI SHIMIZU

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Appeal No. 1997-3503  
Application No. 08/172,866

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HEARD: December 5, 2000

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Before WILLIAM F. SMITH, SPIEGEL and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 29, 31-33, 35-40, 42-44, and 46-53. Claims 13-18 are withdrawn from consideration<sup>1</sup> as drawn to a non-elected invention. Claims 1-12, 19-28, 30, 34, 41, and 45 are canceled.

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<sup>1</sup> Paper No. 26, mailed June 30, 1994.

Claims 29 and 39 are illustrative of the subject matter on appeal and are reproduced below:

29. An immunoassay method for detecting or identifying an analyte contained in a biological sample, comprising the steps of:

(a) adding said sample and magnetic particles, said magnetic particles being coated with an immunological substance which specifically binds to the analyte, to a reaction vessel having an inclined surface for collecting the magnetic particles, said inclined surface being an inner surface of a bottom wall of the reaction vessel, whereby said magnetic particles are reacted with said analyte present in said sample, thereby agglomerating the magnetic particles through binding with said analyte;

(b) arranging a magnet outside said reaction vessel such that magnetic particles which are not agglomerated are caused by the magnetic field to be moved along the inclined surface to reach a bottom portion thereof, while magnetic particles agglomerated on the inclined surface are not moved by the magnetic field, thereby forming a particle pattern concentrated at the center of a lower end portion of the reaction vessel in the absence of said analyte, and forming a particle pattern uniformly spread on the inclined surface in the presence of said analyte; and

(c) determining the presence or absence of the analyte on the basis of the particle pattern of the magnetic particles formed on the inclined surface by the action of the magnetic field.

39. An immunoassay method for detecting or identifying an analyte contained in a biological sample, comprising the steps of:

(a) immobilizing an immunological substance which specifically binds with the analyte, to an inclined surface which is an inner surface of a bottom wall of a reaction vessel;

(b) adding said sample and magnetic particles to said reaction vessel, each of said magnetic particles being coated with an immunological substance which specifically binds with said analyte, whereby said analyte contained in said sample binds with said immunological substance which has been immobilized on said inclined surface in said step (a), and said magnetic particles bind with said bound analyte, thereby binding each of said magnetic particles with said

inclined surface of said reaction vessel through said analyte and said immunological substance;

- (c) arranging a magnet outside said reaction vessel such that magnetic particles which are not agglomerated on the inclined surface are caused by the magnetic field to be moved along the inclined surface to reach a bottom portion thereof, while magnetic particles agglomerated on the inclined surface are not moved by the magnetic field, thereby forming a particle pattern concentrated at the center of a lower end portion of the reaction vessel in the absence of said analyte, and forming a particle pattern uniformly spread on the inclined surface in the presence of said analyte; and
- (d) determining the presence of the absence of the analyte on the basis of the particle pattern of the magnetic particles formed on the inclined surface by the action of the magnetic field.

The references relied upon by the examiner are:

Rosenfield et al. (Rosenfield)	4,328,183	May 4, 1982
Ikeda et al. ('813)	4,416,813	Nov. 22, 1983
Forrest	4,438,068	Mar. 20, 1984
Ikeda et al. ('622)	4,582,622	Apr. 15, 1986
Sakuma	4,661,460	Apr. 28, 1987
Asakura et al. (Asakura)	J5 6142-259	Nov. 6, 1981 <sup>2</sup>
Ikeda et al. ('061)	EP 0 233 061	Aug. 19, 1987

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<sup>2</sup> The examiner relied upon an English language translation of this document.

GROUND OF REJECTION<sup>3</sup>

Claims 29, 31 and 35-37<sup>4</sup> stand rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma.

Claims 32-33, 50 and 51 stand rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma further in view of Forrest.

Claim 38 stands rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma further in view of '813.

Claims 39-40, 42 and 46-48 stand rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma further in view of Rosenfield.

