Examiner’s decision finally rejecting claims 1-38 under 35 U.S.C. § 102(b) (2002) as being anticipated by Kimura, *Fast Formation of Statistically Reliable FDG Parametric Images Based on Clustering and Principal*

The claims on appeal relate to a model-based simulation system which may be used to evaluate radioactive tracers for use in a targeted imaging system and to optimize various imaging parameters to obtain better image quality. (Spec. 5, ¶ 0021.) In at least some diagnostic imaging processes, a radioactive tracer is injected into a patient. Periodic samplings of the signal generated from the decay of the radioactive tracer are used to construct an image of the distribution of the radioactive tracer within the patient. (Spec. 1, ¶ 0003.) The Appellants assert that the effectiveness of new radioactive tracers or imaging protocols may be determined from comparisons performed based on the results of simulations in accordance with the claimed subject matter. (Spec. 5, ¶ 0021.) The Appellants also assert that the interpretation of complex image data may be facilitated by using the claimed subject matter to determine the physiological and physical parameters that might generate the image data. (Id.)

Claims 1, 14, 28 and 38 are independent. All four independent claims may be reproduced without unduly lengthening this opinion:

1. An imaging simulator system, comprising:
   a processor assembly comprising:
   a time activity module configured to
generate time activity data;
an imager module configured to
receive at least one imager parameter and to
generate an imager model; and

a simulator module configured to
receive the imager model and the time activity data
and to generate simulated sensed data.

process, the method comprising the steps of:

generating a set of simulated sensed data
based on an imager model and time activity data.

28. A tangible, machine-readable media,
comprising:

code adapted to generate simulated sensed
data based on an imager model and time activity
data.

38. An imaging simulator system,
comprising:

means for generating a set of simulated
sensed data based on an imager model and time
activity data.

OPINION

This opinion will explain the reasons for sustaining the Examiner’s
rejections of claims 28-37 under § 102(b); for not sustaining the Examiner’s
rejections of claims 1-27 and 38 under the same statutory provision; and for
summarily sustaining the provisional rejection of claims 1-38 on the ground
of nonstatutory obviousness-type double patenting. Next, the opinion will
explain the reasons for entering the new grounds of rejection against claims
subject matter and for entering the new grounds of rejection against claim 38
under the first paragraph of 35 U.S.C. § 112 (2002) for failure to comply
with the enablement requirement.

The Examiner’s Rejections of Claims 1-38

ISSUES

The Appellants contend that Kimura fails to disclose the use or
generation of an imager model. The Appellants also contend that Kimura
fails to disclose a step of generating simulated sensed data based on an
imager model. (Reply Br. 1-2.) The Appellants present these contentions
generally and do not separately argue the patentability of any claim or
claims. In particular, the Appellants do not appear to contend that Kimura
fails to disclose, expressly or inherently, a tangible, machine-readable
medium comprising code. Instead, their argument regarding claim 28 is
limited to the contention that Kimura fails to disclose code adapted to
generate simulated sensed data based on an imager model and time activity
data.

Three issues raised in this appeal are:

Have the Appellants shown that the Examiner erred in
finding that Kimura discloses an imaging simulator system
including an imager module configured to generate an imager
model and a simulator module configured to receive the imager
model as recited in claim 1?

Have the Appellants shown that the Examiner erred in
finding that Kimura discloses a step of generating a set of
simulated sensed data based on an imager model and time
activity data as recited in claim 14 or a means for generating a
set of simulated sensed data based on an imager model and time
activity data as recited in claim 38?

Have the Appellants shown that the Examiner erred in
finding that Kimura discloses a tangible, machine-readable
medium meeting the limitations of claim 28?

The Appellants request that the provisional rejection of claims 1-38 on
the ground of nonstatutory obviousness-type double patenting be withdrawn
if the appealed claims are allowed. (App. Br. 10.) This request does not
demonstrate that the Examiner erred in provisionally rejecting claims 1-38
on the ground of nonstatutory obviousness-type double patenting as being
unpatentable over claims 1-33 of Manjeshwar. The Board does not allow
claims or withdraw rejections. It will not act on the Appellants’ request.

FINDINGS OF FACT

The record supports the following findings of fact (“FF”) by a
preponderance of the evidence.

1. Kimura discusses the kinetic analysis of positron emission
tomography [“PET”] data. More specifically, Kimura discloses that it was
known to model the kinetics of a fluorodeoxyglucose [“FDG”] tracer
injected into a patient by dividing the region to be imaged into an array of
“voxels,” that is, very small, three-dimensional elements; and associating a
tissue time activity curve [“tTAC”] with each voxel. Kimura further
discloses that it was known to model the tTAC associated with each voxel
by means of an equation of the form $C(t) = [K_1 / (k_2 + k_3)] [k_3 + k_2 \exp(-k_2 t)]$. 

$+ k_3 \right] t \} \otimes C_p(t), \text{ where } C(t) \text{ denotes the tTAC; } C_p(t) \text{ denotes a plasma time}$

+ activity curve determined by arterial blood sampling; $K_1$ and $k_2$ denote

+ parameters summarizing the rates that the tracer in plasma enters and leaves

+ the tissue free FDG pool; and $k_3$ denotes a rate constant describing the rate at

+ which FDG is converted to FDG-6-PO$_4$. (Kimura 456 (equation 1); see also

+ id. at 458.) Kinetic analysis of the PET data determines the parameters $K_1,$

+ $k_2$ and $k_3$ from sensed data. (See Kimura, Abstract.)

2. Kimura teaches that the formation of parametric images by

+ conventional methods required voxel-by-voxel estimation of the rate

+ constants, a process sensitive to noise and computationally demanding. (See

+ id.)

3. Kimura discloses reducing noise propagation in parametric

+ images by performing a clustering analysis (see Kimura 456) in four steps:

+ (1) normalizing the tTAC associated with each voxel over the duration of the

+ measurement; (2) determining a set of functions, called principal

+ components, which characterize each tTAC; (3) clustering similarly-shaped

+ tTACs using the principal components and averaging the tTACs in each

+ cluster; and (4) estimating the parameters $k_2$ and $k_3$ for each cluster and the

+ parameter factor $K_1$ as a scaling factor for each voxel. (Kimura 457.) None

+ of these steps appear to generate or use an imager model.

4. Kimura discloses having performed three studies to assess the

+ performance of the clustering methods on simulated data, with and without

+ noise. (Kimura 459.) In the first simulation, a set of simulated noise-free

+ tTACs was generated from clinical pTAC and nominal rate constants. In the

+ second simulation, Gaussian noise was added to simulate clinical voxel

+ based tTACs having signal-to-noise ratios similar to the noise levels in
clinical voxel-based tTACs. In the third simulation, a set of simulated
tTACs was derived from clinical data from an Alzheimer’s patient. (Kimura
459.) Kimura does not describe the use of an imager model or of any
parameter related to the physics associated with an imaging modality or
scanner in performing the kinetic analysis of the simulated sensed data in
any of the three simulations.

5. Section 3.4 of Kimura describes estimating the parameters $K_1$,
$k_3$ and $K_i = K_1 k_3 / (k_2 + k_3)$ from FDG clinical data for patients with
Alzheimer’s disease and cortico-basal degeneration by means of a clustering
analysis using the two most significant principal components to define the
clusters. (Kimura 462.) Figure 8 shows parametric images representing $K_1$,
$k_3$ and $K_i$ for the two patients. Figure 9 of Kimura compares parametric
images of $K_i$ on seven tomographic slices estimated using clustering and
conventional analyses from sensed data from the clinical study of the patient
with Alzheimer’s disease. (Id.; see also Kimura 464 (figs. 8 and 9).)
Section 3.4 does not describe a simulation and does not mention the
generation or use of an imager model.

6. Figures 6 and 7 of Kimura are described in section 3.3.1 and
3.3.2 of Kimura, respectively, rather than in section 3.4. (Kimura 461-62.)
That said, Figure 6 shows graphs comparing estimated values of $K_i$, $k_3$ and
$K_i$ derived from the simulated sensed data of the second simulation by means
of the clustering and conventional analyses to the actual values of $K_i$, $k_3$ and
$K_i$ used to generate the simulated sensed data. Figure 7 shows graphs
illustrating the deviation of estimated values from the actual values. (Id.; see
also Kimura 463 (figs. 6 and 7).) Kimura does not describe the use of an
imager model or of any parameter related to the physics associated with an
imaging modality or scanner in performing the kinetic analysis of the
simulated sensed data in the second simulation.

7. Kimura discloses that programs for carrying out the kinetic
analysis were written in a machine-readable language interpretable through
the MATLAB Statistical Toolbox. (Kimura 458.)

8. Kimura’s disclosure that programs for carrying out the kinetic
analysis were written in a machine-readable language interpretable through
the MATLAB Statistical Toolbox necessarily indicates that the programs
were stored in the form of code on a tangible, machine-readable medium.
The Appellants do not appear to challenge this fact.