Claims 43, 44 and 52-53 stand rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma and Rosenfield further in view of Forrest.

Claim 49 stands rejected under 35 U.S.C. § 103 as being unpatentable over ('061), in view of ('622) and Sakuma, Rosenfield and further in view of '813.

Claims 29, 31, 35-40, 42 and 46-49 stand rejected under 35 U.S.C. § 103 as being unpatentable over Asakura in view of ('622).

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<sup>3</sup> We note the examiner withdrew the final rejection of claim 39 under 35 U.S.C. § 112, first paragraph, in the July 21, 1995 Advisory Action (Paper No. 34).

<sup>4</sup> We note the following typographical error in appellants' Appendix of claims on appeal. Claim 37 should depend from claim 29 not canceled claim 30. See appellants' amendment Paper No. 15, received April 5, 1993, page 4. We considered claim 37 as depending from claim 29.

Claims 32, 33, 43, 44 and 50-53 stand rejected under 35 U.S.C. § 103 as being unpatentable over Asakura in view of ('622) further in view of Forrest.

We affirm the examiner's rejections.

#### DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer<sup>5</sup>, and the examiner's Supplemental Answer<sup>6</sup> for the examiner's reasoning in support of the rejections. We further reference appellants' Brief<sup>7</sup>, and appellants' Reply Brief<sup>8</sup> for the appellants' arguments in favor of patentability. Appellants' Supplemental Reply Brief<sup>9</sup> was not entered into the record<sup>10</sup> and therefore was not considered by this merits panel.

#### CLAIM GROUPING:

Appellants' Brief does not include a statement under 37 CFR § 1.192(c)(7) regarding the "[g]rouping of claims." Accordingly, the claims stand or fall together as set forth at pages 2-3 of the Answer. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

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<sup>5</sup> Paper No. 38, mailed February 8, 1996.

<sup>6</sup> Paper No. 41, mailed July 23, 1996.

<sup>7</sup> Paper No. 39, received September 27, 1995.

<sup>8</sup> Paper No. 39, received April 8, 1996.

<sup>9</sup> Paper No. 42, received September 23, 1996.

<sup>10</sup> See Paper No. 43, mailed December 16, 1996.

THE REJECTIONS UNDER 35 U.S.C. § 103:

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Claims 29, 31 and 35-37:

The examiner argues (Answer, pages 4-5) that '061:

[T]each a reagent for detecting an antibody to human immunodeficiency virus (HIV) by a passive particle agglutination method.... The carrier particles ... include erythrocytes ... and gelatin particles.... Gelatin particles are preferable because they show little non-specific reaction and the gelatin is easily modified to add properties necessary for the use of the particles.... ['061] differs from the instant invention in that they do not specify the particular shape of the reaction vessel utilized or that the particles may be magnetic. ...

['622] teach a gelatin magnetic particulate that can be used as a carrier to immobilize biological proteins such as antigens, antibodies, or enzymes in assays involving antigen-antibody reactions. The magnetic particulate has the following advantages when used as a carrier for immobilization of biological protein: 1) Agglutination time in an antigen antibody reaction can be controlled by a magnet and 2) Magnetic particulates can be easily separated or recovered from a suspension thereof by magnetic force, compared with conventional particulates not containing magnetic substances....

Sakuma teaches a method of detecting antigen-antibody reactions by detection of a pattern formed by particles descending on an inclined bottom surface of a reaction vessel. When there is an antigen-antibody reaction, particles are agglutinated and are deposited uniformly on the inclined bottom surface like snow to form an agglutination pattern. In contrast, when an antigen-antibody reaction does not occur, the particles are not agglutinated and roll down along the inclined bottom surface into the lowermost portion of the reaction vessel to form a non-agglutination pattern.