9. Tangible, machine-readable media were known to those of
ordinary skill in the art. Apart from the inherent disclosure of Kimura, this
knowledge is evidenced by the Appellants’ illustrative, but non-exhaustive,
list of computer readable media in paragraph 0052 of the Specification.
(Spec. 19.)

PRINCIPLES OF LAW

A claim under examination is given its broadest reasonable
interpretation consistent with the underlying specification. In re Am. Acad.
of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004). In the absence of
an express definition of a claim term in the specification or a clear
disclaimer of scope, the claim term is interpreted as broadly as the ordinary
usage of the term by one of ordinary skill in the art would permit. In re
ICON Health & Fitness, Inc., 496 F.3d 1374, 1379 (Fed. Cir. 2007); In re
Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Properties of preferred
embodiments described in the specification which are not recited in a claim
do not limit the reasonable scope of the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003). Nevertheless, where possible, claim language should be construed sufficiently broadly to encompass at least one preferred embodiment disclosed in the specification. *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996).

The subject matter of a claim is anticipated if “a single prior art reference discloses each and every limitation of the claimed invention. . . .” *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted). In addition, “[i]t is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Where printed matter does not interrelate with a known substrate so as to give rise to a novel functional relationship between the printed matter and the substrate, but instead merely provides instructions for performing a process using or involving the substrate, the recitation of the printed matter will not prevent a reference disclosing the known substrate from anticipating a claim to the substrate. *See In re Ngai*, 367 F.3d 1336, 1338-39 (Fed. Cir. 2004).

ANALYSIS
The Appellants do not formally define the term “imager model” as used in the claims on appeal. Nonetheless, the ordinary usage of the term is apparent: an “imager model” is a mathematical model of an imager. In other words, an “imager model” models the physics associated with an
imaging modality or scanner. (See Spec. 7, ¶ 0026.) This ordinary usage is consistent with the usage of the term in the Specification.

Claim 1 recites an imaging simulator system including an imager module configured to generate an imager model and a simulator module configured to receive the imager model. Claim 14 recites a method including the step of generating a set of simulated sensed data based on an imager model. Claim 38 recites an imaging simulator system including means for generating a set of simulated sensed data based on an imager model and time activity data. Those passages cited by the Examiner in support of the finding of anticipation do not support the Examiner’s finding that Kimura describes a system or method meeting the limitations of claim 1, claim 14 or claim 38. (See FF 5 and 6; cf. Ans. 3 and 5-6 (listing and explaining the Examiner’s citations to Kimura).)

On the other hand, claim 28 is directed to tangible, machine-readable media comprising code. The Examiner appears to find, and the Appellants do not appear to contest, that tangible, machine-readable media were known to those of ordinary skill in the art. (FF 9.) Indeed, Kimura inherently discloses tangible, machine-readable media comprising code. (FF 8.) These facts support the Examiner’s finding that Kimura anticipates claim 28.

The nature of the code recited in claim 28 does not provide novelty to the otherwise known tangible, machine-readable media claimed by claim 28. The tangible, machine-readable media “comprises” the code in the sense that the code is matter printed, albeit in machine-readable form, on the media. The code does not interrelate with the known media so as to give rise to a novel functional relationship between the code and the media. More specifically, claim 28 does not recite any elements or features of the media
with which the code might interact. Instead, the code merely provides
instructions to a separate apparatus not recited in the claim, namely, a
processor, to perform a function. Since claim 28 recites known media
performing its accustomed function of serving as a machine-readable
substrate for code, the nature of the code which the media comprises merely
constitutes a new intended use of the media which cannot impart novelty to
the media.

Since the Appellants do not argue dependent claims 29-37 separately
from independent claim 28, from which claims 29-37 depend, claim 28 is
representative of the group including claims 28-37 for purposes of the
29-37 thus fall with claim 28 for the reasons presented above.

CONCLUSIONS
The Appellants have shown that the Examiner erred in finding that
Kimura discloses an imaging simulator system including an imager module
configured to generate an imager model and a simulator module configured
to receive the imager model as recited in claim 1. Therefore, the Appellants
have shown that the Examiner erred in rejecting claim 1 and its dependent
claims 2-13 under § 102(b) as being anticipated by Kimura.