The examiner concludes (Answer, page 5) that:

It would have been obvious ... to utilize the magnetic gelatin particles taught by ... [‘622] in the assay of ... [‘061] because ... [‘622] specifically teach that they can be used as carriers to immobilize biological proteins and that they offer advantages over traditional particles used in agglutination assays, such as control of agglutination time in an antigen-antibody reaction by a magnet and easy separation from a suspension by magnetic force. ... [‘061] teach that detection of an agglutination pattern for determination of an antigen or antibody is well known, [however] they do not specifically describe the vessel utilized and the pattern formed. ... Sakuma teaches that such vessels and patterns are well known and conventional in the prior art. Provision of the magnet at the bottom of one of these conventional vessels would provide the magnetic field described in step (b) of claim 29 (since it would basically replace the force of gravity described by Sakuma).

Appellants argue (Brief, page 16) that ‘622 “do not teach or suggest when to apply a magnetic force and where to dispose a magnet.... [‘622 also does] not teach or suggest a specific agglutination time, making it quite unclear how to control the reaction.” Appellants argue (Brief, page 17) that “[t]he present invention permits a substantial shortening of the time required for the immunoassay by the particle agglutination method and also permits improving assay sensitivity.

Regarding appellants’ arguments concerning unexpected results, we look to the Nakamura Declaration<sup>11</sup> wherein the claimed invention is compared to a method utilizing centrifugal force. Appellants state (Brief, page 9) that “[t]he methods of the present invention utilizing a magnetic force is extraordinarily advantageous when compared to the method utilizing centrifugal force....” Applicants further argue (Brief, page 17) that “the unexpected results of the

present invention cannot be expected from the cited references. Where a gravitational force is utilized as in Sakuma, it is not possible to obtain an [sic] desirable sensitivity as in the present invention.”

The examiner argues (Answer, page 12) that “[o]ne of ordinary skill in the art would have known that when a magnet is used to replace the force of gravity, it should be placed at the bottom of the reaction vessel...” and one would “certainly have expected that use of a magnet for precipitation in place of gravity would have shortened the precipitation time considerably. The clearly distinguishable positive or negative pattern would have naturally resulted from the use of the magnet.” We remind appellant, as set forth in In re Freeman, 474 F.2d 1318, 1324, 177 USPQ 139, 143 (CCPA 1973):

In order for a showing of “unexpected results” to be probative evidence of non-obviousness, it falls upon the applicant to at least establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art, and (2) that the difference actually obtained would not have been expected by one skilled in the art at the time of the invention.

Here appellants have not established that the difference actually obtained by the use of a magnet as set forth in the examiner’s rejection would not have been expected by one skilled in the art at the time of the invention. As explained by the examiner (Supplemental Answer, page 2), “none of the references used for rejection of the claims suggests the use of centrifugation for rapid precipitation.” Accordingly, we are not persuaded by appellants’ arguments and evidence of unexpected results.

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<sup>11</sup> Executed, October 26, 1993.

It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion or motivation to lead an inventor to combine those references. Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). On this record, it is our opinion that the examiner presented the evidence necessary to establish a prima facie case of obviousness. Accordingly, we affirm the examiner's rejection of claims 29, 31 and 35-37 under 35 U.S.C. § 103.

Claims 32, 33, 50 and 51:

The examiner argues (Answer, page 6) that the combination of '061, '622 and Sakuma "do not specify that the magnet is a permanent magnet in the shape of a flat disk or a needle." To make up for this deficiency the examiner applies Forrest to teach (Answer, page 6) "an assembly which is designed for use with immunoassays utilizing magnetic particles and which allows a batchwise separation ... [t]he magnets are permanently located, remaining fixed in position in the base of the device throughout the assay." The examiner further argues (Answer, page 6) that although Forrest does "not specify that the magnets could be disc shaped, such a shape would have been obvious to accomplish the most efficient separation and most defined pattern, particularly in the case where a tube constitutes the reaction vessel, since a disc would most closely resemble the shape of the vessel."

Appellants argue (Brief, page 18) that "the magnet is used in Forrest in the washing step after the reaction. Further, the reaction system in Forrest is not

for forming a pattern.” The examiner argues (Supplemental Answer, bridging paragraph, pages 2-3) that the “claims of Forrest are all generically drawn to ‘[a] test-tube assembly for use in immunoassays utilizing magnetic particles.” Furthermore, in contrast to appellants’ position (Reply Brief, page 3) Forrest does not necessarily involve decanting. Forest contemplates (column 6, lines 8-14) the use of the device wherein “no separation step [decanting] need be used.” Therefore, we agree with the examiner (Supplemental Answer, page 3) that Forrest’s “device for magnetic separation is ... applicable to a magnetic agglutination assay as taught by the references of record.”

Therefore, in our opinion, the examiner met her burden of establishing a prima facie case of obviousness. Accordingly, we affirm the examiner’s rejection of claims 32, 33, 50 and 51 under 35 U.S.C. § 103 over ‘061, ‘622 and Sakuma further in view of Forrest.

Claim 38:

The examiner argues (Answer, page 7) that the combination of ‘061, ‘622 and Sakuma “differ from the instant invention in that they do not specify that the particles can be colored.” To make up for this deficiency the examiner applies ‘813 (Answer, page 7) to “teach that gelatin particles are suitable as a carrier for antigens and antibodies for indirect passive agglutination.... A suitable coloring agent may be added to the particles during formation, or the insolubilized particles may be treated with the coloring agent....” The examiner concludes (Answer, page 7) that:

It would have been obvious for one of ordinary skill in the art to color the particles of the assay of the references as in Ikeda et al. ('813) since it is well known that colored particles are more easily detected in a particle agglutination immunoassay, and Ikeda et al. ('061) specifically suggest utilizing gelatin particles such as those of Ikeda et al. ('13) which can easily be colored as demonstrated.

We are not persuaded by appellants' argument (Brief, page 19) that '813 "do not concern magnetic particles." Appellants did not consider the teachings of the '813 reference in combination with the other prior art references applied in this rejection. Here the examiner presented a reasoned statement, derived from the prior art, as to why it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use colored particles in the magnetic particle immunoassay method. Therefore, in our opinion, the examiner met her burden of establishing a prima facie case of obviousness. Accordingly, we affirm the examiner's rejection of claim 38 under 35 U.S.C. § 103 over '061, '622 and Sakuma further in view of '813.

Claims 39, 40, 42 and 46-48:

The examiner argues (Answer, page 7) that '061, '622 and Sakuma "differ from the instant invention in that they do not teach immobilization on the reaction vessel of an immunological substance which specifically binds to the analyte." To make up for this deficiency the examiner applies Rosenfield to "describe the basics of agglutination assays." According to the examiner (Answer, page 7), "Rosenfield et al. have discovered that agglutination test procedures on blood cells are significantly improved when a monolayer of reactive cells is [sic]

irreversibly bound to a solid matrix....” The examiner concludes (Answer, page 8) that:

It would have been obvious for one of ordinary skill in the art to immobilize a substance which specifically binds to the analyte to the reaction vessel as in Rosenfield et al. prior to incubation with the sample and magnetic particles of the references, because Rosenfield et al. teach that such treatment significantly improves agglutination procedures such as those utilized in the assay of the references.

Appellants argue (Brief, page 19) that “the agglutination pattern is improved in Rosenfield et al. by a washing step for removing the unbound indicator particles, not by immobilization.” According to appellants (Brief, page 19) “[i]t follows that it is not possible to form a clear agglutination pattern as in Rosenfield et al., if the washing step required by Rosenfield et al.[.] is not employed, no matter how Rosenfield et al. may be combined with other references.” In response, the examiner argues (Answer, page 14) that “[t]he instantly claimed assays do not exclude a step of removing the non-reacted particles, as taught in Rosenfield et al.”