The Appellants have shown that the Examiner erred in finding that
Kimura discloses a step of generating a set of simulated sensed data based
on an imager model and time activity data as recited in claim 14 or a means
for generating a set of simulated sensed data based on an imager model and
time activity data as recited in claim 38. Therefore, the Appellants have
shown that the Examiner erred in rejecting claims 14 and 38, and in rejecting
dependent claims 15-27 under § 102(b) as being anticipated by Kimura.

The Appellants have not shown that the Examiner erred in finding that
Kimura discloses a tangible, machine-readable medium meeting the
limitations of claim 28. Therefore, the Appellants have not shown that the
Examiner erred in rejecting claim 28 and its dependent claims 29-37 under
§ 102(b) as being anticipated by Kimura.

The New Grounds of Rejection of Claims 14-27 Under § 101

ISSUE

Subsequent to the filing of the Examiner’s Answer, our reviewing
court clarified that the “machine-or-transformation” test enunciated by the
Supreme Court in Gottschalk v. Benson, 409 U.S. 63 (1972); Parker v.
Flook, 437 U.S. 584 (1978); and Diamond v. Diehr, 450 U.S. 175 (1981),
properly applied, determines whether a method is a statutory process eligible
F.3d 943, 956 (Fed. Cir. 2008). Since the Examiner had no opportunity to
address the eligibility of the subject matter of claims 14-27 for patent
protection in light of this clarification, we address the issue:

Is the subject matter of method claims 14-27 a process
eligible for patent protection under § 101?

PRINCIPLES OF LAW

In Bilski, our reviewing court, sitting en banc, held that “the machine-
or-transformation test, properly applied, is the governing test for determining
patent eligibility of a process under § 101.” Bilski, 545 F.3d at 956. The
court explained that the “machine-or-transformation test is a two-branched
inquiry; an applicant may show that a process claim satisfies § 101 either by
showing that his claim is tied to a particular machine, or by showing that his
claim transforms an article.” *Id.* at 961 (citing *Benson*, 409 U.S. at 70).
“[T]he use of a specific machine or transformation of an article must impose
meaningful limits on the claim’s scope to impart patent-eligibility.” *Id.*
A claimed process is not tied to a particular machine for purposes of
the machine-or-transformation test merely because the process may be
implemented on a programmable, general purpose computer. *See Benson*,
409 U.S. at 71.
A claim may be shown to transform an article if the claimed process
transforms data clearly representing one or more physical and tangible
objects. *Bilski*, 545 F.3d at 962-63. For example, in *In re Abele*, 684 F.2d
902 (CCPA 1982), a predecessor of our reviewing court addressed the
patentability of a claim to:

A method of displaying data in a field comprising
the steps of calculating the difference between the
local value of the data point in the field and the
average value of the data in a region of the field
which surrounds said point for each point in said
field, and displaying the value of said differences
as a signed gray scale at a point in a picture which
corresponds to said data point,
wherein the data was X-ray attenuation data produced in a two-dimensional
field by a computed tomography scanner. *Id.* at 908. As characterized by
our current reviewing court, the court in *Abele* held that the electronic
transformation of raw data into a particular visual depiction of a physical
ANALYSIS

Claim 14 and its dependent claims recite “methods.” As such, the subject matter of claims 14-27 is eligible for patent protection, if at all, only as processes. Claim 14 recites only one step, namely, generating a set of simulated sensed data. Since the simulated sensed data consists of numbers, this step is performed by carrying out mathematical calculations involving the imager model and the time activity data. (See Spec. 5, ¶ 0021 (“The present technique quantitatively models the physiological and physical pathways involved in the production of images.”).) Hence, the sole method step recited in claim 14 is a mathematical algorithm. Dependent claims 15-24, 26 and 27 recite either refinements to this algorithm or additional steps involving mathematical manipulation of data or models. Claim 25 recites a step of displaying one or more simulated images.

The eligibility of the subject matter of claims 14-27 for patent protection is determined by the machine-or-transformation test. The methods of claims 14-27 are not tied to any particular machine. While the method may be performed on a processor, this fact alone is not determinative as to whether the subject matter of claims 14-27 is eligible for patent protection. Here, there is no evidence sufficient to show that the calculations inherently recited in claim 14 are so complex that the calculations could not be performed by hand within a meaningful period of time. In particular, claims 14-27 do not require any minimum size of the imager model or any minimum quantity of time activity data on which to
base the generation of the simulated sensed data. Since the record suggests
that the calculations might be performed by hand, the methods of claims 14-
27 are not tied to a particular machine.