We are not persuaded by appellants argument (Reply Brief, page 5) that “the present invention is distinguished from Rosenfield et al., in which the particles are already removed by washing at the time of the determination.” As noted by the examiner, supra, the “instantly claimed assay does not exclude a step of removing the non-reacted particles.” Therefore, in our opinion, the examiner met her burden of establishing a prima facie case of obviousness. Accordingly, we affirm the examiner’s rejection of claims 39, 40, 42 and 46-48 under 35 U.S.C. § 103 over ‘061, ‘622 and Sakuma further in view of Rosenfield.

Claims 43, 44, 52 and 53:

The examiner argues (Answer, page 9) that '061, '622, Sakuma, and Rosenfield “differ from the instant invention in that they do not specify that the magnet is a permanent magnet in the shape of a flat disk or a needle.”<sup>12</sup> To make up for this deficiency the examiner applies Forrest. According to the examiner (Answer, page 9), “Forrest specifies that single magnets could be employed beneath each reaction vessel....” The examiner further argues (Answer, page 9) that:

It would have been further obvious for one of ordinary skill in the art to utilize a magnet in the shape of a needle placed adjacent to the center of the vessel, since such a magnet and placement would have concentrated the magnetic particles in as small an area as possible in the most recessed portion of the vessel, thereby enhancing the distinction between a positive and negative distribution pattern and increasing sensitivity.

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<sup>12</sup> We note that the examiner included the “Forrest” reference in this statement. However, considering that the statement of the rejection is '061, '622, Sakuma and Rosenfield further in view of Forrest we believe the examiner’s inclusion of “Forrest” in this statement is a typographical error. This typographical error is corrected herein above.

Appellants do not separately argue this rejection. It appears that appellants' rely on their previous arguments regarding the teachings of the prior art. Therefore, for the reasons discussed supra we find no error in the examiner's rejection. Accordingly, we affirm the examiner's rejection of claims 43, 44, 52 and 53 under 35 U.S.C. § 103 over '061, '622, Sakuma and Rosenfield further in view of Forrest.

Claim 49:

The examiner argues (Answer, page 9) that '061, '622, Sakuma and Rosenfield<sup>13</sup> "differ from the instant invention in that they do not specify that the particles can be colored." To make up for this deficiency, the examiner applies '813. According to the examiner (Answer, bridging paragraph, pages 9-10):

It would have been obvious for one of ordinary skill in the art to color the particles of the assay of the references as in Ikeda et al. ('813) since it is well known that colored particles are more easily detected in a particle agglutination immunoassay, and Ikeda et al. ('061) specifically suggest utilizing gelatin particles such as those of Ikeda et al. ('813) which can easily be colored as demonstrated.

Appellants do not separately argue this rejection. It appears that appellants' rely on their previous arguments regarding the teachings of the prior art. Therefore, for the reasons discussed supra we find no error in the examiner's rejection. Accordingly, we affirm the examiner's rejection of claim 49 under 35 U.S.C. § 103 over '061, '622, Sakuma and Rosenfield further in view of

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<sup>13</sup> We note that Rosenfield was not included in the statement of the rejection. However, the statement of the rejection refers to the prior art combination for the rejection of claims 39, 40, 42 and 46-48 that includes Rosenfield. Therefore, it appears that the exclusion of Rosenfield in the statement of this rejection was a typographical error. This typographical error was corrected herein above.

'813.

Claims 29, 31, 35-40, 42 and 46-49:

According to the examiner (Answer, page 10):

Asakura et al. teach an immunoassay for immunosuppressive acidic protein (IAP) wherein anti-IAP antibody is immobilized beforehand on the bottom surface of a test vessel.... The test vessel may be a glass or plastic test tube, but a microplate is preferred. The microplate has a U-shaped or V-shaped bottom.... [T]he test reagent (a support with anti-IAP antibody) is added and the reaction of this reagent and the IAP is detected. The support is a colored organic or inorganic material ... When IAP is present in the test vessel, an agglutination reaction takes place between it and the anti-IAP antibody and forms a positive image.... When the support is, e.g. colored beads, the reaction is detected visually.... When IAP is not present, the agglutination reaction does not take place, and the test reagent collects at a point in the center of the bottom of the tube....