Neither do the methods of claims 14-27 transform or reduce any
article. The method of claim 14 generates a set of simulated sensed data
based on an imager model and time activity data. Nothing in claim 14
implies that the imager model or the time activity data represent physical or
tangible objects; to the contrary, the recitation that the generated data is
simulated implies that the imager model and the time activity data may also
be simulated. This fact distinguishes the facts of the present appeal from the
facts of Abele, where the process held to be statutory performed calculations
and displayed results based on X-ray attenuation data produced by a
computer tomography scanner. See id., 684 F.2d at 908-09.

The recitation of a step of displaying one or more simulated images
does not tie the method of claim 25 to a particular machine. A method is not
tied to a particular machine merely because the machine is involved in an
insignificant extra-solution activity. Bilski, 545 F.3d at 962. For example,
the court in Abele found one claim before it non-statutory even though the
claim recited displaying the results of calculations. Id. at 909. Here, as in
Abele, claim 25 recites no more than calculating and displaying numbers
which do not represent physical or tangible objects.

CONCLUSION

Therefore, the methods of claims 14-27 are neither tied to a particular
machine nor transformative of an article. The subject matter of method
claims 14-27 is not eligible for patent protection under § 101.
The New Grounds of Rejection of Claim 38 Under § 112

Claim 38 recites an imaging simulator system which comprises only one element, namely, “means for generating a set of simulated sensed data based on an imager model and time activity data.” A “single means” claim is a claim which claims a structure comprising only one element and in which the sole element comprising the structure is recited as a “means” for performing a specified function. As such, claim 38 is a “single means claim.”

We address the issue:

Does the Appellant’s Specification enable the subject matter of claim 38 as required by the first paragraph of § 112?

A specification in a patent application is enabling under the first paragraph of § 112 only if the specification teaches those of ordinary skill in the art as of the filing date of the application how to make and use the full scope of the claimed subject matter without undue experimentation. *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1337 (Fed. Cir. 2003). The specification underlying a “single means” claim *per se* fails to enable the full scope of the claim. *In re Hyatt*, 708 F.2d 712, 714-15 (Fed. Cir. 1983).

By its own terms, the sixth paragraph of § 112 limits the scope only of an element in a claim for a *combination*. A single means claim recites a structure having only a single element, not a combination of elements. The sixth paragraph of § 112 does not limit the scope of a claim reciting a structure comprising only one element, even if the element is recited as a “means” for performing a specified function. Without the limitation
provided by the sixth paragraph of § 112, the “means” recited in a single
means claim encompasses any structure which might be capable of
performing the specified function. Since the disclosure of any specification
will be limited to those means known by the inventor, no specification can
be drawn sufficiently broadly to teach how to make and use the full scope of
a single means claim. *Id.* at 715.

Claim 38 is a single means claim. The Appellants’ Specification *per
se* fails to enable the full scope of the claim. The Appellants’ Specification
does not enable the subject matter of claim 38 as required by the first
paragraph of § 112.

DECISION

We AFFIRM the Examiner’s decision rejecting claims 28-37 under
§ 102(b).

We REVERSE the Examiner’s decision rejecting claims 1-27 and 38
under § 102(b).

We AFFIRM the Examiner’s decision provisionally rejecting claims
1-38 on the ground of nonstatutory obviousness-type double patenting.

We enter NEW GROUNDS OF REJECTION against claims 14-27
under § 101 as being directed to non-statutory subject matter.

We enter NEW GROUNDS OF REJECTION against claim 38 under
the first paragraph of § 112 for failing to comply with the enablement
requirement.
Regarding the affirmed rejection(s), 37 C.F.R. § 41.52(a)(1) provides “Appellant may file a single request for rehearing within two months from the date of the original decision of the Board.”

In addition to affirming the Examiner’s rejection(s) of one or more claims, under 37 C.F.R. § 41.50(b) a new ground of rejection has been entered. 37 C.F.R. § 41.50(b) provides that, “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

Regarding the new ground of rejection, Appellants must, **WITHIN TWO MONTHS FROM THE DATE OF THE DECISION**, exercise one of the following options with respect to the new ground of rejection, in order to avoid termination of the appeal as to the rejected claims:

1. **(1) Reopen prosecution.** Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . [; or]

2. **(2) Request rehearing.** Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . .

Should Appellants elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If Appellants elect prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this
case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)

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GENERAL ELECRIC COMPANY (PCPI)
C/O FLETCHER YODER
P.O. BOX 692289
HOUSTON, TX  77269-2289