The examiner explains (Answer page 10) that "Asakura et al. differ from the instant invention in that they do not specify that the particles may be magnetic." However, to make up for this deficiency the examiner applies (Answer, bridging paragraph, pages 10-11) '622 to teach magnetic gelatin or magnetic latex particles and the advantages of these particles over traditional particles.

Appellants state (Brief, page 21) that "[i]t is respectfully submitted that the Final Rejection has failed to set forth a prima facie case of obviousness. Furthermore, even assuming arguendo that the combination of references is proper, for the reasons discussed above, it is respectfully submitted that the combination would not lead to the claimed invention." Appellants did not provide a statement in the Brief as to why they believe the examiner "failed to set forth a

prima facie case of obviousness.” However, appellants argue (Reply Brief, bridging paragraph, pages 6-7) that “Asakura et al. teach that the precipitation which occurs in a period of one hour is considered to be at an appropriate precipitation speed and the precipitation which occurs more rapid than that speed is not considered preferable by Asakura et al.” Appellants conclude (Reply Brief, page 7) that “Asakura et al. do not provide any motivation for the promotion of the precipitation, and if there is such a motivation, it would contradict the teachings of Asakura et al.”

The examiner argues (Supplemental Answer, page 3) that “[t]he excerpt referred to by appellants states that the disclosed particles ‘precipitate at a moderate rate of precipitation’ ... and that such particles ‘are satisfactory’ ... no teaching of ‘an appropriate precipitation speed’ as alleged by appellants can be found.” Therefore, the examiner argues (Supplemental Answer, bridging sentence, page 4) that Asakura “certainly would not contradict any suggestion in the prior art to increase the rate of precipitation by magnetic separation, as alleged” by appellants.

While we agree with the principles set forth in appellants’ case law citations (Brief, pages 22-24), appellants’ failed to explain how these principles apply to the instant rejection. In our opinion, the examiner met her burden of establishing a prima facie case of obviousness after consideration of the claimed invention as a whole. Accordingly, we affirm the examiner’s rejection of claims 29, 31, 35-40, 42 and 46-49 under 35 U.S.C. § 103 over Asakura in view of ‘622. Claims 32, 33, 43, 44 and 50-53:

The examiner argues (Answer, page 11) that Asakura, and '622 "differ from the instant invention in that they do not specify that the magnet is a permanent magnet in the shape of a flat disk or a needle.<sup>14</sup>" To make up for this deficiency the examiner applies Forrest. According to the examiner (Answer, page 11), "Forrest specifies that single magnets could be employed beneath each reaction vessel...." The examiner further argues (Answer, page 11) that:

It would have been further obvious for one of ordinary skill in the art to utilize a magnet in the shape of a needle placed adjacent to the center of the vessel, since such a magnet and placement would have concentrated the magnetic particles in as small an area as possible in the most recessed portion of the vessel, thereby enhancing the distinction between a positive and negative distribution pattern and increasing sensitivity.

Appellants do not separately argue this rejection. It appears that appellants' rely on their previous arguments regarding the teachings of the prior art. Therefore, for the reasons discussed supra we find no error in the examiner's rejection. Accordingly, we affirm the examiner's rejection of claims

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<sup>14</sup> We note that the examiner included the "Forrest" reference in this statement. However, considering that the statement of the rejection is '061, '622, Sakuma and Rosenfield further in view of Forrest we believe the examiner's inclusion of "Forrest" in this statement is a typographical error. This typographical error is corrected herein above.

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32, 33, 43-44 and 50-53 under 35 U.S.C. § 103 over Asakura in view of '622,  
further in view of Forrest.

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

AFFIRMED

William F. Smith	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Carol A. Spiegel	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Donald E. Adams	)	
Administrative Patent Judge	)	

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Application No. 08/172,866

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